Table of Abbreviations		
Category	**Abbreviation**	**Text**
Action - Subject	N	No action
	O	Other
	P	Drug withdrawn (study intervention discontinued)
	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
	W	Withdrawn from study
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders

Table of Abbreviations		
Category	**Abbreviation**	**Text**
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	129.6 kg	46.2 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present
Sleep apnea	Sleep apnoea syndrome	2013	Present
Gastroesophageal reflux	Gastrooesophageal reflux disease	2018	Present
Gastric sleeve	Gastrectomy	SEP2019	Past
Supraventricular tachycardia	Supraventricular tachycardia	08OCT2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	13:11
2	BNT162b2	20AUG2020 (22)	11:45

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Cardiac arrest	Cardiac Arrest	18OCT2020 (81)		21OCT2020 (84)		4	4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Fatal (21OCT2020)	NOT RELATED/OTHER: Heart attack. Occurred 2 months after last receipt of study agent	2	60	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	17SEP2020	
Withdrawn	FOLLOW-UP	21OCT2020	DEATH

Narrative Comment
Subject C4591001 1007 10071101, a 56-year-old white female with pertinent medical history of obesity (since 2000), sleep apnea syndrome (since 2013), and supraventricular tachycardia (on 08 Oct 2019), received Dose 1 on 30 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 22). The subject died because of cardiac arrest on 21 Oct 2020, 62 days after receiving Dose 2. On 18 Oct 2020 (Day 81), the subject presented to the emergency room following an intubation at home after a cardiac arrest. Her electrocardiogram was abnormal with initial rhythm of pulseless electrical activity and ischemic changes. The down time was reported as 15 minutes. On the same day (Day 81), a computed tomogram of the head showed cerebral edema. Emergency department spoke with cardiology who deferred an intervention and a targeted temporal management (TTM) was ordered. The laboratory results on 18 Oct 2020 (Day 81) showed blood chloride 124 mEq/L (normal range [NR]: 98 - 111 mEq/L), blood glucose 393 mg/dL (NR: 70 - 99 mg/dL), blood potassium of 3.5 mEq/L (NR: 3.6 - 5.1 mEq/L), blood sodium of 155 mEq/L (NR: 135 - 145 mEq/L), carbon dioxide of 18 mmol/L (NR: 21 - 31 mmol/L), and glomerular filtration rate of 58 mL/minute/1.73 m2 (NR: >59 mL/minute/1.73 m2). The subject was admitted to the intensive care unit and was intubated along with the pressors. On 19 Oct 2020 (Day 82), the subject was on TTM with high urine output overnight, which was concerning for diabetes insipidus. On the same day (Day 82), the subject's troponin I was high at 491 ng/L (NR: <15 ng/L), that was considered critical. The SARS CoV-2 test was negative. On 20 Oct 2020 (Day 83), a magnetic resonance imaging showed anoxic brain injury and possible herniation and an electroencephalogram showed absent brain activity. On the same day (Day 83), the subject was rewarmed. On 21 Oct 2020 (Day 84), the subject was pronounced dead at 1859 hours due to a cardiac arrest. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention or clinical trial procedures, as the death occurred 2 months after receiving Dose 2. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	84.23 kg	25.1 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa allergy	Drug hypersensitivity	1980	Present
morphine allergy	Drug hypersensitivity	1985	Present
anxiety	Anxiety	1990	Present
GERD	Gastrooesophageal reflux disease	2000	Present
hypertension	Hypertension	2000	Present
insomnia	Insomnia	2000	Present
L4-L5 laminotomy with diskectomy	Spinal laminectomy	2012	Past
spinal stenosis	Spinal stenosis	2012	Past
hyponatremia	Hyponatraemia	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
history of seizure	Seizure	2015	Past
history of alcohol abuse	Alcohol abuse	2018	Past
cardiomyopathy	Cardiomyopathy	MAR2018	Present
myocardial infarction	Myocardial infarction	MAR2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	13:32

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocardial infarction	myocardial infarction	03NOV2020 (16)		03NOV2020 (16)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	P/W	Y	Fatal (03NOV2020)	NOT RELATED/OTHER: disease progression	1	16	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Withdrawn	VACCINATION	03NOV2020	DEATH
Withdrawn	FOLLOW-UP	03NOV2020	DEATH

Narrative Comment
Subject C4591001 1066 10661350, a 58-year-old white male with a pertinent medical history of hypertension (since 2000), gastroesophageal reflux disease (since 2000), insomnia (since 2000), hyponatremia (since 2015), seizures (in 2015), alcohol abuse (from 2010 to 2018), myocardial infarction (in Mar 2018), and cardiomyopathy (coronary angiography, left ventriculography, and left heart catheterization; since Mar 2018), received Dose 1 on 19 Oct 2020. The subject died because of a myocardial infarction on 03 Nov 2020, 15 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of myocardial infarction included omeprazole (Protonix) for gastroesophageal reflux disease (since 2015), trazodone for insomnia (since 2015), Depade and acamprosate calcium (Campral) for alcohol dependence (since 2018), and levetiracetam (Keppra) for seizures (since 2018). When the subject did not return for Visit 2 on 09 Nov 2020 (Day 22), the subject's wife was contacted on the same day and she stated that the subject suffered a heart attack and died in his sleep on 03 Nov 2020 (Day 16). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medication, or clinical trial procedures, but rather it was related to disease progression. Pfizer concurred with the investigator's causality assessment and additionally considered that the myocardial infarction was mostly coincidental and associated with underlying cardiac conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	95.82 kg	34 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	1995	Present
Allergy to Sulfa drugs	Drug hypersensitivity	2002	Present
Allergy to oral NSAIDs	Drug hypersensitivity	2007	Present
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015	Present
Hypertension	Hypertension	2015	Present
Attention deficit disorder	Attention deficit hyperactivity disorder	2017	Present
Osteoarthritis of the knees	Osteoarthritis	2018	Present
Postmenopausal	Postmenopause	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	12:44
2	Placebo	29SEP2020 (20)	13:39

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Death	Death	01NOV2020 (53)		01NOV2020 (53)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (01NOV2020)	NOT RELATED/OTHER: Unknown cause of death at this time	2	34	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
Withdrawn	FOLLOW-UP	01NOV2020	DEATH

Narrative Comment
Subject C4591001 1081 10811194, a 51-year-old white female with a medical history of hypothyroidism (since 1995), drug hypersensitivity (allergy to sulfa drugs since 2002 and allergy to oral NSAIDs since 2007), chronic obstructive pulmonary disease and hypertension (both since 2015), attention deficit hyperactivity disorder (since 2017), and osteoarthritis and postmenopause (both since 2018), received Dose 1 on 10 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 20). The subject was scheduled for her convalescent visit on 11 Nov 2020 but did not show up for her appointment. The family was contacted and it was reported that the subject was found deceased in her home on 04 Nov 2020 and likely died 3 days prior. A family member had spoken with the subject on 01 Nov 2020 and the subject told her family member that she just got out of the shower and was going to go lay down due to having “stomach pains”. This was the final conversation with the subject before she died. No autopsy was performed. A copy of the death certificate was requested. The cause of death was reported as unknown. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator’s causality assessment, and considered that the death was not related to concomitant medications and was most likely coincidental and associated with underlying clinical conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	84.09 kg	28.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic sinusitis	Chronic sinusitis	2000	Present
seasonal allergies	Seasonal allergy	2000	Present
breast cancer	Breast cancer	2001	Past
lumpectomy left breast	Breast conserving surgery	2001	Past
breast cancer	Breast cancer	2017	Past
lumpectomy left breast	Breast conserving surgery	2017	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	19AUG2020 (1)	10:38

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Unevaluable event	Unknown of Unknown Origin	26AUG2020 (8)		26AUG2020 (8)		1	4

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	P/W	Y	Fatal (26AUG2020)	NOT RELATED/OTHER: Waiting on death certificate	1	8	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	26AUG2020	DEATH
Withdrawn	FOLLOW-UP	26AUG2020	DEATH

Narrative Comment

Subject C4591001 1152 11521085, a 42-year-old white female with a pertinent medical history of recurrent breast cancer (in 2001 and 2017) and lumpectomy (left breast; in 2001 and 2017) and implantation of an Essure permanent birth control device (implanted in 2017), received Dose 1 on 19 Aug 2020. The subject was not taking any concomitant medications.

The subject's husband stated that the subject had no adverse events after receiving Dose 1. She had a normal evening and went to bed on 25 Aug 2020 (Day 7). By the next morning (26 Aug 2020), the subject had died (Day 8). An autopsy was performed and the results are still pending at the time of this report.

In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention. The investigator further stated that although the full autopsy report was pending and determining cause of death at this time was essentially an educated guess, the subject had possible risk factors. She possibly had a thromboembolic event related to a history of breast cancer, or there was a potential toxicity related to the Essure permanent birth control device. Essure implant for permanent birth control was taken off the market in the United States by the Food and Drug Administration (FDA) in 2018. A brief review revealed almost 50,000 reports to the FDA regarding the device and approximately 50 deaths. Pfizer commented that there was not enough evidence to suggest a causal relationship between the study intervention and the subject's death.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.5 cm	100.4 kg	32.6 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
autoimmune thyroiditis	Autoimmune thyroiditis	2010	Present
overweight/obese	Obesity	2010	Present
traumatic brain injury	Craniocerebral injury	2011	Past
depression	Depression	2011	Present
hip replacement	Hip arthroplasty	2015	Past
reading glasses	Corrective lens user	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	12:09

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Arteriosclerosis	Atherosclerotic Disease	13SEP2020 (4)		13SEP2020 (4)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (13SEP2020)	NOT RELATED/OTHER: underlying disease	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Withdrawn	VACCINATION	13SEP2020	DEATH
Withdrawn	FOLLOW-UP	13SEP2020	DEATH

Narrative Comment
Subject C4591001 1162 11621327, a 60-year-old white male with a pertinent medical history of obesity (since 2010), traumatic brain injury (in 2011, recovered), depression (since 2011), and hip replacement (in 2015), received Dose 1 on 10 Sep 2020. The subject died of arteriosclerosis on 13 Sep 2020, 3 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of arteriosclerosis included venlafaxine hydrochloride (from 2015) and aripiprazole (from 2011), both for depression. The study site received a police report indicating that the police visited the subject's home to perform a welfare check on 13 Sep 2020 (Day 4) and found him dead. It was reported that the subject's body was cold and had visible lividity. According to the medical examiner, the probable cause of death was progression of atherosclerotic disease. Relevant tests were unknown. Autopsy results were not available at the time of this report. In the opinion of the investigator, there was no reasonable possibility that the arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to suspected underlying disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	61 kg	22.7 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	03MAR2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	16:20
2	Placebo	13SEP2020 (20)	15:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Haemorrhagic stroke	Hemorrhagic stroke	27SEP2020 (34)	09:00	28SEP2020 (35)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/W	Y	Fatal (28SEP2020)	NOT RELATED/OTHER: unknown	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	28SEP2020	DEATH
Withdrawn	FOLLOW-UP	28SEP2020	DEATH

Narrative Comment
Subject C4591001 1231 12313972, a 61-year-old white female with a pertinent medical history of hypertension (since 2017), received Dose 1 on 25 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 20). The subject was diagnosed with a hemorrhagic stroke on 27 Sep 2020, 14 days after receiving Dose 2. Concomitant medication reported within 2 weeks before the onset of the hemorrhagic stroke included losartan (since 2017) for arterial hypertension. On 27 Sep 2020 (Day 34), the subject contacted the medical team complaining of a severe headache and incoercible vomiting, and she was advised to call the emergency system. The subject arrived at the emergency room unconscious (unknown Glasgow score) on the same day (Day 34) with nonreactive intermediate pupils and requiring life support measures including invasive mechanical ventilation and pharmacological support (inotropics, unknown drugs and doses). The subject's son informed the site that the subject was admitted to the intensive care unit at the hospital. A computed tomography of the brain on the same day (Day 35) showed subarachnoid hemorrhage, intraventricular hemorrhage, and right cerebral hemisphere hematoma (Fisher Scale 4). A brain angiography showed cerebral circulatory arrest, and therefore the location of the aneurysm could not be established. Per protocol, a PCR SAR-COV-2 swab test was performed and the results were negative. The subject did not respond to life support measures and died of hemorrhagic stroke on 28 Sep 2020 (Day 35). In the opinion of the investigator, there was no reasonable possibility that the hemorrhagic stroke was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and considered the hemorrhagic stroke as most likely related to the subject's underlying arterial hypertension.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	65.91 kg	26.5 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraines	Migraine	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	17:01
2	BNT162b2	09SEP2020 (24)	15:20

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_SNAP_2MPD2_Safety_Narratives/profile Date of Generation: 20NOV2020 (21:12)

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	EYE	Corneal irritation	Right corneal irritation	17AUG2020 (1)	22:54	20AUG2020 (4)		4
2	GENRL	Shoulder injury related to vaccine administration	SIRVA - shoulder injury related to vaccine administration	09SEP2020 (24)	18:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Contact lens wear	1	1	N
2	3	N	Y	Yes	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1015 10151047, a 30-year-old Asian female with no pertinent medical history, received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24), both in her left deltoid. The subject experienced a shoulder injury related to vaccine administration (SIRVA) on 09 Sep 2020 (Day 24), on the same day as Dose 2. Concomitant medication reported within 2 weeks before the onset of the shoulder injury included cetirizine hydrochloride for allergies (since an unknown date). On 09 Sep 2020 (Day 24), late in the evening, the subject experienced pain in the left arm. She noted that the bandage from Dose 2 was very high on her arm and experienced some soreness of her upper arm with very limited range of motion for the first few days and burning pain down her arm. Initially, she also had a tingling sensation down her arm; however, this resolved. On 15 Sep 2020 (Day 30), the subject had a sensation of numbness, which affected her arm and hand, with a sensation of loss of dexterity, notable when typing. The subject reported that her condition was improving gradually, especially in terms of pain, but she still had a significant limitation in range of motion and daily activities. On examination, she had no obvious swelling, color change, bruising, or tenderness over the left deltoid. She could raise her left arm slightly higher than 90 degrees and with assistance could lift higher, but this caused significant discomfort; she could not extend her left arm behind her back well. The strength was noted to be 5/5. When moving her arm against resistance, she experienced pain down her arm and increased sensation of numbness. The principal investigator (PI) reported a possible diagnosis of shoulder injury related to vaccine administration that was considered an important medical event. The subject was aware that the shoulder injury could be self-limited but could last for some time; however, she was hopeful that it would resolve soon and was considering physical therapy as an option. The PI suggested a neurology consultation and also discussed arrangements for physical therapy. The subject was seen by a neurologist who noted the following findings: motor function had normal muscle bulk and tone. No apparent fasciculations or scapular winging were noted. Shoulder abduction was limited to 70 degrees, shoulder internal rotation limited as well but she was able to extend her left hand behind her back. The neurologist considered 2 diagnoses: SIRVA and IPBN, noting that the clinical picture demonstrated components of both. An electromyography (EMG) was recommended to determine if there was nerve involvement and if so, to what degree. At the time of the neurological evaluation, the subject had started physical therapy. On 02 Oct 2020 (Day 47), a needle EMG of the left upper extremity for all muscles was performed and reported to be unremarkable. The deltoid sample was not collected due to the suspected prior injury to the area. It was reported that since onset, both the pain and limitation in range of motion had improved at this time; additionally, there was great improvement in the shoulder and upper arm but less so in the hand or fingers. The EMG results did not reveal any neurophysiological evidences of a left brachial plexopathy, median dysfunction at the left wrist, ulnar dysfunction across the left elbow, or left cervical radiculopathy. On 07 Oct 2020 (Day 52), the neurologist considered SIRVA as the diagnosis was mostly likely based on the clinical improvement and the EMG result that did not reveal nerve involvement. The subject reported continued improvement especially of the upper arm with increased range of motion but continued to experience decreased dexterity of the left hand. The subject was attending physical therapy twice weekly and reported satisfaction with the gradual and continued improvement. On 03 Nov 2020, the subject informed that 5 weeks of physical therapy had been completed and that the improvement was significant. The shoulder injury was ongoing at the time of the last available report. In the opinion of the investigator, there was a reasonable possibility that the SIRVA was related to the study intervention and to a clinical trial procedure (vaccine administration), but not related to concomitant medications. Pfizer concurred with the investigator's causality assessment. Additionally, it was reported that the vaccine was erroneously administered into or near the shoulder joint capsule. As postulated in the medical literature, unintentional injection of vaccines into the shoulder joint synovial tissues may result in an immune-mediated inflammatory reaction causing SIRVA.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	62.27 kg	19.9 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obstructive breathing due to deviated septum	Nasal septum deviation	(b) (6) 1967	Past
benign cyst removed	Cyst removal	1993	Past
Fibrocystic Breast Disease	Fibrocystic breast disease	1993	Past
Migraines once or twice a month	Migraine	2008	Present
Rhinoplasty	Rhinoplasty	2008	Past
Breast augmentation	Mammoplasty	2010	Past
Vitamin D deficiency	Vitamin D deficiency	2013	Past
right shoulder dislocation	Joint dislocation	2014	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right Shoulder Repair	Shoulder operation	2014	Past
Rhinoplasty	Rhinoplasty	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	11:33
2	BNT162b2	04SEP2020 (22)	16:07

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1			Lower back pain and bilateral lower extremity pain with radicular paresthesia	20OCT2020 (68)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC	Y	Yes	Study Treatment	2	47	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1018 10181159, a 53-year-old white female with a pertinent medical history of osteopenia (dates unknown), vitamin D deficiency (from 2013 to 2014), vitamin B12 deficiency, migraine and neck pain (both since 2008), joint dislocation (right shoulder) and shoulder operation (both in 2014), and occipital neuralgia (since 2014), received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). The subject had lower back pain and bilateral lower extremity pain with radicular paresthesia on 20 Oct 2020, 46 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the lower back pain and bilateral lower extremity pain with radicular paresthesia included zolmitriptan (since 2008) for migraines and vitamin D NOS (since 2013) for vitamin D deficiency.

Narrative Comment
On 07 Oct 2020 (Day 55), at Visit 3, the subject reported feeling fine. On 20 Oct 2020 (Day 68), she began having back and leg pain. On 28 Oct 2020 (Day 76), she had a nasal/sinus operation and received codeine phosphate/paracetamol for 3 days. On 02 Nov 2020 (Day 81), she had lower back pain and bilateral lower extremity pain that was described as shooting pain worse on the right side. Her legs and parietal area of the scalp were sensitive to touch with an associated burning pain. She also reported tenderness in the bilateral inguinal area. The symptoms had gradually developed over approximately past 3 weeks. The subject's spine magnetic resonance imaging (Oct 2020) was unremarkable; and the subject did not consult her primary care physician or a neurologist at this time. She denied any neurological or lower back problems and any other vitamin deficiencies. The subject stated that when she began experiencing the symptoms, her pain score was assessed as 8-9 on a scale of 10 for a couple of weeks and she did not use any analgesics. She also reported that there had been a significant decrease in her level of activity. On 10 Nov 2020 (Day 89), during a follow-up visit with the investigator the subject reported that the paresthesia and skin sensitivity over the parietal area had improved. The subject reported that she used paracetamol, ibuprofen, and codeine phosphate/paracetamol initially, and later received celecoxib for neck pain. After treatment with analgesics, her pain score at its worst was 6-7 on a scale of 10. She continued to use analgesics daily and was able to function adequately despite persistence of mild (1-2/10 in severity) constant pain in her lower back and legs. The subject also reported that she had not noticed any exacerbating factors and denied any recent injury, travel, infection, or change in diet. On 10 Nov 2020 (Day 89), the subject reported that she walked approximately one mile without any problem. Despite still not having an official diagnosis, the investigator had opted to report this as an important medical event since symptoms had persisted and the subject believed they started closer to 5 weeks after vaccination, which was close to the 4 week post-vaccination observation period. The site obtained the medical records from the neurologist and the subject was seen on 06 Nov 2020 (Day 85). As per the neurologist's note, magnetic resonance imaging (MRI) of cervical spine performed several years before showed mild degenerative changes and spondylosis. The MRI of lumbar spine performed recently showed "degenerative discopathy with small left central disc protrusion at T5-T6 with minimal indentation thecal sac. No spinal cord compression, spinal canal stenosis, or neural foramina narrowing was observed. Multilevel hypertrophic changes of the facets within the lumbar spine with no neural foramina stenosis was noted. Incidental finding revealed multilevel small hemangiomas in the cervical and thoracic vertebral bodies". A neurological examination on the same day (Day 85) was normal including gait and tandem walk. Tenderness was noted in lower extremities musculature bilaterally throughout and large mobile inguinal lymph node palpable bilaterally. The laboratory tests ordered by neurologist were normal including vitamin B12: 635 pg/mL (normal range [NR]: 200 - 960 pg/mL), folate: 19.6 µg/L (NR: ≥6.0 µg/L), vitamin D 25-hydroxy: 33 ng/mL (NR: 30 - 100 ng/mL), total creatine phosphokinase: 45 U/L (NR: 28 - 176 U/L), erythrocyte sedimentation rate: 15 mm/hour (NR: 0 - 20 mm/hour), C-reactive protein: 0.3 mg/dL (NR: <0.5 mg/dL), serum aldolase: 3.9 U/L (NR: 1.5 - 7.2 U/L), thyroid stimulating hormone: 1.130 µIU/mL (NR: 0.400 - 4.100 µIU/mL), free thyroxine: 1.42 ng/dL (NR: 0.80 - 1.90 ng/dL), lyme antibody: 0.25 (negative less than 0.9); antinuclear antibody was negative, serum protein electrophoresis was normal, and no monoclonal protein was seen. Imaging study reports not available; neurologist impression included possible post-viral syndrome or an autoimmune process. There was no mention of concern for myelitis or any plan for further work-up. Neurologist's recommendation was to continue celecoxib, as needed and follow-up with primary care physician if labs were unrevealing. It was planned to have the subject return to clinic to obtain more in depth history and possibly some labs as well as request reports of MRIs. The lower back pain and bilateral lower extremity pain with radicular paresthesia was ongoing at the time of last available report. In the opinion of the investigator, there was a reasonable possibility that the lower back pain and bilateral lower extremity pain with radicular paresthesia were related to the study intervention, but not related to concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment and considered that there is not enough evidence to establish a causal relationship with the study vaccine apart from a chronological association at this time of the report. Based on the information currently available, it was more likely that the lower back pain and bilateral lower extremity pain with radicular paresthesia was associated with the subject's underlying known neurological conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	60.09 kg	22 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to penicillin	Drug hypersensitivity	1970	Present
breast cancer	Breast cancer	1992	Past
(R) breast reconstruction	Breast reconstruction	1992	Past
(R) mastectomy	Mastectomy	1992	Past
Atrioventricular block, complete	Atrioventricular block complete	1996	Present
Cardiac pacemaker in situ	Cardiac pacemaker insertion	1996	Present
Sinoatrial Node Dysfunction	Sinus node dysfunction	27JUN2012	Present
Paroxysmal Atrial Fibrillation	Atrial fibrillation	08APR2015	Present
Paroxysmal supraventricular tachycardia	Supraventricular tachycardia	11MAY2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	10:03
2	BNT162b2	14OCT2020 (24)	15:16

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Ventricular arrhythmia	Ventricular arrhythmias	14OCT2020 (24)		21OCT2020 (31)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	8	3	TC	Y	Resolved (21OCT2020)	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1142 11421247, a 71-year-old white female, with a pertinent medical history of complete atrioventricular block and cardiac pacemaker insertion (both since 1996), sinus node dysfunction (since 27 Jun 2012), atrial fibrillation (since 08 Apr 2015), and supraventricular tachycardia (since 11 May 2015), received Dose 1 on 21 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 24). The subject experienced ventricular arrhythmia on 14 Oct 2020, on the same day as Dose 2. Concomitant medications reported within 2 weeks prior to the onset of ventricular arrhythmia included fluticasone propionate (since 30 Jun 2010) and cetirizine hydrochloride (since 03 Nov 2010) both for allergic rhinitis, atorvastatin (since 22 Feb 2013) for hyperlipidemia, duloxetine hydrochloride (since 17 Sep 2014), metoprolol succinate (since 08 Apr 2015) for paroxysmal supraventricular tachycardia, apixaban (since 28 Dec 2015) for atrial fibrillation, and alendronate sodium (since 03 Sep 2019) for osteoporosis. On the evening of 14 Oct 2020 (Day 24), the subject experienced a 4-beat episode of ventricular tachycardia (VT). At 2308 hours, the subject's pacemaker recorded non-sustained ventricular tachycardia (NSVT) with an average heart rate of 134 beats per minute (bpm) lasting 8 seconds. On 15 Oct 2020 (Day 25), in the morning, the subject reported a 2-beat episode. At 0956 hours, the pacemaker recorded NSVT with average heart rate of 199 bpm lasting 15 seconds. On 16 Oct 2020 (Day 26) at 1854 hours, the pacemaker recorded NSVT with an average heart rate of 164 bpm lasting 9 seconds. On 17 Oct 2020 (Day 27) at 1308 and 1322 hours, the subject had 2 episodes of NSVT with average heart rates of 185 bpm and 194 bpm lasting 9 seconds and 8 seconds, respectively. On 18 Oct 2020 (Day 28) at 1308 hours, the subject had an episode of NSVT with average heart rate of 174 bpm lasting 9 seconds. The subject reported fatigue and general malaise during the NSVT episodes. On 20 Oct 2020 (Day 30), the subject reported that she experienced subsequent episodes of ventricular tachycardia every day since the second vaccination; therefore, her cardiologist recommended a defibrillator placement. The investigator considered the ventricular arrhythmia as serious and an important medical event. Relevant laboratory test results on 21 Oct 2020 (Day 31) included troponin I of 0.016 ng/mL (normal range [NR]: 0-0.034 ng/mL), creatine kinase (CK) of 98 U/L (NR: 33-194 U/L), CK-MB of 2.76 ng/mL (NR: 0-3.50 ng/mL), CK-MB index of 2.8% (NR: 0%-2.5%), sodium of 140 mmol/L (NR: 135-145 mmol/L), potassium of 4.5 mmol/L (NR: 3.5-5.0 mmol/L), chloride of 104 mmol/L (NR: 98-108 mmol/L), carbon dioxide of 26 mmol/L (NR: 23-31 mmol/L), and anion gap of 10 (NR: 2-16; units not reported). According to her cardiologist, the CK-MB index result was within acceptable limits and the other test results were also normal. The ventricular arrhythmia was considered resolved on 21 Oct 2020 (Day 31). On 27 Oct 2020 (Day 37), the COVID-19 polymerase chain reaction molecular test and SARS-CoV-2 IgG antibody test results were negative. An electrophysiology study on 29 Oct 2020 (Day 39) showed no evidence of sustained VT/pmVT/VF; however, brief paroxysms of pmVT were seen "with aggressive phase of electrical stimulation protocol at 400/260/200/200", which was nonspecific. No indication for an implantable cardioverter-defibrillator was observed. In the opinion of the investigator, there was a reasonable possibility that the ventricular arrhythmia was related to the study intervention based on the temporal relationship since the arrhythmias began within 24 hours of Dose 2, but not related to concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Additionally, Pfizer commented that there was not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at this time of the report. In absence of evidence for an inflammatory response to study intervention, it was more likely that the ventricular arrhythmia was associated with the subject's underlying known cardiac conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	113.64 kg	36.9 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1977	Present
sinus headache	Sinus headache	1977	Present
pitocin allergy	Drug hypersensitivity	1998	Present
benign paroxysmal vertigo	Vertigo positional	1998	Present
menorrhagia	Menorrhagia	2003	Past
uterine fibroids	Uterine leiomyoma	2003	Past
hysterctomy	Hysterectomy	2005	Past
osteoarthritis, bilateral knees and feet	Osteoarthritis	2015	Present
eczema	Eczema	2017	Present

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_SNAP_2MPD2_Safety_Narratives/profile Date of Generation: 20NOV2020 (21:12)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	13:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	05SEP2020 (2)	18:00	05SEP2020 (2)	20:00
2	GENRL	Injection site erythema	injection site redness	04SEP2020 (1)	19:00	05SEP2020 (2)	19:00
3	GENRL	Injection site pain	injection site muscle soreness	04SEP2020 (1)	19:00	06SEP2020 (3)	
4	GENRL	Injection site warmth	injection site warmth	04SEP2020 (1)	19:00	05SEP2020 (2)	19:00
5	BLOOD	Lymphadenopathy	right axilla lymphadenopathy	16SEP2020 (13)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	TC	N	Resolved (05SEP2020)	Study Treatment	1	2	N
2	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	1	N
3	3	2	N	N	Resolved (06SEP2020)	Study Treatment	1	1	N
4	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	1	N
5		2	TC/P	Y	Yes	Study Treatment	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	25SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781107, a 48-year-old white female with a pertinent medical history of drug hypersensitivity to Pitocin, received Dose 1 on 04 Sep 2020 in her left deltoid. The subject was diagnosed with lymphadenopathy on 16 Sep 2020, 12 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the event included cetirizine hydrochloride (since 2015) for seasonal allergies, ibuprofen (since 2000) for headache and osteoarthritis, and crisaborole (since 2017) for eczema. On 04 Sep 2020 (Day 1), approximately 6 hours after Dose 1 administration, the subject reported mild injection site erythema and warmth, and moderate injection site pain. On 05 Sep 2020 (Day 2), she reported mild chills. That same day (Day 2), the injection site erythema, warmth, and chills were considered resolved, and on 06 Sep 2020 (Day 3), the injection site pain resolved. On 21 Sep 2020 (Day 18), the subject called and reported discomfort in her right arm, shoulder, and chest region on 16 Sep 2020 (Day 13), which she described as feeling like a pulled muscle even at rest. She was treated with ibuprofen 400 mg orally as needed starting on 16 Sep 2020. Additionally, the subject reported that she had called her physician, who referred her to the regional hospital emergency room (ER) for further evaluation. On 20 Sep 2020 (Day 17), the subject visited the ER, at which time her right axilla was examined, and a subsequent ultrasound of the right axilla on the same day revealed at least 4 enlarged lymph nodes, largest 2.5 × 1.1 × 2.4 cm. The laboratory results on the same day showed a white blood cell count of 7.0 k/µL (NR: 4.0 - 10.0 k/µL) with 35.2% lymphocytes (normal range [NR]: 20% - 40%), and an absolute lymphocyte count of 2.4 k/µL (NR: 1.0 - 4.0 k/µL). The subject denied any injuries, cuts, or puncture wounds to the right arm or having a similar problem previously. It was reported that no other areas other than the right axilla were assessed for lymphadenopathy. The subject received ketorolac 10 mg intravenously once (on 20 Sep 2020) while in the ER for lymphadenopathy. The lymphadenopathy was considered medically significant by the investigator. The biopsy was completed on 05 Oct 2020 (Day 32) without issue. On 12 Oct 2020, the subject communicated via phone the results of her work-up stating that her blood tests returned to normal and the biopsy showed no markers for lymphoma or other cancer. Per subject report, the oncologist considered the vaccine as the most likely etiology for her lymphadenopathy. A follow-up oncological visit is planned in 3 months with a possible repeat of the axillary ultrasonogram. The medical records have been requested by the investigator. The subject was discontinued from the study intervention on 25 Sep 2020 because of the lymphadenopathy that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the lymphadenopathy was related to the study intervention. Pfizer did not concur with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	110.82 kg	37.1 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MENOPAUSE	Menopause	1994	Present
HIGH CHOLESTEROL	Blood cholesterol increased	2000	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2000	Present
HIGH BLOOD PRESSURE	Hypertension	2000	Present
SWELLING OF FEET	Peripheral swelling	2000	Present
DEPRESSION	Depression	2015	Present
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2018	Present
TYPE II DIABETES	Type 2 diabetes mellitus	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	15:14

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Facial pain	FACIAL TENDERNESS	06SEP2020 (4)		16SEP2020 (14)		11	2	TC/P	N
2	GENRL	Injection site pain	INJECTION SITE PAIN	04SEP2020 (2)		07SEP2020 (5)		4	2	N	N
3	GENRL	Swelling face	FACIAL SWELLING	06SEP2020 (4)		16SEP2020 (14)		11	2	TC/P	N
4	INFEC	Upper respiratory tract infection	UPPER RESPIRATORY INFECTION	06SEP2020 (4)		16SEP2020 (14)		11	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (16SEP2020)	NOT RELATED/OTHER: ALLERGIC REACTION TO UNKNOWN AGENT	1	4	Y
2	Resolved (07SEP2020)	Study Treatment	1	2	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
3	Resolved (16SEP2020)	NOT RELATED/OTHER: ALLERGIC REACTION TO UNKNOWN AGENT	1	4	Y
4	Resolved (16SEP2020)	NOT RELATED/OTHER: CONCURRENT ILLNESS	1	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Withdrawn	VACCINATION	13SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1005 10051214, a 71-year-old white female with no pertinent medical history, received Dose 1 on 03 Sep 2020. On 04 Sep 2020 (Day 2), the subject experienced moderate injection site pain that resolved on 07 Sep 2020 (Day 5) and facial pain and swelling that began on 06 Sep 2020, 3 days after receiving Dose 1. The facial pain and facial swelling resolved on 16 Sep 2020 (Day 14). The subject was discontinued from the study intervention on 13 Sep 2020 because of the facial pain and facial swelling and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the facial pain and facial swelling were related to the study intervention, but rather they were related to an allergic reaction to an unknown agent.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	80.45 kg	24 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FACTOR 5 LIDEN	Coagulation factor V level	(b) (6) 1944	Present
RECURRENT PEPTIC ULCER	Peptic ulcer	1980	Present
DEEP VEIN THROMBOPHLEBITIS RIGHT LEG	Deep vein thrombosis	1983	Present
CORONARY ARTERY DISEASE	Coronary artery disease	1989	Present
MITRAL VALVE PROLAPSE	Mitral valve prolapse	1989	Past
CORONARY ATHEROSCLEROSIS	Arteriosclerosis coronary artery	DEC1989	Present
HEART ATTACK	Myocardial infarction	DEC1989	Past
LEFT BACK PAIN	Back pain	1990	Present
DIABETES TYPE 2	Type 2 diabetes mellitus	21AUG1995	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2000	Present
RECURRENT BILATERAL LOWER EXTREMITIES EDEMA	Oedema peripheral	2000	Present
CARDIAC STENT PLACEMENT	Coronary arterial stent insertion	25MAR2004	Past
HEART ATTACK	Myocardial infarction	25MAR2004	Past
FLATULENCE	Flatulence	2008	Present
CAUTERIZED ULCERS ON DUODENUM	Duodenal ulcer repair	09FEB2008	Past
BOWEL BLOCKAGE	Intestinal obstruction	01APR2008	Past
BOWEL BLOCKAGE REMOVAL	Intestinal operation	01APR2008	Past
BASAL CELL CARCINOMA, RECURRENT, MULTIPLE LOCATIONS	Basal cell carcinoma	2010	Present
CATARACT SURGERY	Cataract operation	AUG2010	Past
XEROSIS CUTIS	Dry skin	2015	Present
POLYNEUROPATHY, DIABETIC BILATERAL FEET	Diabetic neuropathy	2016	Present
PLANTAR FACIITIS OF RIGHT FOOT	Plantar fasciitis	2016	Present
TRANSIENT ISCHEMIC ATTACK	Transient ischaemic attack	JAN2016	Past
RIGHT BUNDLE BRANCH BLOCK	Bundle branch block right	2017	Present
CARDIAC STENT PLACEMENT	Coronary arterial stent insertion	MAR2017	Past
HEART ATTACK	Myocardial infarction	MAR2017	Past
ANAL FISSURE	Anal fissure	2018	Present
HYPERTENSION	Hypertension	2018	Present
TRANSIENT ISCHEMIC ATTACK	Transient ischaemic attack	JUL2018	Past
CARDIOVASCULAR ACCIDENT	Cardiovascular disorder	06MAR2019	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	12AUG2020 (1)	11:32

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	CARD	Acute myocardial infarction	NON-ST ELEVATED MYOCARDIAL INFARCTION	25AUG2020 (14)		27AUG2020 (16)		3	3	TC/TCN
2	CARD	Angina pectoris	ANGINA	21AUG2020 (10)		27AUG2020 (16)		7	2	TCN
3	CARD	Coronary artery occlusion	CORONARY ARTERY OCCLUSION	25AUG2020 (14)		27AUG2020 (16)		3	4	TC/TCN/P/W
4	RESP	Dyspnoea exertional	DYSPNEA ON EXERTION	25AUG2020 (14)		27AUG2020 (16)		3	2	TCN
5	CARD	Mitral valve incompetence	MITRAL VALVE REGURGITATION	25AUG2020 (14)		27AUG2020 (16)		3	3	TCN

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ARTHEROSCLEROSIS	1	14	N
2	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	10	N
3	Y	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	14	Y

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
4	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	14	N
5	N	Resolved (27AUG2020)	NOT RELATED/OTHER: PROGRESSION OF MYXOMATOUS MITRAL VALVE	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1006 10061020, a 75-year-old white male with a pertinent medical history of factor V Leiden (since (b) (6) 1944), deep vein thrombosis (since 1983), coronary artery disease (since 1989), mitral valve prolapse (in 1989), myocardial infarction (in Dec 1989, on 25 Mar 2004, and in Mar 2017), coronary arterial stent insertion (on 25 Mar 2004 and in Mar 2017), type 2 diabetes (since 21 Aug 1995), hypercholesterolemia (since 2000), transient ischemic attack (in Jan 2016 and in Jul 2018), right bundle branch block (since 2017), hypertension (since 2018), and cardiovascular accident (on 06 Mar 2019), received Dose 1 on 12 Aug 2020. The subject was diagnosed with angina and acute myocardial infarction due to coronary artery occlusion on 25 Aug 2020, 13 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the coronary artery occlusion included warfarin (since 2005) for factor V Leiden; metformin (since 2010), insulin aspart (since 2019), and insulin glargine (since Feb 2019), all for type 2 diabetes; atorvastatin calcium (since 2018) for hypercholesterolemia; and lisinopril (since 2018) for hypertension. On 21 Aug 2020 (Day 10), the subject reported a nonserious adverse event of angina pectoris. On 25 Aug 2020 (Day 14), the subject presented to the emergency room (ER) reporting shortness of breath, for which he was admitted to the hospital with chief complaints of exertional dyspnea (reported as a nonserious adverse event) and angina with little exertion that did not abate as usual. In the ER, the subject received enoxaparin 80 mg subcutaneously once and atorvastatin 40 mg orally once daily. A chest x-ray showed no evidence of acute cardiopulmonary disease. An electrocardiogram (ECG) showed previously diagnosed right bundle branch block with ST depression in II and T-wave inversion in leads I, Vl, and aVF and inferior infarct of undetermined age with no ST elevation; the subject had an elevated troponin level of 0.84 ng/mL (normal range [NR]: 0 – 0.15 ng/mL). He was diagnosed with acute myocardial infarction (reported as a nonserious adverse event). Additional laboratory values included an elevated glucose level (value not reported) and a prothrombin time of 20.6 seconds (NR: 12.2 – 15.5 seconds). Other laboratory results included brain natriuretic peptide, fibrin D-dimer, complete blood count, and lipase, which were within normal limits (values not provided). No COVID-19 testing was performed. That same day (Day 14), the subject was also diagnosed with mitral valve incompetence (reported as a nonserious adverse event). On 26 Aug 2020 (Day 15), an angiogram was performed, which showed worsening of coronary artery disease and severe multivessel coronary artery occlusion. The coronary artery disease was considered life-threatening. The subject was given vitamin K and, on 27 Aug 2020 (Day 16), he underwent a coronary artery bypass graft, during which the mitral valve was repaired. The subject was treated with Cardene, albumin 250 mg, and epinephrine 0.03 µg/kg/min but was quickly weaned off. On 27 Aug 2020 (Day 16), the exertional dyspnea, angina pectoris, coronary artery occlusion, acute myocardial infarction, and mitral valve incompetence were considered resolved. The subject was discharged from the hospital on an unknown date. The subject was withdrawn from the study on 16 Sep 2020 because of the coronary artery occlusion. In the opinion of the investigator, there was no reasonable possibility that the coronary artery occlusion was related to the study intervention, concomitant medications, or clinical trial procedures, but rather related to coronary atherosclerosis. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	85.45 kg	32.3 kg/m2	08OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08OCT2020 (1)	14:40

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	NERV	Paraesthesia	Tingling at finger tips	08OCT2020 (1)	15:15	08OCT2020 (1)	16:15
2	GASTR	Paraesthesia oral	Tingling around the mouth	08OCT2020 (1)	15:15	08OCT2020 (1)	16:14

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	1	N	N	Resolved (08OCT2020)	Study Treatment	1	1	N
2	1	1	P	N	Resolved (08OCT2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08OCT2020	
Withdrawn	VACCINATION	08OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1011 10111181, a 57-year-old white female with no reported medical history, received Dose 1 on 08 Oct 2020. The subject experienced oral paresthesia on 08 Oct 2020, on the same day as Dose 1. On 08 Oct 2020 (Day 1), the subject also experienced paresthesia of fingertips. On the same day (Day 1), the oral paresthesia and paresthesia of fingertips resolved. The subject was discontinued from the study intervention on 08 Oct 2020 because of the oral paresthesia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the oral paresthesia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	63.18 kg	20.5 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cat Scratch Disease	Cat scratch disease	1982	Present
Penicillin Allergy (Anaphylactic Shock)	Anaphylactic shock	1984	Present
Codeine Allergy	Drug hypersensitivity	1984	Present
Allergic Atopic Dermatitis	Dermatitis atopic	2016	Present
Iodine Allergy	Iodine allergy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09SEP2020 (1)	16:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site dermatitis	LEFT UPPER ARM DERMATITIS AT INJECTION SITE	11SEP2020 (3)		ONGOING	
2	PSYCH	Insomnia	INSOMNIA	12SEP2020 (4)		ONGOING	
3	INV	Weight decreased	WEIGHT LOSS	14SEP2020 (6)		04OCT2020 (26)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	P/W	N	Yes	Study Treatment	1	3	Y
2		2	TC	N	Yes	Study Treatment	1	4	N
3	21	3	N	N	Resolved (04OCT2020)	Study Treatment	1	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	24SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	17OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1012 10121163, a 41-year-old white female with a pertinent medical history of atopic dermatitis (since 2016), received Dose 1 on 09 Sep 2020. The subject experienced injection site dermatitis on 11 Sep 2020, 2 days after receiving Dose 1. The subject was discontinued from the study intervention on 24 Sep 2020 because of the injection site dermatitis and subsequently was withdrawn from the study on 17 Oct 2020 because of injection site dermatitis. The injection site dermatitis was ongoing as of the last available report. In the opinion of the investigator, there was a reasonable possibility that the injection site dermatitis was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	75 kg	22.4 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Childhood asthma	Childhood asthma	1975	Present
Acid reflux	Gastrooesophageal reflux disease	2000	Present
Vertigo	Vertigo	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	14:39

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	28AUG2020 (2)		28AUG2020 (2)	
2	NERV	Headache	Headache	28AUG2020 (2)		01SEP2020 (6)	
3	GASTR	Nausea	Nausea	28AUG2020 (2)		01SEP2020 (6)	
4	EAR	Vertigo	Worsening and continuing episode of Veritgo	28AUG2020 (2)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (28AUG2020)	Study Treatment	1	2	N
2	5	1	N	N	Resolved (01SEP2020)	Study Treatment	1	2	N
3	5	1	N	N	Resolved (01SEP2020)	Study Treatment	1	2	N
4		2	P	N	Yes	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluzone Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	28SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Withdrawn	VACCINATION	06NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1015 10151134, a 55-year-old white male with a pertinent medical history of vertigo (since 2012), received Dose 1 on 27 Aug 2020. The subject experienced worsening and continuing episodes of vertigo on 28 Aug 2020, 1 day after receiving Dose 1. On 28 Aug 2020 (Day 2), the subject also experienced diarrhea, headache, and nausea. The diarrhea resolved on the same day (Day 2) and the headache and nausea resolved on 01 Sep 2020 (Day 6). The subject was discontinued from the study intervention on 06 Nov 2020 because of the worsening and continuing vertigo that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the worsening and continuing vertigo was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	77.32 kg	24.4 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	APR1994	Present
allergy to flagyl	Drug hypersensitivity	APR2002	Present
meniscus repair	Meniscus operation	JUL2009	Past
migraines	Migraine	APR2010	Present
ovarian fibroid	Ovarian fibroma	JAN2015	Past
hysterectomy	Hysterectomy	JUN2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10AUG2020 (1)	10:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site swelling	injection site swelling	10AUG2020 (1)		19AUG2020 (10)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	10	3	TC/P	N	Resolved (19AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Withdrawn	VACCINATION	31AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161087, a 43-year-old white female with no pertinent medical history, received Dose 1 on 10 Aug 2020. On the same day (Day 1), the subject reported severe injection site swelling, after receiving Dose 1. The injection site swelling resolved on 19 Aug 2020 (Day 10). The subject was discontinued from the study intervention on 31 Aug 2020 because of the injection site swelling and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the injection site swelling was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	65.45 kg	24.1 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraine Headaches	Migraine	1995	Present
Allergy to Shellfish	Food allergy	1996	Present
Allergy to Iodine	Iodine allergy	1996	Present
Mitral Valve Prolapse	Mitral valve prolapse	2007	Present
Hypertension	Hypertension	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	15:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	IMMUN	Allergy to vaccine	Allergic Reaction to Study Vaccine	29AUG2020 (2)		11SEP2020 (15)		14
2	MUSC	Back pain	Lower back pain	08SEP2020 (12)		11SEP2020 (15)		4
3	MUSC	Back pain	Mid back pain	11SEP2020 (15)		14SEP2020 (18)		4
4	GENRL	Chest pain	Left-sided chest pain	08SEP2020 (12)		08SEP2020 (12)		1
5	GASTR	Gastrooesophageal reflux disease	GERD	08SEP2020 (12)		ONGOING		
6	NERV	Hypoaesthesia	Right arm numbness	11SEP2020 (15)		11SEP2020 (15)		1
7	MUSC	Muscular weakness	Right leg weakness	10SEP2020 (14)		10SEP2020 (14)		1
8	RESP	Pharyngeal swelling	Throat Swelling	29AUG2020 (2)		08SEP2020 (12)		11

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/P	N	Resolved (11SEP2020)	Study Treatment	1	2	Y
2	1	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: GERD	1	12	N
3	1	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: GERD	1	15	N
4	1	TC	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Gerd	1	12	N
5	1	TC	N	Yes	NOT RELATED/OTHER: acid reflux	1	12	N

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
6	1	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: Unknown	1	15	N
7	2	TCN	N	Resolved (10SEP2020)	NOT RELATED/OTHER: Unknown	1	14	N
8	2	TC	N	Resolved (08SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Withdrawn	VACCINATION	11SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1027 10271105, a 46-year-old black or African American female with a pertinent medical history of allergy to shellfish and iodine (since 1996), received Dose 1 on 28 Aug 2020. The subject developed pharyngeal swelling considered to be an allergic reaction to the vaccine on 29 Aug 2020, 1 day after receiving Dose 1. The allergic reaction resolved on 11 Sep 2020 (Day 15). The subject was discontinued from the study intervention on 11 Sep 2020 because of the allergic reaction and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the allergic reaction was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	107.3 kg	32 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	2010	Present
GASTROESPPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	01AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	12:09
2	BNT162b2	13OCT2020 (23)	10:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1			FATIGUE	14OCT2020 (24)		15OCT2020 (25)		2
2			FEVER	14OCT2020 (24)		15OCT2020 (25)		2
3			MUSCLE ACHES	14OCT2020 (24)		15OCT2020 (25)		2
4	GASTR	Nausea	Nausea	07OCT2020 (17)		07OCT2020 (17)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	P	N	Resolved (15OCT2020)	Study Treatment	2	2	Y
2	1	N	N	Resolved (15OCT2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (15OCT2020)	Study Treatment	2	2	N
4	1	N	N	Resolved (07OCT2020)	NOT RELATED/OTHER: UNK	1	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1037 10371252, a 59-year-old black or African American male with a pertinent medical history of obesity (since 2010), received Dose 1 on 21 Sep 2020 and Dose 2 on 13 Oct 2020 (Day 23). The subject reported fatigue on 14 Oct 2020, 1 day after receiving Dose 2. On 14 Oct 2020 (Day 24), the subject also reported fever and muscle aches. The fatigue, fever, and muscle aches resolved on 15 Oct 2020 (Day 25). At the time of the data snapshot (17 Nov 2020) this subject was erroneously reported as having withdrawn from the study intervention because of the fatigue. The subject continues in the study. The data have since been corrected, which will be reflected in the next data snapshot. In the opinion of the investigator, there was a reasonable possibility that the fatigue was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	84.35 kg	28.3 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lactose intolerance	Lactose intolerance	2016	Present
appendectomy	Appendicectomy	14FEB2017	Past
appendicitis	Appendicitis	14FEB2017	Past
cyst, R axilla	Cyst	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	12:32

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Dizziness	lightheadedness	23SEP2020 (1)	12:40	23SEP2020 (1)	14:40
2	GASTR	Nausea	nausea	23SEP2020 (1)	12:40	23SEP2020 (1)	14:40

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	P	N	Resolved (23SEP2020)	Study Treatment	1	1	Y
2	1	1	P	N	Resolved (23SEP2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Withdrawn	VACCINATION	23SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1054 10541186, a 71-year-old black or African American female with no pertinent medical history, received Dose 1 on 23 Sep 2020. The subject experienced dizziness and nausea on 23 Sep 2020, after receiving Dose 1, which resolved on the same day. The subject was discontinued from the study intervention on 23 Sep 2020 because of the dizziness and nausea and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the dizziness and nausea were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	89 kg	32.3 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	14:35

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Cerebral capillary telangiectasia	Cerebral Capillary telangiectasia	26SEP2020 (30)		ONGOING			1
2	GASTR	Dysphagia	Dysphagia	AUG2020 ()		ONGOING			1
3	MUSC	Pain in extremity	Right upper extremity pain	10OCT2020 (44)		ONGOING			1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Yes	NOT RELATED/OTHER: anatomical abnormality	1	30	N
2	P	N	Yes	NOT RELATED/OTHER: unknown, GI or neurological abnormality			Y
3	N	N	Yes	NOT RELATED/OTHER: Cause is being evaluated	1	44	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Withdrawn	VACCINATION	14OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1055 10551145, a 35-year-old white female with no reported medical history, received Dose 1 on 28 Aug 2020. The subject experienced dysphagia on an unknown date in Aug 2020. The subject was discontinued from the study intervention on 14 Oct 2020 because of the dysphagia that was ongoing at the time of last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the dysphagia was related to the study intervention, but rather it was related to unknown GI or neurological abnormality.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.7 cm	100.7 kg	33.8 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PARTIAL HYSTERECTOMY	Hysterectomy	2012	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2013	Present
HYPERTENSION	Hypertension	2015	Present
TYPE II DIABETES	Type 2 diabetes mellitus	2016	Present
CONGESTIVVE HEART FAILURE	Cardiac failure congestive	2017	Present
ALLERGIC RHINITIS	Rhinitis allergic	2017	Present
STROKE	Cerebrovascular accident	2019	Past
CORONARY ARTERY DISEASE	Coronary artery disease	2019	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	JAN2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BILATERAL LEG EDEMA	Oedema peripheral	JAN2019	Present
BILATERAL ANKLE EDEMA	Oedema peripheral	JUN2019	Present
VISION LOSS	Blindness	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	12:15

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Coronary artery disease	WORSENING coronary artery disease	23AUG2020 (12)		ONGOING			2	TCN/P/W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Hypertensive cardiovascular disease or arteriosclerotic heart disease	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	23AUG2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	28AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1071 10711023, a 56-year-old black or African American female with a pertinent medical history of hypertension (since 2015), congestive cardiac failure (since 2017), hypercholesterolemia (since Jan 2019), cerebrovascular accident (in Feb 2020), and coronary artery disease (since 2019 with 6 coronary stents placed in Sep 2019), received Dose 1 on 12 Aug 2020. The subject was diagnosed with worsening coronary artery disease on 23 Aug 2020, 11 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the worsening coronary artery disease included omeprazole (since 2010) for gastroesophageal reflux disease, sacubitril/valsartan sodium hydrate (since Jan 2018) and isosorbide dinitrate and clopidogrel (both since 2018) for congestive heart failure, acetylsalicylic acid (since 2018) for cardiovascular prophylaxis, cyanocobalamin (since 2018) as a nutritional supplement, metformin (since 2018) and empagliflozin (since Jan 2020) for type 2 diabetes, fexofenadine (since 2018) for allergic rhinitis, atorvastatin (since Jan 2019) for hypercholesterolemia, metoprolol (since Jan 2019) for hypertension, and spironolactone (since Jan 2019) and furosemide (since Jun 2019) both for edema. On 19 Aug 2020 (Day 8), at 0950 hours, the subject reported she was being evaluated for blocked stents in the hospital. During this conversation, the subject stated that she was informed by her cardiologist on 17 Aug 2020 (Day 6) that she would have her stents examined on 18 Aug 2020 (Day 7). On 18 Aug 2020 (Day 7), the subject went to the emergency room at 1700 hours and was admitted for testing; however, she was unsure about why the procedures became inpatient procedures. She reported that this planned visit to a cardiologist resulted in an overnight hospitalization. On 21 Aug 2020 (Day 10), the subject stated that previously she was never in the hospital overnight and was at the hospital only for a stress test. The site staff requested the medical records to verify the stress test. On a subsequent date, the staff spoke with the subject again regarding medical records needed for the stress test. The subject said that she had quadruple bypass surgery on 24 Aug 2020 (Day 13) for coronary artery disease, was currently in the hospital, and would be discharged the next day (31 Aug 2020). In addition, the subject reported that she had been exercising 5 times per week before the coronavirus disease (COVID) outbreak. She switched to walking daily since the COVID outbreak, and noticed getting easily winded since Jun 2020; therefore, she visited her doctor, who performed a stress test on 17 Aug 2020 (Day 6). According to the subject, her doctor called her back later that week and told her she needed surgery. The medical records were received and reviewed, which confirmed the details of the tests performed and the surgery; it was noted that a stress test was not performed on 18 Aug 2020 (Day 7), but rather an angiogram was performed; the results were not available. The subject was discontinued from the study intervention on 23 Aug 2020 because of the worsening coronary artery disease and was withdrawn from the study on 28 Aug 2020. On 31 Aug 2020, the subject recovered from the worsening coronary artery disease. According to the medical records her postoperative course was unremarkable, she recovered, and was discharged. In the opinion of the investigator, there was no reasonable possibility that the worsening coronary artery disease was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was due to hypertensive cardiovascular disease or arteriosclerotic heart disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	77.1 kg	24.4 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ECZEMA	Eczema	1970	Present
ALCOHOL ABUSE	Alcohol abuse	1982	Present
DEPRESSION	Depression	1982	Present
DRUG ABUSE	Drug abuse	1982	Present
SEIZURE DISORDER	Seizure	1986	Present
ALLERGIC RHINITIS	Rhinitis allergic	2013	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
ATAXIA	Ataxia	2018	Present
CHOLELITHIASIS	Cholelithiasis	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEPATOSTEATOSIS	Hepatic steatosis	2018	Present
PERIPHERAL NEUROPATHY BILATERAL FEET	Neuropathy peripheral	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	16:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Alcohol poisoning	ACUTE ALCOHOL INTOXICATION	02OCT2020 (18)		15OCT2020 (31)		14	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P/W	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: ALCOHOL DEPENDENCE	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Withdrawn	VACCINATION	15OCT2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	15OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1071 10711169, a 56-year-old white male with a pertinent medical history of alcohol abuse, drug abuse, and depression (all since 1982), seizures (since 1986), and ataxia, hepatic steatosis, and peripheral neuropathy (all since 2018), received Dose 1 on 15 Sep 2020. The subject was diagnosed with alcohol poisoning on 02 Oct 2020, 17 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of alcohol poisoning included loratadine (since 2013) for allergic rhinitis and levetiracetam (since Mar 2019) for a seizure disorder. On 02 Oct 2020 (Day 18), the subject went to the emergency room because of acute alcohol intoxication and was hospitalized. It was reported that the subject had a history of alcohol intake since he was a teenager and had a grand mal seizure in 2015 due to alcohol intake. On 15 Oct 2020 (Day 31), the alcohol poisoning resolved and the subject was discharged from the hospital to a rehabilitation facility. The subject was withdrawn from the study on 15 Oct 2020 because of the alcohol poisoning. In the opinion of the investigator, there was no reasonable possibility that the alcohol poisoning was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to alcohol dependence. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.2 cm	61.05 kg	25.7 kg/m2	29JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	1986	Present
IBS-M	Irritable bowel syndrome	1998	Present
Insomnia	Insomnia	1999	Present
Allergic Rhinitis - Seasonal	Seasonal allergy	2010	Present
GERD	Gastrooesophageal reflux disease	2012	Present
Hypothyroidism	Hypothyroidism	2012	Present
Fibromyalgia	Fibromyalgia	2017	Present
Cholelithiasis - Gallstones	Cholelithiasis	28JUL2020	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hydronephrosis	Hydronephrosis	28JUL2020	Present
Ovarian cyst	Ovarian cyst	28JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	14:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Adenocarcinoma gastric	INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	20AUG2020 (23)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	P/W	Y	Yes	NOT RELATED/OTHER: n/a	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29JUL2020	
Withdrawn	VACCINATION	20AUG2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	27AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1079 10791004, a 48-year-old white female with a pertinent medical history of irritable bowel syndrome (since 1998) and gastroesophageal reflux disease (since 2012), received Dose 1 on 29 Jul 2020. The subject was diagnosed with poorly differentiated gastric adenocarcinoma on 20 Aug 2020, 22 days after receiving Dose 1. On 20 Aug 2020 (Day 23), the subject visited her physician's office and an upper gastrointestinal endoscopic biopsy revealed infiltrating poorly differentiated adenocarcinoma. No information was available on the symptoms; staging and chemotherapy were planned but no details are available at this time. The subject was withdrawn from the study on 27 Aug 2020 because of the gastric adenocarcinoma that was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the poorly differentiated gastric adenocarcinoma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	132.18 kg	40.6 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic sinus infection	Chronic sinusitis	1990	Past
Intermittent Headache	Headache	1990	Present
tonsillitis	Tonsillitis	1993	Past
bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2002	Past
bilateral carpal tunnel repair	Carpal tunnel decompression	2003	Past
obesity	Obesity	2004	Present
balloon sinuplasty	Sinuplasty	2011	Past
allergy to cedar	Allergy to plants	2013	Present
allergy to oak	Allergy to plants	2013	Present

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_SNAP_2MPD2_Safety_Narratives/profile Date of Generation: 20NOV2020 (21:12)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2013	Present
heartburn	Dyspepsia	2018	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2018	Present
anxiety	Anxiety	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	12:21

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	Paroxysmal Atrial fibrillation with rapid ventricular response	23AUG2020 (20)		08SEP2020 (36)	00:00	17
2	CARD	Atrial flutter	Atrial Flutter	02SEP2020 (30)	00:00	08SEP2020 (36)	00:00	7
3	VASC	Hypertension	Hypertension	24AUG2020 (21)	00:00	ONGOING		
4	CARD	Left atrial enlargement	Left Atrial Enlargement	09SEP2020 (37)	00:00	ONGOING		
5	CARD	Left ventricular hypertrophy	Left Ventricular Hypertrophy	24AUG2020 (21)	00:00	ONGOING		
6	CARD	Mitral valve incompetence	Mitral Regurgitation	09SEP2020 (37)	00:00	ONGOING		
7	CARD	Mitral valve prolapse	Bileaflet mitral valve prolapse	09SEP2020 (37)	00:00	ONGOING		

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
8	CARD	Myocardial infarction	Prior Septual Myocardinal Infarction	08SEP2020 (36)	00:00	08SEP2020 (36)	00:00	1
9	INJ&P	Skin laceration	Laceration-Left Index Finger	01SEP2020 (29)	00:00	15SEP2020 (43)	00:00	15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN/P	Y	Resolved (08SEP2020)	NOT RELATED/OTHER: Heart Disease	1	20	Y
2	3	TC/TCN	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Cardiac Disease	1	30	N
3	1	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
4	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
5	1	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
6	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
7	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
8	1	N	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Heart Disease	1	36	N
9	2	TCN	N	Resolved (15SEP2020)	NOT RELATED/OTHER: Hobby Injury	1	29	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Withdrawn	VACCINATION	23AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1083 10831029, a 50-year-old white male with a pertinent medical history of obesity (since 2004), received Dose 1 on 04 Aug 2020. The subject was diagnosed with atrial fibrillation on 23 Aug 2020, 19 days after receiving Dose 1.

Concomitant medications reported within 2 weeks before the onset of the atrial fibrillation, hypertension, and left ventricular hypertrophy included naproxen sodium and acetylsalicylic acid (since 1990) for headache; fluticasone propionate (since 2013) for seasonal allergies; omeprazole (since 2018) for gastroesophageal reflux disease; and pregabalin, desvenlafaxine succinate, and lorazepam (all since 2019) for anxiety.

On 23 Aug 2020 (Day 20), the subject presented to the emergency room (ER) with palpitations associated with a funny sensation in his head and was hospitalized on 24 Aug 2020 (Day 21). An electrocardiogram (ECG) showed atrial fibrillation with rapid ventricular response of 141 beats/min, no PR interval, normal QRS, and normal-appearing ST and T waves. The ventricular rate was controlled by treatment with diltiazem and a beta blocker. Cardiac telemetry showed a heart rate ranging from 80 to 90's (beats/min). The subject's echocardiography revealed mild left ventricular hypertrophy. The estimated ejection fraction was 55% to 60%. Additional laboratory results showed an elevated blood glucose level of 195 mg/dL (normal range [NR]: 70 - 110 mg/dL). The physician notes stated that a nonfasting glucose test was performed, and the subject had eaten some high-sugar food prior to the ER visit; however, the subject was not treated, nor was the elevated test result reported as an adverse event. An event of elevated glucose was reported in the hospital medical records once. Additional laboratory results included blood urea of 25 mg/dL (NR: 7 - 18 mg/dL) and low blood potassium of 3.4 mmol/L (NR: 3.5 - 5.1 mmol/L).

Narrative Comment
Additionally, the subject was treated with ketorolac tromethamine 10 mg orally (PO) as needed (PRN) and apixaban 5 mg PO twice a day (BID) (both since 25 Aug 2020) for atrial fibrillation, and metoprolol tartrate 50 mg PO from 25 Aug 2020 to 02 Sep 2020 and then at 50 mg PO BID since 02 Sep 2020 for hypertension. The subject was monitored for his response on the beta blocker and calcium channel blocker. On 25 Aug 2020 (Day 22), the subject's laboratory results showed elevated alanine aminotransferase of 107 IU/L (NR: 30 - 65 IU/L), aspartate aminotransferase of 57 IU/L (NR: 15 - 37 IU/L), chloride of 108 mmol/L (NR: 98 - 107 mmol/L), and magnesium of 2.5 mg/dL (NR: 1.8 - 2.4 mg/dL); and low anion gap of 5 (NR: 7 - 16; units not reported). On the same day (Day 22), the subject was discharged from the hospital and was scheduled for a cardioversion with a transesophageal echocardiogram. On 02 Sep 2020 (Day 30), the subject followed up with his cardiologist for cardio evaluation after hospitalization. On the same day (Day 30), a stress test and cardiac catheterization were performed and the results were not available. An ECG performed that same day was abnormal and showed atrial fibrillation with a nonspecific T-wave abnormality, and the subject was diagnosed with atrial flutter with an onset date of 02 Sep 2020 (Day 30). On 08 Sep 2020 (Day 36), the ECG results revealed new cardiac findings of septal myocardial infarction that was considered probably old per the surgeon's postoperative report, mitral regurgitation, bileaflet mitral valve prolapse, and left atrial enlargement. On the same day (Day 36), the atrial fibrillation and atrial flutter were considered resolved. On 09 Sep 2020 (Day 37), the subject was diagnosed with bileaflet mitral valve prolapse and left atrial enlargement, and mitral regurgitation. On 08 Sep 2020 (Day 36), a transesophageal echocardiography with cardioversion was performed with no complications. The cardiac rhythm was successfully converted from atrial fibrillation to normal sinus rhythm with a ventricular rate of 69 beats per minute. The subject was treated with acetylsalicylic acid 81 mg PO daily (since 30 Sep 2020) as prophylaxis. On 03 Oct 2020 (Day 61), the subject returned to the site for Visit 3 (follow-up safety evaluation). The subject was discontinued from the study intervention on 23 Aug 2020 because of the atrial fibrillation and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The hypertension, mitral valve incompetence, left atrial enlargement, left ventricular hypertrophy, and mitral valve prolapse were ongoing as of the last available report. In the opinion of the investigator, there was no reasonable possibility that the paroxysmal atrial fibrillation with rapid ventricular response was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to medical illness. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	81.91 kg	27.4 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic Rhinitis-Seasonal	Seasonal allergy	1976	Present
Hair Loss	Alopecia	2000	Present
Umbilical hernia	Umbilical hernia	2010	Present
Pectoralis Tendon Tear-Right	Tendon rupture	2013	Past
Pectoralis tendon Tear Repair-Right	Tenoplasty	2013	Past
Partial Achilles Tendon Tear-Right Foot	Tendon rupture	MAR2018	Past
Right Foot Achilles Tendon Repair	Tenoplasty	MAR2018	Past
Stomach Cramps	Abdominal pain upper	03AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	11:30

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	Worsening of Abdominal Pain	14AUG2020 (9)	00:00	24AUG2020 (19)	11:32	11	4
2	INFEC	Cellulitis	Phlegmon Formation	20AUG2020 (15)	00:00	20AUG2020 (15)	00:00	1	3
3	GASTR	Diverticular perforation	Ruptured diverticulum	14AUG2020 (9)	00:00	24AUG2020 (19)	00:00	11	4
4	INFEC	Diverticulitis	Diverticulitis	20AUG2020 (15)	00:00	ONGOING			4
5	INJ&P	Postoperative ileus	Post Operative Ileus	18AUG2020 (13)	00:00	23AUG2020 (18)	00:00	6	2
6	GASTR	Small intestinal obstruction	Small Bowel Obstruction	20AUG2020 (15)	00:00	20AUG2020 (15)	00:00	1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (24AUG2020)	NOT RELATED/OTHER: Ruptured Diverticulum	1	9	N
2	TC/TCN	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Diverticulitis	1	15	N
3	TC/TCN/P	Y	Resolved (24AUG2020)	NOT RELATED/OTHER: Infection	1	9	Y
4	TC/TCN	N	Yes	NOT RELATED/OTHER: Infection	1	15	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
5	TC	N	Resolved (23AUG2020)	NOT RELATED/OTHER: Surgical Side Effect	1	13	N
6	TC/TCN	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Ruptured Diverticulum	1	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Withdrawn	VACCINATION	14AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1083 10831060, a 45-year-old white male with a pertinent medical history of upper abdominal pain (since 03 Aug 2020), received Dose 1 on 06 Aug 2020. The subject was diagnosed with a diverticular perforation on 14 Aug 2020, 8 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the diverticular perforation included finasteride (since Apr 2020) for hair loss, dicyclomine and omeprazole magnesium (since 11 Aug 2020) for stomach cramps, and acetaminophen (since 11 Aug 2020) for fever. On 06 Aug 2020 (Day 1), the subject did not report any symptoms related to diverticular perforation. On 07 Aug 2020 (Day 2), a magnetic resonance imaging scan with and without contrast showed a benign liver mass. On 08 Aug 2020 (Day 3), the subject had a fever, and on 11 Aug 2020 (Day 6), he experienced abdominal pain and reported both to the site. The subject was prescribed dicyclomine and omeprazole for possible gastritis by (b) (6) , who was a family physician; additionally, the subject was also taking acetaminophen before the onset of the abdominal pain for fever. The subject stated he had abdominal cramps since 03 Aug 2020 (Day -3); however, he did not report this to the clinical research coordinator at the time of screening. On 13 Aug 2020 (Day 8), the subject visited a primary care physician for a Helicobacter pylori test; the result was not provided. On 14 Aug 2020 (Day 9), the subject presented to the emergency department with worsening right-sided abdominal pain and was hospitalized ultimately for a small-bowel obstruction. He was diagnosed with a heterogeneous cecal mass via a computed tomogram of the abdomen/pelvis with contrast performed on the same day. On 16 Aug 2020 (Day 11), 4 benign lymph nodes, ruptured diverticulum, sessile serrated polyps/adenoma, and focal serosal colon adhesions were observed via an exploratory laparotomy. The subject underwent bowel resection with a right hemicolectomy and allograft tissue reinforcement of anastomosis and abdominal wall excision; the right colon and appendix were removed. The pathology was negative for malignancy. On 18 Aug 2020 (Day 13), the subject experienced postoperative ileus. On 20 Aug 2020 (Day 15), the subject was diagnosed with (phlegmon formation), small-intestinal obstruction, and diverticulitis. The small-intestinal obstruction and (phlegmon formation) resolved on the same day (Day 15), and the subject was able to tolerate an oral diet without difficulties. On 23 Aug 2020 (Day 18), the postoperative ileus was considered resolved. On 24 Aug 2020 (Day 19), the subject's laboratory tests showed an elevated alanine aminotransferase of 114 IU/L (normal range [NR]: 16 - 61 IU/L), aspartate aminotransferase of 82 IU/L (NR: 15 - 37 IU/L), immature granulocytes 1.0% (NR: 0% - 0.7%), and repeat immature granulocytes 0.06% (NR: 0% - 0.05%). A culture was performed on an unspecified date, which was negative. The subject recovered from the diverticular perforation and worsening abdominal pain on 24 Aug 2020 (Day 19). The subject was discharged from the hospital on the same day (Day 19) with the following medications: gabapentin 300 mg orally (PO) 3 times a day, docusate sodium 100 mg PO daily, pantoprazole 40 mg PO every morning, sucralfate 1 g PO 4 times a day as needed, and tramadol 50 mg PO every 8 hours. The investigator considered the diverticular perforation as life-threatening. On 18 Sep 2020 (Day 44), the subject reported he was not stable enough to travel or attend the safety visit. The subject was discontinued from the study intervention on 14 Aug 2020 because of the diverticular perforation and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The diverticulitis was ongoing as of the last available report. In the opinion of the investigator, there was no reasonable possibility that the diverticular perforation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to infection. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	73.75 kg	23.3 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
INSOMNIA	Insomnia	1990	Present
GERD	Gastrooesophageal reflux disease	2010	Present
Alcoholic Cirrhosis	Cirrhosis alcoholic	2019	Present
Esophageal Ulcers	Oesophageal ulcer	2019	Present
Esophageal varices	Varices oesophageal	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	14:43

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Blood loss anaemia	Acute blood loss anemia	07SEP2020 (20)		09SEP2020 (22)		3	3
2	HEPAT	Cirrhosis alcoholic	Worsening of alcoholic cirrhosis	07SEP2020 (20)		ONGOING			3
3	GASTR	Gastrointestinal haemorrhage	GI Bleed	07SEP2020 (20)		09SEP2020 (22)		3	3
4	GASTR	Haematochezia	Hematochezia	07SEP2020 (20)		09SEP2020 (22)		3	3
5	METAB	Hypernatraemia	Hypernatremia	07SEP2020 (20)		09SEP2020 (22)		3	2
6	GASTR	Oesophageal ulcer	Worsening of esophageal ulcers	07SEP2020 (20)		09SEP2020 (22)		3	3
7	BLOOD	Thrombocytopenia	Thrombocytopenia	07SEP2020 (20)		ONGOING			3
8	GASTR	Varices oesophageal	Worsening of esophageal varices	07SEP2020 (20)		09SEP2020 (22)		3	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: due to varices	1	20	N
2	N	N	Yes	NOT RELATED/OTHER: Worsening of previous condition	1	20	N
3	TC/TCN/P/W	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: Due to Ulcers	1	20	Y
4	TC	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Due to ulcers	1	20	N
5	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Spontaneous event	1	20	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
6	TC/TCN	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Worsening of previous condition	1	20	N
7	N	N	Yes	NOT RELATED/OTHER: Due to cirrhosis	1	20	N
8	TC/TCN	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Worsening of previous condition	1	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	09SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	09SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1087 10871121, a 67-year-old white male, with a pertinent medical history of gastroesophageal reflux disease (since 2010) and alcoholic cirrhosis, esophageal ulcers, and esophageal varices (all since 2019), received Dose 1 on 19 Aug 2020. The subject was diagnosed with a gastrointestinal hemorrhage on 07 Sep 2020, 19 days after receiving Dose 1. Concomitant medication reported within 2 weeks before the onset of the event included tramadol (since 01 Jun 2020) for insomnia. On 07 Sep 2020 (Day 20), the subject was diagnosed with anemia due to blood loss, alcoholic cirrhosis, hematochezia, esophageal ulcer, thrombocytopenia, esophageal varices, and hypernatremia. An esophagogastroduodenoscopy performed the next day revealed postbanding ulcers and residual esophageal varices. The esophageal varices were rebanded, and the subject was observed overnight. It was reported that the subject failed to report a past history of esophageal varices and alcoholic cirrhosis. Laboratory results on 08 Sep 2020 (Day 21) revealed a hematocrit (Hct) of 22.9, hemoglobin (Hb) of 7.1, and platelet count of 70. On 09 Sep 2020 (Day 22), laboratory results showed Hct of 21.4, Hb of 7.0, sodium of 143, potassium of 3.6, chloride of 115, carbon dioxide (CO2) of 21.0, blood urea nitrogen (BUN) of 14, and creatinine of 0.73 (normal ranges and units were not reported). The clinical chemistry laboratory results on 07 Sep 2020 (Day 20) showed sodium of 147, potassium of 3.7, chloride of 116, CO2 of 16.6, BUN of 22, creatinine of 1.07, international normalized ratio (INR) of 1.18, albumin of 3.0, total protein of 6.5, direct bilirubin of 0.61, alanine aminotransferase (ALT) of 24, aspartate aminotransferase (AST) of 28, and alkaline phosphatase (ALP) of 96 (normal ranges and units were not reported). Repeat laboratory results on 08 Sep 2020 (Day 21) showed a white blood cell count of 2.9, sodium of 147, potassium of 3.7, chloride of 119, CO2 of 19.8, BUN of 18, creatinine of 0.86, albumin of 2.7, total protein of 5.3, ALT of 15, AST of 31, and ALP of 82 (normal ranges and units were not reported). The anemia, gastrointestinal hemorrhage, hematochezia, hypernatremia, esophageal ulcer, and esophageal varices were considered resolved on 09 Sep 2020 (Day 22). It was noted that the bleeding did not reoccur, and the subject was discharged on the same day (Day 22). The subject notified the site that he was feeling well and had recovered from the event. The subject was withdrawn from the study on 09 Sep 2020 because of the gastrointestinal hemorrhage. The alcoholic cirrhosis and thrombocytopenia were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the gastrointestinal hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to ulcers. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.9 cm	92.5 kg	27.7 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	2005	Present
GROUT	Gout	2017	Present
BILATERAL FOOT PAIN	Pain in extremity	2018	Present
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	JAN2020	Present
CONGESTIVE HEART FAILURE	Cardiac failure congestive	FEB2020	Present
CHRONIC KIDNEY DISEASE	Chronic kidney disease	FEB2020	Present
CORONARY ARTERY DISEASE	Coronary artery disease	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	13:02

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	VASC	Accelerated hypertension	Accelerated Hypertension	03SEP2020 (9)		06SEP2020 (12)		4	3	N	N
2	RENAL	Acute kidney injury	Acute Kidney Injury	03SEP2020 (9)		07SEP2020 (13)		5	2	N	N
3	RESP	Acute respiratory failure	Acute Respiratory Failure	03SEP2020 (9)		04SEP2020 (10)		2	3	TC	N
4	CARD	Atrial fibrillation	PAROXYSMAL ATRIAL Fibrillation	03SEP2020 (9)		08SEP2020 (14)		6	2	N	N
5	CARD	Cardiac failure congestive	Worsening of Chronic Congestive Heart Failure	03SEP2020 (9)		08SEP2020 (14)		6	3	TC/P/W	Y
6	METAB	Dehydration	DEHYDRATION	03SEP2020 (9)		04SEP2020 (10)		2	2	TCN	N
7	NERV	Dizziness	Dizziness	05SEP2020 (11)		08SEP2020 (14)		4	2	TCN	N
8	RESP	Dyspnoea	SHORTNESS OF BREATH	03SEP2020 (9)		04SEP2020 (10)		2	3	N	N
9	METAB	Hypokalaemia	HYPOKALEMIA	04SEP2020 (10)		06SEP2020 (12)		3	2	TC	N
10	VASC	Hypotension	Hypotension	05SEP2020 (11)		07SEP2020 (13)		3	2	N	N
11	MUSC	Pain in extremity	WORSENING OF BILATERAL FOOT PAIN	05SEP2020 (11)		06SEP2020 (12)		2	2	TC	N
12	RESP	Pulmonary oedema	BILATERAL PULMONARY EDEMA	03SEP2020 (9)		05SEP2020 (11)		3	2	N	N

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
13	GENRL	Pyrexia	LOW-GRADE FEVER	05SEP2020 (11)		06SEP2020 (12)		2	2	N	N
14	INFEC	Urinary tract infection	Urinary Tract Infection	03SEP2020 (9)		08SEP2020 (14)	08:08	6	2	TC	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (06SEP2020)	NOT RELATED/OTHER: worsening of pre-existing condition	1	9	N
2	Resolved (07SEP2020)	NOT RELATED/OTHER: Dehydration	1	9	N
3	Resolved (04SEP2020)	NOT RELATED/OTHER: due to congestive heart failure	1	9	N
4	Resolved (08SEP2020)	NOT RELATED/OTHER: URINARY TRACT INFECTION	1	9	N
5	Resolved (08SEP2020)	NOT RELATED/OTHER: worsening of pre-existing condition	1	9	Y
6	Resolved (04SEP2020)	NOT RELATED/OTHER: DUE TO DIURETICS	1	9	N
7	Resolved (08SEP2020)	NOT RELATED/OTHER: due to UTI	1	11	N
8	Resolved (04SEP2020)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	1	9	N
9	Resolved (06SEP2020)	NOT RELATED/OTHER: DUE TO DIURESIS	1	10	N
10	Resolved (07SEP2020)	NOT RELATED/OTHER: due to diuresis	1	11	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
11	Resolved (06SEP2020)	NOT RELATED/OTHER: WORSENING OF PRE-EXISTING CONDITION	1	11	N
12	Resolved (05SEP2020)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	1	9	N
13	Resolved (06SEP2020)	NOT RELATED/OTHER: URINARY TRACT INFECTION	1	11	N
14	Resolved (08SEP2020)	NOT RELATED/OTHER: spontaneous	1	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

Narrative Comment

Subject C4591001 1087 10871228, a 72-year-old white male with a pertinent medical history of hypertension (since 2005), benign prostatic hyperplasia (since Jan 2020), and congestive cardiac failure, chronic kidney disease and coronary artery disease (all since Feb 2020), received Dose 1 on 26 Aug 2020. The subject experienced worsening of chronic congestive heart failure on 03 Sep 2020, 8 days after receiving Dose 1.

Concomitant medications reported within 2 weeks prior to the onset of worsening of chronic congestive heart failure included metoprolol (from 2005 to 03 Sep 2020) for hypertension, rivaroxaban (since Feb 2020) for coronary artery disease, colchicine (since Feb 2020) for gout, tamsulosin (since Mar 2020) for benign prostatic hyperplasia, and nifedipine (since Jul 2020) for hypertension.

On 03 Sep 2020 (Day 9), the subject went to emergency room with dyspnea (shortness of breath), worsening hypertension, and acute kidney injury and was subsequently admitted with exacerbation of chronic congestive heart failure resulting in acute respiratory failure. A chest x-ray performed on the same day (Day 9), revealed bilateral pulmonary edema for which the subject was treated with furosemide intravenously, then transitioned to oral (PO). While in the hospital, the subject's SARS-CoV-2 (COVID-19) test was negative. The subject also experienced urinary tract infection, paroxysmal atrial fibrillation, and dehydration (all on 03 Sep 2020 [Day 9]); hypokalemia on 04 Sep 2020 (Day 10); and dizziness, hypotension, worsening of bilateral foot pain, and pyrexia (low-grade fever) (all on 05 Sep 2020 [Day 11]). On 04 Sep 2020 (Day 10), the dyspnea, acute respiratory failure, and dehydration resolved and on 05 Sep 2020 (Day 11), the pulmonary edema resolved. On 06 Sep 2020 (Day 12), the worsening hypertension, hypokalemia, worsening of bilateral foot pain, and pyrexia resolved. On 07 Sep 2020 (Day 13), the acute kidney injury and hypotension resolved. On 08 Sep 2020 (Day 14), the atrial fibrillation, worsening of chronic congestive heart failure, dizziness, and urinary tract infection resolved, and the subject was discharged on furosemide PO and supplemental oxygen.

The subject was withdrawn from the study on 16 Sep 2020 because of the worsening of chronic congestive heart failure.

In the opinion of the investigator, there was no reasonable possibility that the worsening of chronic congestive heart failure was related to the study intervention, concomitant medications, or clinical trial procedures; but rather it was related to worsening of a pre-existing condition. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	Asian	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	55.92 kg	23.3 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to under cooked shrimp	Food allergy	2005	Present
POLYCYSTIC OVARIAN SYNDROME	Polycystic ovaries	2005	Present
Vitamin D Deficiency	Vitamin D deficiency	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14OCT2020 (1)	13:08

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	24OCT2020 (11)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1				P	N	Yes	Study Treatment	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Withdrawn	VACCINATION	05NOV2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1087 10871557, a 34-year-old Asian female with a pertinent medical history of polycystic ovaries (since 2005), received Dose 1 on 14 Oct 2020. The subject had a positive urine pregnancy test on 05 Nov 2020 (Day 23) with an estimated date of conception of 24 Oct 2020, 10 days after receiving Dose 1. Concomitant medications reported 2 weeks prior to the exposure during pregnancy included cyanocobalamin (since 2018) as a dietary supplement and cholecalciferol (since 2018) for vitamin deficiency. A repeat pregnancy test was also positive. The subject confirmed she used contraceptives (condom with spermicide), was unaware that she was pregnant, and planned to follow-up with her obstetrician/gynecologist. The first date of her last menstrual period was 17 Sep 2020 and the estimated date of conception was 24 Oct 2020 (Day 11). The subject had no previous pregnancies. She did not smoke, drink alcohol, or use illicit drugs during her pregnancy. She also reported that her 34-year-old husband did not have any potential environmental or occupational exposures. The subject and her husband did not have any family history of congenital abnormalities, genetic diseases, or consanguinity. Her husband smoked, drank alcohol, and used recreational drugs during her pregnancy. The subject was discontinued from the study intervention on 05 Nov 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
150 cm	57.6 kg	25.6 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insect Allergy	Allergy to arthropod sting	1973	Present
Mushroom Allergy	Food allergy	1973	Present
Allergic Rhinitis	Rhinitis allergic	1973	Present
Allergy to Pollen	Seasonal allergy	1973	Present
Grass Allergy	Seasonal allergy	1973	Present
Osteopenia	Osteopenia	1996	Present
Chronic Back Pain	Back pain	2000	Present
Post-Menopausal	Postmenopause	2000	Present
Chronic Urinary Tract Infections	Urinary tract infection	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vaginal Dryness	Vulvovaginal dryness	2000	Present
Insomnia	Insomnia	2015	Present
Osteoarthritis of Neck	Spinal osteoarthritis	2015	Present
Recurrent GERD	Gastrooesophageal reflux disease	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	13:08

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Headache	Headache	30SEP2020 (14)		20OCT2020 (34)		21	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/P	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Possible sinus infection	1	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	03OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Withdrawn	VACCINATION	13NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901415, a 68-year-old white female with a pertinent medical history of allergic rhinitis (since 1973), received Dose 1 on 17 Sep 2020. The subject reported headache on 30 Sep 2020, 13 days after receiving Dose 1. The headache resolved on 20 Oct 2020 (Day 34). The subject was discontinued from the study intervention on 13 Nov 2020 because of the headache and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the headache was related to the study intervention, but rather it was related to possible sinus infection.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.6 cm	80.6 kg	29.7 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2007	Present
Recurrent Constipation	Constipation	2007	Present
Depression	Depression	2007	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2007	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	11:18

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Urticaria	Hives, upper chest	19OCT2020 (4)		22OCT2020 (7)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	2	TC/P	N	Resolved (22OCT2020)	Study Treatment	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	04NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901507, a 31-year-old black or African American female with no pertinent medical history, received Dose 1 on 16 Oct 2020. The subject experienced urticaria (hives, upper chest) on 19 Oct 2020, 3 days after receiving Dose 1. On 22 Oct 2020 (Day 7), the urticaria resolved. The subject was discontinued from the study intervention on 04 Nov 2020 because of the urticaria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	61.91 kg	23.7 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	17:21

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	28AUG2020 (4)	00:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: PREGNANCY	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	18SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1093 10931058, a 25-year-old white female with no reported medical history, received Dose 1 on 25 Aug 2020. The subject reported an exposure during pregnancy on 28 Aug 2020, 3 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the pregnancy confirmation included ethinyl estradiol/levonorgestrel (since 01 Jun 2020) for contraception. On 18 Sep 2020 (Day 25), the subject came in for her second vaccination visit and a urine pregnancy test result was positive; therefore, the second dose was not administered. The subject was using birth control during this time. The first day of her last menstrual period was reported as 27 Jul 2020 (Day -29). She did not have any medical risk factors or a previous pregnancy. The exposure during pregnancy was considered an important medical event by the investigator. The estimated date of conception or delivery was not reported at the time of this report. The subject was discontinued from the study intervention on 18 Sep 2020 because of exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	99.7 kg	35.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type II Diabetes	Type 2 diabetes mellitus	2000	Present
Hypercholesterolemia	Hypercholesterolaemia	2014	Present
Excessive Perspiration	Hyperhidrosis	2014	Present
Hypertension	Hypertension	2014	Present
Deep Vein Thrombosis	Deep vein thrombosis	2015	Present
Itching of Legs	Pruritus	2015	Present
Osteomyelitis	Osteomyelitis	2017	Past
Post Traumatic Stress Disorder	Post-traumatic stress disorder	2017	Present
Amputation of 10 Toes	Toe amputation	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Environmental Allergies	Hypersensitivity	2019	Present
Pain in feet post-op toe amputations	Procedural pain	DEC2019	Present
Cataracts Left eye	Cataract	JUN2020	Past
cataracts right eye	Cataract	JUN2020	Past
Peripheral Neuropathy secondary to Type II Diabetes	Diabetic neuropathy	05JUN2020	Present
Right Eye Cataract Surgery	Cataract operation	12AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	12:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Diabetic foot	Diabetic Foot Ulcer R Foot	14SEP2020 (20)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TCN/W	N	Yes	NOT RELATED/OTHER: Diabetes	1	20	Y

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_SNAP_2MPD2_Safety_Narratives/profile Date of Generation: 20NOV2020 (21:12)

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1095 10951141, a 50-year-old white female with a pertinent medical history of type 2 diabetes mellitus (since 2000), toe amputation (in 2017), and diabetic neuropathy (since 05 Jun 2020), received Dose 1 on 26 Aug 2020. The subject was diagnosed with a diabetic foot ulcer (right foot) on 14 Sep 2020, 19 days after receiving Dose 1. The subject was withdrawn from the study on 16 Sep 2020 due to diabetic foot. The diabetic foot ulcer (right foot) was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the diabetic foot ulcer was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	87.5 kg	31.4 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2006	Present
vasectomy	Vasectomy	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	15:16

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1			Coronary Artery Disease	05SEP2020 (8)		ONGOING			2
2	CARD	Acute myocardial infarction	STEMI: ST elevation Myocardial Infarction	05SEP2020 (8)		09SEP2020 (12)		5	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: CAD	1	8	N
2	TC/TCN/P	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: undiagnosed Obstructive CAD	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine 1 dose IM once for influenza prevention	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Withdrawn	VACCINATION	05SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1095 10951173, a 49-year-old Asian male with no pertinent medical history, received Dose 1 on 29 Aug 2020. The subject experienced an acute myocardial infarction on 05 Sep 2020, 7 days after receiving Dose 1. Concomitant medication reported 2 weeks prior to the acute myocardial infarction included loratadine (since 2018) for seasonal allergies. On 05 Sep 2020 (Day 8), the site received a phone call from the subject reporting that he had a heart attack in the morning. The subject reported that he experienced nausea and chest tightness upon waking up that day requiring an emergency room (ER) visit. A COVID-19 test performed in the ER was negative. He was transferred to a local hospital; a subsequent angiogram performed on 05 Sep 2020 (Day 8) revealed right-sided coronary blockage resulting in a myocardial infarction. There was no evidence of pulmonary embolic disease, acute cardiopulmonary abnormality, or aortic dissection. The subject reported that 4 stents were placed. Blood culture for bacteriology on 06 Sep 2020 (Day 9) was negative. The acute myocardial infarction was considered resolved on 09 Sep 2020 (Day 12) and the subject was discharged from the hospital. The discharge medications included atorvastatin 80 mg once daily (QD), prasugrel hydrochloride 10 mg orally (PO) QD, metoprolol 25 mg PO QD, and acetylsalicylic acid 81 mg PO QD for acute myocardial infarction. The subject was discontinued from the study intervention on 05 Sep 2020 because of the acute myocardial infarction and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to the study intervention, but rather it was related to undiagnosed obstructive coronary artery disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153.67 cm	87.64 kg	37 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CAT ALLERGY	Allergy to animal	2000	Present
ATHLETIC ASTHMA	Asthma exercise induced	2004	Past
INTERMITTENT HEADACHES	Headache	2005	Present
MASTITIS	Mastitis	2016	Past
CESAREAN SECTION	Caesarean section	08JUN2016	Past
MASTITIS REMOVAL SURGERY	Breast operation	OCT2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	18:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	14AUG2020 (1)		22SEP2020 (40)		40
2	RESP	Nasal congestion	Nasal congestion	05OCT2020 (53)		ONGOING		
3	RESP	Oropharyngeal pain	Sore throat	05OCT2020 (53)		07OCT2020 (55)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		P	N	Resolved (22SEP2020)	NOT RELATED/OTHER: PREGNANCY	1	1	Y
2	1	N	N	Yes	NOT RELATED/OTHER: Personal illness	1	53	N
3	1	N	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Personal illness	1	53	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Withdrawn	VACCINATION	04SEP2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1096 10961031, a 22-year-old white female with a pertinent obstetrical history of 2 previous pregnancies, 1 full term pregnancy with live birth on requiring a caesarean section (on 08 Jun 2016) and a miscarriage at 13 weeks (in Oct 2019) with a history of an irregular menstrual cycle (since Oct 2019), received Dose 1 on 14 Aug 2020. The subject reported an exposure during pregnancy on 14 Aug 2020, on the day of Dose 1. On 14 Aug 2020 (Day 1), the subject's pregnancy test at Visit 1 was negative prior to receiving Dose 1. On 04 Sep 2020 (Day 22), during Visit 2 prior to Dose 2, the subject's urine pregnancy test was positive. A repeat pregnancy test was also positive. The subject's first day of her last menstrual period was 04 Jul 2020 and the estimated date of conception was 09 Aug 2020. Gestation at the time of initial exposure was first trimester. An ultrasound on 21 Sep 2020 (Day 39) confirmed the pregnancy with a gestational age of 6 weeks and 2 days with no abnormalities. It was reported that the mother did not smoke, drink alcohol, or use illicit drugs. .On 22 Sep 2020 (Day 40), the subject underwent an elective abortion at 6 weeks and 3 days of gestation. The subject was discontinued from the study intervention on 04 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	66.82 kg	26.9 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
POSTMENOPAUSAL	Postmenopause	1999	Present
ASTHMA	Asthma	2012	Present
HYSTERECTOMY	Hysterectomy	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11SEP2020 (1)	15:37

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	ABDOMINAL PAIN RUQ	SEP2020 ()		30SEP2020 (20)			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P	N	Resolved (30SEP2020)	NOT RELATED/OTHER: GALBLADDER DESEASE			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Withdrawn	VACCINATION	30SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091503, a 64-year-old white female with no pertinent medical history, received Dose 1 on 11 Sep 2020. The subject experienced abdominal pain upper (right quadrant) on an unspecified date in Sep 2020. On 30 Sep 2020 (Day 20), the abdominal pain upper resolved. The subject was discontinued from the study intervention on 30 Sep 2020 because of the abdominal pain upper and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the abdominal pain upper was related to the study intervention, but rather it was related to gallbladder disease.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	77.36 kg	26.7 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Partial Hysterectomy	Hysterectomy	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	14:39

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Pruritus	Generalized Pruritus	12AUG2020 (2)		12AUG2020 (2)	
2	CARD	Tachycardia	Tachycardia	12AUG2020 (2)		12AUG2020 (2)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	3	TC	N	Resolved (12AUG2020)	Study Treatment	1	2	N
2	1	3	TC/P	N	Resolved (12AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	12AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1112 11121118, a 56-year-old white female with no pertinent medical history, received Dose 1 on 11 Aug 2020. The subject reported pruritus and tachycardia on 12 Aug 2020 (resolved the same day), 1 day after receiving Dose 1. The subject was discontinued from the study intervention on 12 Aug 2020 because of the pruritus and tachycardia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the pruritus and tachycardia were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	52 kg	21.6 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	1970	Present
Hysterectomy	Hysterectomy	1984	Past
Ovarian Cysts	Ovarian cyst	1984	Past
Postmenopausal	Postmenopause	1995	Present
Anxiety	Anxiety	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06OCT2020 (1)	10:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	06OCT2020 (1)		07OCT2020 (2)	
2	NERV	Headache	Headaches	06OCT2020 (1)		07OCT2020 (2)	
3	MUSC	Myalgia	Muscle Aches	06OCT2020 (1)		07OCT2020 (2)	
4	GENRL	Pyrexia	Fever	06OCT2020 (1)		07OCT2020 (2)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y
2	2	3	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y
3	2	2	TC	N	Resolved (07OCT2020)	Study Treatment	1	1	N
4	2	2	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06OCT2020	
Withdrawn	VACCINATION	07OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1112 11121255, a 65-year-old white female with no pertinent medical history, received Dose 1 on 06 Oct 2020. The subject experienced chills, headache, and pyrexia on 06 Oct 2020 after Dose 1 administration. On the same day (Day 1), the subject also experienced myalgia. The chills, headache, pyrexia, and myalgia resolved on 07 Oct 2020 (Day 2). The subject was discontinued from the study intervention on 07 Oct 2020 because of the chills, headache, and pyrexia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the chills, headache, and pyrexia were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	77.27 kg	27.4 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergic rhinitis	Seasonal allergy	1947	Present
Perennial allergic rhinitis	Rhinitis perennial	1955	Present
Endometriosis	Endometriosis	1972	Past
Hysterectomy	Hysterectomy	1974	Past
Irritable Bowel Syndrome	Irritable bowel syndrome	1980	Present
Osteoarthritis, generalized	Osteoarthritis	1990	Present
Hypertension	Hypertension	1995	Present
Meralgia Paresthetica, right thigh	Meralgia paraesthetica	2005	Present
Hyperlipidemia	Hyperlipidaemia	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Esophageal stricture	Oesophageal stenosis	2010	Present
Diverticulitis	Diverticulitis	2013	Present
Osteopenia	Osteopenia	2013	Present
Asthma, moderate	Asthma	2015	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2015	Present
Diabetes, type 2	Type 2 diabetes mellitus	2015	Present
Depression, situational	Adjustment disorder with depressed mood	APR2017	Present
Vaginal dryness	Vulvovaginal dryness	SEP2017	Present
Fracture, left foot	Foot fracture	20JAN2020	Past
Surgery, left foot	Foot operation	20JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	17:28

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	22OCT2020 (2)		25OCT2020 (5)	
2	GENRL	Fatigue	Fatigue	22OCT2020 (2)		28OCT2020 (8)	
3	NERV	Headache	Headache	22OCT2020 (2)		28OCT2020 (8)	

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
4	MUSC	Myalgia	Muscle Aches	22OCT2020 (2)		28OCT2020 (8)	
5	GASTR	Nausea	Nausea	22OCT2020 (2)		25OCT2020 (5)	
6	GASTR	Vomiting	Vomiting	25OCT2020 (5)		25OCT2020 (5)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	3	TC/W	N	Resolved (25OCT2020)	Study Treatment	1	2	Y
2	7	2	P	N	Resolved (28OCT2020)	Study Treatment	1	2	Y
3	7	2	TC	N	Resolved (28OCT2020)	Study Treatment	1	2	N
4	7	2	TC	N	Resolved (28OCT2020)	Study Treatment	1	2	N
5	4	2	TC	N	Resolved (25OCT2020)	Study Treatment	1	2	N
6	1	2	N	N	Resolved (25OCT2020)	Study Treatment	1	5	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21OCT2020	
Withdrawn	VACCINATION	26OCT2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	26OCT2020	ADVERSE EVENT

Narrative Comment

Subject C4591001 1112 11121337, a 79-year-old white female with a pertinent medical history of irritable bowel syndrome (since 1980), diverticulitis (since 2013), and type 2 diabetes mellitus (since 2015), received Dose 1 on 21 Oct 2020. The subject experienced diarrhea and fatigue on 22 Oct 2020, 1 day after receiving Dose 1.
On 22 Oct 2020 (Day 2), the subject also experienced headache, myalgia, and nausea. On 25 Oct 2020 (Day 5), the subject had vomiting. The diarrhea, nausea, and vomiting resolved on the same day (Day 5).
The subject was discontinued from the study intervention on 26 Oct 2020 because of the fatigue and was later withdrawn from the study on the same day because of the diarrhea. The fatigue, headache, and myalgia resolved on 28 Oct 2020 (Day 8).
In the opinion of the investigator, there was a reasonable possibility that the diarrhea and fatigue were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	60 kg	21.3 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VISION IMPAIRMENT, BILATERAL	Visual impairment	1990	Present
ALLERGY, NICKEL	Allergy to metals	1995	Present
DEPRESSION	Depression	2016	Present
ANXIETY	Anxiety	2019	Present
CANNABIS HYPEREMESIS SYNDROME	Cannabinoid hyperemesis syndrome	2019	Present
CANNABIS ABUSE	Drug abuse	2019	Present
VENOUS THROMBOSIS/EMBOLISM	Embolism venous	2019	Present
INSOMNIA	Insomnia	2019	Present
MIGRAINE	Migraine	2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BUTALBITAL USE DISORDER	Drug abuse	15MAR2019	Present
SUICIDAL IDEATION W/ ATTEMPT	Suicide attempt	15MAR2019	Past
MEDICATION TREATEMENT NONCOMPLAINCE	Treatment noncompliance	15MAR2019	Present
SUICIDAL IDEATION W/ ATTEMPT	Suicide attempt	24DEC2019	Past
EPIGASTRIC PAIN W/ ADMISSION	Abdominal pain upper	24SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06OCT2020 (1)	14:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	ABDOMINAL PAIN	26OCT2020 (21)		27OCT2020 (22)		2	2
2	PSYCH	Depression	DEPRESSION, WORSENING	19OCT2020 (14)		ONGOING			3
3	GASTR	Gastritis	ACUTE GASTRITIS W/O HEMMORRHAGE	23OCT2020 (18)		ONGOING			2
4	PSYCH	Suicide attempt	SUICIDAL IDEATION WITH ATTEMPT	19OCT2020 (14)		26OCT2020 (21)		8	3
5	GASTR	Vomiting	BILIOUS VOMITING	23OCT2020 (18)		27OCT2020 (22)	01:26	5	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (27OCT2020)	NOT RELATED/OTHER: ACUTE GASTRITIS	1	21	N
2	TCN	N	Yes	NOT RELATED/OTHER: SITUATIONAL	1	14	N
3	TC/TCN	N	Yes	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	1	18	N
4	TC/TCN/W	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: MAJOR DEPRESSION	1	14	Y
5	TC/TCN	N	Resolved (27OCT2020)	NOT RELATED/OTHER: ACTUE GASTRITIS	1	18	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	26OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1117 11171186, a 30-year-old black or African American female with a pertinent medical history of depression (since 2016), anxiety and insomnia (both since 2019), drug abuse (cannabis abuse and butalbital use disorder; both since 15 Mar 2019), treatment noncompliance (since 15 Mar 2019), and suicide attempt (on 15 Mar 2019 and 24 Dec 2019), received Dose 1 on 06 Oct 2020. The subject attempted suicide on 19 Oct 2020, 13 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the suicide attempt included aspirin/butalbital/caffeine for migraine, lorazepam for anxiety, ondansetron for nausea/vomiting, mirtazapine (7.5 mg from Jun 2020 and 30 mg from an unspecified date), celecoxib, loperamide hydrochloride, omeprazole, sertraline hydrochloride, and topiramate for unspecified indications, and trazodone for sleep (all from unknown dates). On 19 Oct 2020 (Day 14), the subject experienced worsening of depression and presented to the emergency department (ED) via emergency medical services. The subject reported suicidal ideation and attempted to end her life due to depression related to family issues and stress a few days prior to this report. Her plan was to (b) (6) . The subject was hospitalized for depression with suicidal ideation and treated with haloperidol 5 mg, lorazepam 2 mg, and trazodone 100 mg (all on 19 Oct 2020), hydroxyzine 25 mg (on 19 Oct 2020 and 20 Oct 2020), sertraline 100 mg (on 20 Oct 2020), and fluoxetine 10 mg (since 21 Oct 2020). On 23 Oct 2020 (Day 18), the subject developed acute gastritis without hemorrhage and bilious vomiting with nausea. On 26 Oct 2020 (Day 21), the subject denied suicidal ideation and self-harm thoughts. On that same day (Day 21), the suicide attempt was considered resolved and the subject was discharged from the hospital. Of note, the subject had a prior history of psychiatric admission (in Dec 2019) for similar behavior and had previously struggled with anxiety for the past 2 years requiring hospitalization. The subject did not disclose the prior history of depression including prior suicide attempts, treatment noncompliance, drug abuse (cannabis abuse and butalbital/aspirin/caffeine use disorder), anxiety, insomnia, at the time of screening. On 26 Oct 2020 (Day 21), the subject was re-admitted to the ED as she experienced abdominal pain (epigastric pain) with a diagnosis of acute gastritis without hemorrhage and bilious vomiting with nausea. The subject refused advised treatments and requested pain medication and benzodiazepines for which the request for pain medication and benzodiazepines was refused by the ED. The subject was treated medically with diphenhydramine 25 mg, famotidine 20 mg, hydroxyzine 25 mg, ioversol at 350/100 mL, aluminum/magnesium/simethicone/lidocaine 40 mL, metoclopramide 10 mg, morphine 1 mg, and ondansetron 4 mg (all on 26 Oct 2020). The abdominal pain and bilious vomiting resolved on 27 Oct 2020 (Day 22). The subject was discharged from the ED on 27 Oct 2020 (Day 22) with the following medications: aripiprazole 2 mg, famotidine 20 mg, and fluoxetine 10 mg; all starting from 27 Oct 2020. The subject was discontinued from the study intervention on 26 Oct 2020 since she no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The worsening depression and acute gastritis without hemorrhage were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the suicide attempt was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a major depression. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189 cm	130.4 kg	36.5 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	1990	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1990	Present
hyperlipidemia	Hyperlipidaemia	2005	Present
Allergy to Allbuterol	Drug hypersensitivity	2020	Present
Post Traumatic stress disorder	Post-traumatic stress disorder	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	13:18

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	12AUG2020 (2)		14AUG2020 (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	3	TC/P/W	N	Resolved (14AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	14AUG2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	14AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1120 11201127, a 74-year-old white male with no pertinent medical history, received Dose 1 on 11 Aug 2020. The subject experienced diarrhea on 12 Aug 2020, 1 day after receiving Dose 1. The subject was withdrawn from the study on 14 Aug 2020 because of the diarrhea, which resolved on the same day (Day 4). In the opinion of the investigator, there was a reasonable possibility that the diarrhea was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	88.4 kg	27.9 kg/m2	28OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to bee stings	Allergy to arthropod sting	1965	Present
depression	Depression	1980	Present
vasectomy	Vasectomy	1989	Past
nephrogenic diabetes insipidus	Nephrogenic diabetes insipidus	2000	Present
hyperlipidemia	Hyperlipidaemia	2017	Present
pacemaker	Cardiac pacemaker insertion	APR2019	Present
anemia	Anaemia	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28OCT2020 (1)	14:30

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	PSYCH	Depression	worsening of depression	29OCT2020 (2)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	P	N	Yes	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28OCT2020	
Withdrawn	VACCINATION	29OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1120 11201408, a 71-year-old white male with a pertinent medical history of depression (since 1980), received Dose 1 on 28 Oct 2020. The subject experienced worsening of depression on 29 Oct 2020, 1 day after receiving Dose 1. The subject was discontinued from the study intervention on 29 Oct 2020 because of worsening of the depression that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the worsening of the depression was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	24	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Presyncope	pre-syncope	11SEP2020 (1)		11SEP2020 (1)		1
2	GASTR	Vomiting	vomiting	11SEP2020 (1)		11SEP2020 (1)		1

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	W	N	Resolved (11SEP2020)	NOT RELATED/OTHER: blood draw			Y
2	1	W	N	Resolved (11SEP2020)	NOT RELATED/OTHER: blood draw			Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11SEP2020	
	VACCINATION		
Withdrawn	FOLLOW-UP	11SEP2020	ADVERSE EVENT

Narrative Comment

Subject C4591001 1122 11221026, a 24-year-old white male with no reported medical history, reported presyncope and vomiting during the prevaccination blood sample collection on 11 Sep 2020 (Day 1), which resolved that same day.
The subject was withdrawn from the study before study vaccination on 11 Sep 2020 because of the presyncope and vomiting.
In the opinion of the investigator, there was no reasonable possibility that the presyncope and vomiting were related to the study intervention, but rather related to the blood sample collection.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	American Indian or Alaska	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	75.6 kg	28.1 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1988	Present
Astigmatism	Astigmatism	2014	Present
Vitamin D Deficiency	Vitamin D deficiency	2015	Past
Depression	Depression	JAN2016	Past
Cholelithiasis	Cholelithiasis	JUN2016	Present
Cellulitis - Diffuse	Cellulitis	MAR2019	Past
Trichomoniasis	Trichomoniasis	JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	17:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	joint pain	31JUL2020 (2)		ONGOING		
2	NERV	Headache	Headache	15SEP2020 (48)		ONGOING		
3	NERV	Headache	headache	03AUG2020 (5)		16AUG2020 (18)		14
4	GENRL	Influenza like illness	Flu like symptoms	26SEP2020 (59)		ONGOING		
5	PSYCH	Insomnia	Insomnia	22AUG2020 (24)		ONGOING		
6	PSYCH	Schizophrenia	Schizophrenia	22AUG2020 (24)		ONGOING		
7	INFEC	Sinusitis	Sinus infection	04AUG2020 (6)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Yes	Study Treatment	1	2	N
2	1	TC	N	Yes	NOT RELATED/OTHER: viral	1	48	N
3	3	TC	N	Resolved (16AUG2020)	Study Treatment	1	5	N
4	1	N	N	Yes	NOT RELATED/OTHER: viral	1	59	N
5	1	TC	N	Yes	NOT RELATED/OTHER: mental disease	1	24	N

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	1	TC/P	N	Yes	NOT RELATED/OTHER: mental disease	1	24	Y
7	2	TC	N	Yes	NOT RELATED/OTHER: bacterial	1	6	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Withdrawn	VACCINATION	17SEP2020	PHYSICIAN DECISION
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1127 11271022, a 38-year-old American Indian or Alaska male with a pertinent medical history of depression (in Jan 2016), received Dose 1 on 30 Jul 2020. The subject reported schizophrenia and insomnia on 22 Aug 2020, 23 days after receiving Dose 1. The subject was withdrawn from the study on 17 Sep 2020 because of the physician's decision. In the opinion of the investigator, there was no reasonable possibility that the schizophrenia was related to the study intervention, but rather it was considered to be related to an ongoing psychiatric disease.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.3 cm	119.1 kg	36.6 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seafood Allergy	Food allergy	1975	Present
Allergic Rhinitis	Rhinitis allergic	1975	Present
Acid Reflux	Gastrooesophageal reflux disease	1982	Present
Tonsillectomy	Tonsillectomy	1992	Past
Tonsillitis	Tonsillitis	1992	Past
Appendectomy	Appendicectomy	1993	Past
Appendicitis	Appendicitis	1993	Past
Essential Tremor	Essential tremor	2010	Present
Hypertension	Hypertension	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	15:54

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Hypertension	Worsening of Hypertension	04SEP2020 (22)	12:15	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/P	N	Yes	NOT RELATED/OTHER: History of Hypertension	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Withdrawn	VACCINATION	19OCT2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	19OCT2020	PHYSICIAN DECISION

Narrative Comment
Subject C4591001 1133 11331170, a 55-year-old white male with a pertinent medical history of hypertension (since 2017), received Dose 1 on 14 Aug 2020. The subject experienced worsening of hypertension on 04 Sep 2020, 21 days after receiving Dose 1. The subject was discontinued from the study intervention on 19 Oct 2020 because of the worsening of hypertension that was ongoing at the time of the last available report. The subject was withdrawn from the study on 19 Oct 2020 because of physician's decision. In the opinion of the investigator, there was no reasonable possibility that the worsening of hypertension was related to the study intervention, but rather it was related to a history of hypertension.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.21 cm	57.73 kg	23.6 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillitis	Tonsillitis	1990	Past
tonsillectomy	Tonsillectomy	1993	Past
anxiety	Anxiety	2000	Present
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2000	Present
cholecystectomy	Cholecystectomy	2008	Past
allergic rhinitis	Rhinitis allergic	2010	Present
breast cancer	Breast cancer	2016	Past
bilateral mastectomy	Mastectomy	2017	Past
post menopausal	Postmenopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	16:10

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Abdominal discomfort	upset stomach	25AUG2020 (2)		21SEP2020 (29)	
2	GASTR	Diarrhoea	diarrhea	25AUG2020 (2)		25AUG2020 (2)	
3	GASTR	Diarrhoea	loose stools	25AUG2020 (2)		21SEP2020 (29)	
4	EYE	Eye pain	right eye pain	25AUG2020 (2)		21SEP2020 (29)	
5	GENRL	Fatigue	fatigue	25AUG2020 (2)		21SEP2020 (29)	
6	NERV	Headache	headache	25AUG2020 (2)		25AUG2020 (2)	
7	NERV	Headache	headache	25AUG2020 (2)		25AUG2020 (2)	
8	MUSC	Muscular weakness	muscle weakness	25AUG2020 (2)		21SEP2020 (29)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	28	2	TC/P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y
2	1	1	P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y
3	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
4	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y
5	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y
6	1	1	P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y
7	1	2	TC/P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y
8	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	25AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341153, a 44-year-old white female with no pertinent medical history, received Dose 1 on 24 Aug 2020. The subject reported abdominal discomfort, diarrhea (2 episodes), right eye pain, fatigue, headache (2 episodes), and muscular weakness on 25 Aug 2020, 1 day after receiving Dose 1. On 25 Aug 2020 (Day 2), the diarrhea (first episode) and headache (2 episodes) resolved and on 21 Sep 2020 (Day 29), the abdominal discomfort, diarrhea (second episode), right eye pain, fatigue, and muscular weakness resolved. The subject was discontinued from the study intervention on 25 Aug 2020 because of the abdominal discomfort, diarrhea (2 episodes), right eye pain, fatigue, headache (2 episodes) and muscular weakness and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the abdominal discomfort, diarrhea (2 episodes), right eye pain, fatigue, headache (2 episodes), and muscular weakness were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	79.18 kg	31.4 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hospitalization for childbirth	Delivery	2015	Past
hospitalization for childbirth	Delivery	2017	Past
headache	Headache	2018	Present
stress induced muscle pain in back	Back pain	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	11:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chest discomfort	CHEST TIGHTNESS	30AUG2020 (5)		06SEP2020 (12)		8
2	NERV	Headache	WORSENING HEADACHE	27AUG2020 (2)		03SEP2020 (9)		8
3	METAB	Hypokalaemia	HYPOKALEMIA	30AUG2020 (5)		01SEP2020 (7)		3
4	GENRL	Injection site pain	PAIN AT INJECTION SITE	26AUG2020 (1)		30AUG2020 (5)		5
5	MUSC	Pain in extremity	ARM PAIN (LEFT)	28AUG2020 (3)		02SEP2020 (8)		6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (06SEP2020)	Study Treatment	1	5	N
2	2	TC/P	N	Resolved (03SEP2020)	Study Treatment	1	2	Y
3	1	TC	N	Resolved (01SEP2020)	NOT RELATED/OTHER: IDIOPATHIC	1	5	N
4	3	P	N	Resolved (30AUG2020)	Study Treatment	1	1	Y
5	3	TC/P	N	Resolved (02SEP2020)	Study Treatment	1	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	30AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341174, a 36-year-old white female with a pertinent medical history of headache (since 2018), received Dose 1 on 26 Aug 2020. The subject reported severe injection site pain on 26 Aug 2020, after Dose 1 administration, worsening headache on 27 Aug 2020, 1 day after receiving Dose 1, and severe pain in extremity (left arm), 2 days after receiving Dose 1. On 30 Aug 2020 (Day 5), the injection site pain resolved. On 02 Sep 2020 (Day 8), the pain in extremity resolved and on 03 Sep 2020 (Day 9), the worsening headache resolved. The subject was discontinued from the study intervention on 30 Aug 2020 because of the injection site pain, worsening headache, and pain in extremity and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the injection site pain, worsening headache, and pain in extremity were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.78 cm	91.82 kg	29.3 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peritonsillar abscess	Peritonsillar abscess	1984	Past
(+) purified protein derivative	Tuberculin test positive	1984	Past
Idiopathic Urticaria	Idiopathic urticaria	2008	Present
Deviated septum repair	Nasal septal operation	2009	Past
Fever of Unknown Origin	Pyrexia	2012	Past
High cholesterol	Blood cholesterol increased	JAN2012	Present
hypertension	Hypertension	JAN2012	Present
GERD	Gastrooesophageal reflux disease	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	15:01

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	SKIN	Urticaria	urticaria	13AUG2020 (10)		13AUG2020 (10)		1	2	TC/P/W	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (13AUG2020)	NOT RELATED/OTHER: idiopathic urticaria (pre-existing on med hx)	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Withdrawn	VACCINATION	22SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	22SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1140 11401035, a 62-year-old white male with a pertinent medical history of idiopathic urticaria (since 2008), received Dose 1 on 04 Aug 2020. The subject reported urticaria on 13 Aug 2020, 9 days after receiving Dose 1. On 13 Aug 2020 (Day 10), the urticaria resolved. The subject was withdrawn from the study on 22 Sep 2020 because of the urticaria. In the opinion of the investigator, there was no reasonable possibility that the urticaria was related to the study intervention, but rather it was related to idiopathic urticaria (a pre-existing medical history).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.4 cm	82 kg	23.3 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1971	Present
acid reflux	Gastrooesophageal reflux disease	1988	Past
left tarsal bone fracture, foot	Foot fracture	2002	Past
left avulsion fracture, foot	Avulsion fracture	2007	Past
fundal plication	Oesophagogastric fundoplasty	2007	Past
eye allergies	Eye allergy	2010	Present
osteoarthritis, both knees	Osteoarthritis	2016	Present
hypothyroidism	Hypothyroidism	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	16:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Amnesia	short term memory loss	07NOV2020 (17)	19:00	10NOV2020 (20)	08:00	4	1
2	NERV	Paraparesis	working diagnosis was spastic paraparesis	07NOV2020 (17)	14:00	ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/P	Y	Resolved (10NOV2020)	NOT RELATED/OTHER: unknown at this time	1	17	Y
2	TC/TCN/P	Y	Yes	NOT RELATED/OTHER: Unknown at this time	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22OCT2020	
Withdrawn	VACCINATION	13NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1140 11401306, a 53-year-old white male with a pertinent medical history of hypothyroidism (since 2018) and left leg weakness (since Sep 2020), received Dose 1 on 22 Oct 2020. The subject reported amnesia (short term memory loss) and paraparesis on 07 Nov 2020, 16 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of amnesia and paraparesis included omeprazole (since 2007) for acid reflux prevention, olopatadine hydrochloride eye drops (since 2010) for eye allergies, and levothyroxine (since 2018) for hypothyroidism. On 07 Nov 2020 (Day 17), the subject visited the emergency room because of a sudden onset of change in visual perception, short term memory loss, and chronic spastic paraparesis. He was hospitalized for further blood work-up, a lumbar puncture, and imaging studies. A blood test on the same day (Day 17) showed C-reactive protein of 2.1 mg/L (upper limit of normal [ULN]: <8 mg/L), blood copper of 96 µg/dL (normal range [NR]: 72 – 166 µg/dL), blood folate of 10.47 ng/mL (lower limit of normal: 4.77 ng/mL), and vitamin B12 of 753 pg/mL (NR: 211 – 946 pg/mL). A nonenhanced head computed tomography showed no intracranial hemorrhage or acute territorial infarction. There was a mild asymmetry of the lateral ventricles with dilatation of the atrium of the right lateral ventricle; however, the remainder of the ventricles were normal in size and configuration. The basal cisterns and foramen magnum were patent and there were no depressed calvarial fractures. The extracranial soft tissue structures were unremarkable, and the paranasal sinuses and mastoid air cells were clear. A computed angiography (CTA) of the head showed that the intracranial segments of the

Narrative Comment
internal carotid arteries and basilar, anterior, middle, and posterior cerebral arteries were patent without flow-limiting stenosis. No aneurysm or arteriovenous malformation was visualized. The CTA of the neck showed conventional branching of the great vessels from the aortic arch. The origins of the great vessels and vertebral arteries were patent. There was no occlusion of the common carotid, external carotid, cervical segments of the internal carotid arteries, or the cervical segments of the vertebral arteries. The vertebral arteries were codominant. The imaging results of lungs, thyroid, and bones were unremarkable. A magnetic resonance imaging (MRI) of the brain to evaluate possible encephalitis in comparison with CTA of head performed on 07 Nov 2020 (Day 17) showed no abnormal signal intensity within the brain parenchyma. A developmental venous anomaly was observed in the right frontal lobe. There was asymmetric enlargement of the atrium and occipital horn of the right lateral ventricle. There were no intraventricular masses seen and the basal cisterns were patent. No acute intracranial hemorrhage, evidence of acute infarction, space-occupying mass, shift of the midline structures, or any abnormal extra-axial fluid collections were observed. The pituitary gland was not enlarged and the pineal and cervico-medullary regions were normal. Normal flow voids of the major intracranial arterial vessels were observed and there was no abnormal enhancement following contrast administration. Mild mucosal thickening was present in the maxillary, ethmoid, sphenoid, and frontal sinuses. On 08 Nov 2020 (Day 18), the subject was seen by a neurologist, at which time the subject reported the symptoms of mental fogginess associated with visual changes that was described as poor depth perception. He also reported subtle unsteadiness and admitted to having a longer history of clumsiness. On examination, he was noted to have mild spasticity in the legs, brisk reflexes in the legs, and bilateral Babinski sign. His gait was slightly abnormal due to subtle circumduction of the right leg and he had mild issues with tandem gait. On 08 Nov 2020 (Day 18), a syphilis IgM/IgG screen test (*Treponema* test) was nonreactive and the human T-lymphotropic virus-1/-2 antibody test was negative. Autoimmune work-up performed on the same day (Day 18) was within normal limits with centromere antibody of 4 AU/mL (NR: 0-99 AU/mL), double-stranded deoxyribonucleic acid of 9 AU/mL (NR: 0-99 AU/mL), histone antibody of 16 AU/mL (NR: 0-99 AU/mL), JO-1 autoantibody of 5 AU/mL (NR: 0-99 AU/mL), ribonucleoprotein autoantibody of 31 U/mL (NR: 0-99 U/mL), scleroderma-70 autoantibody of 15 AU/mL (NR: 0-99 AU/mL), Smith autoantibody of 10 AU/mL (NR: 0-99 AU/mL), Sjogren's syndrome-A (SSA) autoantibody of 35 AU/mL (NR: 0-99 AU/mL), SSB autoantibody of 10 AU/mL (NR: 0-99 AU/mL), and GAD-65 autoantibody of <5.0 U/mL (NR: 0.0-5.0 U/mL). On 10 Nov 2020 (Day 20), the hepatitis panel (hepatitis A, B, and C virus) and human immunodeficiency virus (antigen/antibody combo) tests were nonreactive. An MRI of the cervical spine was performed for possible transverse myelitis, which showed no evidence of transverse myelitis or other acute or chronic process in the spinal cord. Mild multilevel spinal canal stenosis secondary to disc bulging and small disc protrusions were present at C2-C3 and C4-C5 through C6-C7. There was no spinal cord impingement or diffuse degenerative disc desiccation noted. An MRI of the thoracic spine was obtained with and without gadolinium contrast for possible myelopathy, which revealed minimal to mild degenerative changes in the thoracic spine. Vertebral body heights were maintained, and the bone marrow signals were within normal limits. No spondylolisthesis or high-grade central canal or neural foraminal stenosis was observed. The spinal cord demonstrated normal signal intensity. No evidence of abnormal enhancement was noted. There were no intradural or extradural masses, and the paraspinal soft tissues were unremarkable. On the same day (Day 20), a lumbar puncture was performed and the cerebrospinal fluid (CSF) analysis showed clear and colorless CSF with a red blood cell count of 114/µL (ULN: <2/µL), total nucleated cells of <3/µL (ULN: <5/µL); white blood cell count of 3+, CSF glucose of 66, and protein of 51 (units and normal ranges not provided). The Gram stain showed no organisms and culture results showed no growth for 5 days. The amnesia was considered resolved on 10 Nov 2020 (Day 20). On 11 Nov 2020 (Day 21), the subject reported that he might have had mild injection site discomfort for 3 days after receiving Dose 1; however, he did not report it to the site at that time. The subject remained hospitalized at the time of this report. The subject was discontinued from the study intervention on 13 Nov 2020 because of the amnesia and paraparesis and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The paraparesis was ongoing at the time of the last available report.

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the amnesia and paraparesis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and considered the amnesia and paraparesis as coincidental and associated with underlying neurological conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	72.82 kg	25.1 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	13:17

Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GASTR	Abdominal pain	Abdominal Pain	26AUG2020 (10)		05OCT2020 (50)	
2	SKIN	Night sweats	Night sweats	29AUG2020 (13)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	41	2	P	N	Resolved (05OCT2020)	Study Treatment	1	10	Y
2		3	P	N	Yes	Study Treatment	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Withdrawn	VACCINATION	04SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1142 11421111, a 61-year-old white male with a pertinent medical history of hypothyroidism (since 2015), received Dose 1 on 17 Aug 2020. The subject reported abdominal pain on 26 Aug 2020 and night sweats on 29 Aug 2020, 9 and 12 days after receiving Dose 1; respectively. The subject was discontinued from the study intervention on 04 Sep 2020 because of the abdominal pain and night sweats and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The abdominal pain resolved on 05 Oct 2020 and night sweats were ongoing at the time of the last available report. In the opinion of the investigator, there was a reasonable possibility that the abdominal pain and night sweats were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	74.09 kg	23.4 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SHOULDER PAIN	Arthralgia	2015	Present
SHINGLES VACCINE DOSE 1 [vaccination]	Herpes zoster immunisation	13FEB2020	Past
SHINGLES VACCINE DOSE 2 [vaccination]	Herpes zoster immunisation	25JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	12:30

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Parkinsonism	parkinsonism	18SEP2020 (15)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	P	N	Yes	NOT RELATED/OTHER: natural progression of parkinsonism	1	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu shot	INFLUENZA VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	21SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1145 11451076, a 64-year-old Asian male with no pertinent medical history, received Dose 1 on 04 Sep 2020. The subject was diagnosed with Parkinsonism on 18 Sep 2020, 14 days after receiving Dose 1. The subject was discontinued from the study intervention on 21 Sep 2020 because of the Parkinsonism that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the Parkinsonism was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153.67 cm	67.36 kg	28.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left breast cancer	Breast cancer	1991	Past
allergy to adhesive tape	Dermatitis contact	1991	Present
hypertension	Hypertension	1991	Present
melanoma left arm	Malignant melanoma	1991	Past
left breast mastectomy	Mastectomy	1991	Past
melanoma left arm excised	Skin neoplasm excision	1991	Past
hypothyroid	Hypothyroidism	1992	Present
allergy to codeine	Drug hypersensitivity	1993	Present
osteoporosis	Osteoporosis	1993	Present

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_SNAP_2MPD2_Safety_Narratives/profile Date of Generation: 20NOV2020 (21:12)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
varicose veins	Varicose vein	2000	Present
right upper quadrant pain	Abdominal pain upper	2003	Past
cholecystectomy	Cholecystectomy	2003	Past
insomnia	Insomnia	2010	Present
multiple lipomas	Lipoma	2012	Past
lipomas excised	Lipoma excision	2012	Past
angina	Angina pectoris	2013	Present
rheumatoid arthritis	Rheumatoid arthritis	2017	Present
anxiety	Anxiety	2018	Present
depression	Depression	2018	Present
Type II diabetes	Type 2 diabetes mellitus	2018	Present
urinary incontinence	Urinary incontinence	FEB2019	Present
cataract right eye	Cataract	MAR2019	Past
cataract surgery right eye	Cataract operation	MAR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	12:18

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Dysgeusia	sour taste	06SEP2020 (3)		10SEP2020 (7)		5	2
2	GENRL	Injection site induration	injection site induration	05SEP2020 (2)		07SEP2020 (4)		3	1
3	GENRL	Injection site pain	injection site tenderness	05SEP2020 (2)		07SEP2020 (4)		3	1
4	MUSC	Muscle spasms	back muscle spasms	04SEP2020 (1)	16:01	05SEP2020 (2)		2	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (10SEP2020)	Study Treatment	1	3	N
2	N	N	Resolved (07SEP2020)	Study Treatment	1	2	N
3	N	N	Resolved (07SEP2020)	Study Treatment	1	2	N
4	P	N	Resolved (05SEP2020)	NOT RELATED/OTHER: likely postural/trauma	1	1	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	11SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521359, a 68-year-old white female with pertinent medical history of osteoporosis (since 1993), rheumatoid arthritis (since 2017), and anxiety and type 2 diabetes mellitus (both since 2018), received Dose 1 on 04 Sep 2020. The subject was diagnosed with muscle spasms (back muscle spasms) on 04 Sep 2020, after receiving Dose 1. On 05 Sep 2020 (Day 2), the muscle spasms resolved. On the same day (Day 2), the subject experienced injection site induration and injection site pain. On 06 Sep 2020 (Day 3), the subject experienced dysgeusia. On 07 Sep 2020 (Day 4), the injection site induration and injection site pain resolved and dysgeusia resolved on 10 Sep 2020 (Day 7). The subject was discontinued from the study intervention on 11 Sep 2020 because of the muscle spasms and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the muscle spasms were related to the study intervention, but rather they were related to poor posture over time.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149.86 cm	58.91 kg	26.2 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin Allergy	Drug hypersensitivity	1970	Present
allergy to black olives	Food allergy	1975	Present
Aspirin Allergy	Drug hypersensitivity	1985	Present
Breast Surgery for Fibrocystic Removal (right)	Breast cyst excision	1990	Past
Fibrocystic Right Breast	Fibrocystic breast disease	1990	Past
Gall Bladder Removal	Cholecystectomy	2001	Past
Gall Bladder Stones	Cholelithiasis	2001	Past
Breast Surgery for Fibrocystic Removal (left)	Breast cyst excision	2005	Past
Fibrocystic Left Breast	Fibrocystic breast disease	2005	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	09:33

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EAR	Deafness unilateral	hearing loss right ear	14OCT2020 (20)		23OCT2020 (29)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	10	3	P	N	Resolved (23OCT2020)	Study Treatment	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	15OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521476, a 61-year-old white female with no pertinent medical history, received Dose 1 on 25 Sep 2020. The subject was diagnosed with unilateral deafness (right ear) on 14 Oct 2020, 19 days after receiving Dose 1. The subject was discontinued from the study intervention on 15 Oct 2020 because of the unilateral deafness and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 23 Oct 2020 (Day 29), the unilateral deafness resolved. In the opinion of the investigator, there was a reasonable possibility that the unilateral deafness was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	78.27 kg	25.1 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lithotripsy	Lithotripsy	1999	Past
nephrolithiasis	Nephrolithiasis	1999	Past
allergy to celery	Food allergy	2000	Present
allergy to mango	Food allergy	2000	Present
hearing loss	Deafness	2010	Present
osteoarthritis	Osteoarthritis	2010	Present
Type II diabetes	Type 2 diabetes mellitus	2010	Present
hypertension	Hypertension	2018	Present
prostatism	Prostatism	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07OCT2020 (1)	12:52

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Syncope	vasovagal syncope	26OCT2020 (20)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN/P	Y	Resolved ()	NOT RELATED/OTHER: Unknown	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07OCT2020	
Withdrawn	VACCINATION	06NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521497, a 72-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 2010) and hypertension (since 2018), received Dose 1 on 07 Oct 2020. The subject reported syncope on 26 Oct 2020, 19 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of syncope included metformin (since 2013) for diabetes, ibuprofen (since 2015) for osteoarthritis, lisinopril (since 2018) for hypertension, and doxazosin (since 2019) for benign prostatic hypertrophy. The subject missed Visit 2 on 28 Oct 2020 (Day 22). On 06 Nov 2020 (Day 31), it was reported that the subject was admitted to the hospital on 26 Oct 2020 (Day 20) since he fainted in the middle of the night. The subject was transferred to the intensive care unit. Family medical history relevant to the syncope was unknown. The subject tested negative for COVID-19 at the hospital. On an unspecified date, the syncope resolved and the subject was discharged from the hospital. The subject was discontinued from the study intervention on 06 Nov 2020 and remains in the study to be evaluated for safety, immunogenicity, and efficacy. During the follow-up, the site contacted the subject's sister, who confirmed that the subject died on 11 Nov 2020. The cause of death was reported as unknown. It was not reported if an autopsy was performed. A death certificate might be available at a later date. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the syncope was most likely coincidental and associated with underlying clinical conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	25	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.8 cm	69.1 kg	23.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seafood Allergy	Food allergy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	16:05

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	21AUG2020 (1)	12:25	ONGOING				P	N

Adverse Events				
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: THERE IS NOT AN UNDERLYING CAUSE. THIS EVENT IS A STANDARD PREGNANCY.	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	28SEP2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561015, a 25-year-old black or African American female with no pertinent medical history, received Dose 1 on 21 Aug 2020. The subject had an exposure during pregnancy on 21 Aug 2020, the day of receiving Dose 1. On 28 Sep 2020, the subject's exposure during pregnancy was reported. The subject's first day of her last menstrual period was 04 Aug 2020. The estimated date of conception was 21 Aug 2020, which was also the same day of initial exposure. The mother did not smoke, drink alcohol, or use illicit drugs. The subject had 5 previous pregnancies and 5 other children. The father was 23 years old and was unemployed. The subject underwent laboratory tests and procedures that included urine human chorionic gonadotropin on 28 Sep 2020, which was positive. The subject was discontinued from the study intervention on 28 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator considered there was not a reasonable possibility that the exposure during pregnancy was related to the study intervention or clinical trial procedures. Causality with concomitant drugs was not applicable.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	69.55 kg	26.3 kg/m2	07AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	12:19

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1			UPPER BODYRASH DUE TO VACCINE	08AUG2020 (2)	08:00	25AUG2020 (19)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	18	2	TC/P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Withdrawn	VACCINATION	08AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1163 11631059, a 30-year-old white female with no reported medical history, received Dose 1 on 07 Aug 2020. The subject developed an upper body rash due to vaccine on 08 Aug 2020, 1 day after receiving Dose 1. The subject was discontinued from the study intervention on 08 Aug 2020 because of the upper body rash due to vaccine and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The upper body rash due to vaccine was considered resolved on 25 Aug 2020 (Day 19). In the opinion of the investigator, there was a reasonable possibility that the upper body rash due to vaccine was related to the study.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.3 cm	60.7 kg	19.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Flat feet	Foot deformity	1980	Present
Scoliosis	Scoliosis	1980	Present
Smoker	Tobacco user	1988	Present
Left leg femoral artery repair	Arterial repair	2011	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Dizziness	Dizziness	31AUG2020 (1)	15:30	31AUG2020 (1)	17:30

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	P	N	Resolved (31AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Withdrawn	VACCINATION	31AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1166 11661047, a 50-year-old black or African American male with no pertinent medical history, received Dose 1 on 31 Aug 2020. The subject reported dizziness on 31 Aug 2020, approximately half an hour after receiving Dose 1. On 31 Aug 2020 (Day 1), the dizziness resolved. The subject was discontinued from the study intervention on 31 Aug 2020 because of the dizziness and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the dizziness was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	64 kg	26.3 kg/m2	30OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INV	Blood pressure increased	Increasing of systolic and diastolic blood pressure	30OCT2020 (1)	14:55	30OCT2020 (1)		1	2	W	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30OCT2020)	NOT RELATED/OTHER: Blood pressure values of volunteer were high during vaccine preparation period.			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30OCT2020	
	VACCINATION		
Withdrawn	FOLLOW-UP	30OCT2020	ADVERSE EVENT

Narrative Comment

Subject C4591001 1205 12051028, a 38-year-old white male with no reported medical history, experienced increased blood pressure before administration of study vaccination on 30 Oct 2020, which resolved on the same day.
The subject was withdrawn from the study before administration of study vaccination on 30 Oct 2020 because of the increased blood pressure.
In the opinion of the investigator, there was no reasonable possibility that the increased blood pressure was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	75	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	65.18 kg	26.2 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	1990	Present
Parkinson's Disease	Parkinson's disease	1990	Present
Hypothyroidism	Hypothyroidism	2000	Present
Insomnia	Insomnia	2015	Present
Post-Menopausal	Postmenopause	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	13:23

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	Ankle fracture	Lateral Malleolus Fracture - left ankle	19AUG2020 (7)		ONGOING			2	TC/TCN/P/W
2	INJ&P	Fall	FALL	19AUG2020 (7)		19AUG2020 (7)		1	2	W
3	MUSC	Muscular weakness	Diffuse weakness in extremities (Bilateral legs and Left arm)	19AUG2020 (7)		25AUG2020 (13)		7	2	W
4	NERV	Transient ischaemic attack	Suspected TIA	19AUG2020 (7)		19AUG2020 (7)		1	2	W

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Yes	NOT RELATED/OTHER: Patient fell; Pt under evaluation for suspected Transient Ischemic Attack	1	7	Y
2	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Pt under evaluation for suspected Transient Ischemic Attack	1	7	Y
3	N	Resolved (25AUG2020)	NOT RELATED/OTHER: Pt under evaluation for suspected Transient Ischemic Attack	1	7	Y
4	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Unknown; pt is following up with PCP	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Withdrawn	VACCINATION	25AUG2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	25AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1224 12241012, a 75-year-old white female with a pertinent medical history of Parkinson's disease (since 1990) and hypothyroidism (since 2000), received Dose 1 on 13 Aug 2020. The subject experienced a transient ischemic attack that resulted in muscular weakness (diffuse weakness in extremities [bilateral legs and left arm]), fall, and ankle fracture (lateral malleolus fracture - left ankle) on 19 Aug 2020, 6 days after receiving Dose 1. The subject was following up with her primary care physician and was under evaluation for the suspected transient ischemic attack. The subject recovered from the suspected transient ischemic attack on 19 Aug 2020 (Day 7) and the muscular weakness resolved on 25 Aug 2020 (Day 13). The subject was withdrawn from the study on 25 Aug 2020 because of the transient ischemic attack that led to muscular weakness, fall, and ankle fracture. The ankle fracture was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the transient ischemic attack, muscular weakness, fall, and ankle fracture were related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.43 cm	65.45 kg	22.5 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Acne	Acne	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	10:47

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INV	Blood pressure increased	Increased Blood Pressure	24AUG2020 (1)		10SEP2020 (18)	
2	GASTR	Diarrhoea	Diarrhea	24AUG2020 (1)		06SEP2020 (14)	
3	GENRL	Fatigue	Fatigue	24AUG2020 (1)		02SEP2020 (10)	
4	INV	Heart rate irregular	Irregular Heart Rate	24AUG2020 (1)		10SEP2020 (18)	
5	GENRL	Pyrexia	Feverish Chills	24AUG2020 (1)		02SEP2020 (10)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	18	2	N	N	Resolved (10SEP2020)	Study Treatment	1	1	N
2	14	2	N	N	Resolved (06SEP2020)	Study Treatment	1	1	N
3	10	2	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N
4	18	2	P/W	N	Resolved (10SEP2020)	Study Treatment	1	1	Y
5	10	2	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	05SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	05SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1224 12241065, a 30-year-old white female with no pertinent medical history, received Dose 1 on 24 Aug 2020. The subject was diagnosed with irregular heart rate on 24 Aug 2020 after Dose 1 administration. On 24 Aug 2020 (Day 1), the subject also experienced increased blood pressure, diarrhea, fatigue, and pyrexia. The fatigue and pyrexia resolved on 02 Sep 2020 (Day 10), the diarrhea resolved on 06 Sep 2020 (Day 14), and the increased blood pressure resolved on 10 Sep 2020 (Day 18). The subject was withdrawn from the study on 05 Sep 2020 because of the irregular heart rate which resolved on 10 Sep 2020. In the opinion of the investigator, there was a reasonable possibility that the irregular heart rate was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.5 cm	83.7 kg	29.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	2010	Present
Anxiety	Anxiety	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	09:52

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_SNAP_2MPD2_Safety_Narratives/profile Date of Generation: 20NOV2020 (21:12)

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	MUSC	Myalgia	Muscle pain (shoulders and neck, on the right body side)	18AUG2020 (8)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC/P	N	Yes	Study Treatment	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	01SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261072, a 42-year-old white female with a pertinent medical history of hypothyroidism (since 2010) and anxiety (since 2016), received Dose 1 on 11 Aug 2020. The subject reported myalgia on 18 Aug 2020, 7 days after receiving Dose 1. The subject was discontinued from the study intervention on 01 Sep 2020 because of the myalgia that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	53.9 kg	20.5 kg/m2	28SEP2020 (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
C-Section	Caesarean section	08OCT2015	Past
Preeclampsia	Pre-eclampsia	08OCT2015	Past
HIV	HIV test positive	SEP2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29SEP2020 (1)	13:54

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	20OCT2020 (22)	10:25	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29SEP2020	
Withdrawn	VACCINATION	20OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1230 12301045, a 27-year-old black or African American female with pertinent obstetrical history of 1 previous pregnancy with a live birth requiring cesarean section due to pre-eclampsia (on 08 Oct 2015) and positive human immunodeficiency virus test (since Sep 2018), received Dose 1 on 29 Sep 2020. The subject reported exposure during pregnancy on 20 Oct 2020, 21 days after receiving Dose 1. Concomitant medications reported 2 weeks prior to the exposure during pregnancy included dolutegravir sodium/lamivudine/tenofovir disoproxil fumarate (Acriptega) for human immuno deficiency virus infection (since Sep 2018) and norethisterone for contraception (since Sep 2019). On 28 Sep 2020, the subject's pregnancy test at Visit 1 was negative prior to receiving Dose 1. On 20 Oct 2020 (Day 22), during Visit 2, the subject's pregnancy test was positive. She had confirmed the use of contraceptives (norethisterone and use of condom by partner). The subject's first day of last menstrual period approximately around 01 Sep 2020. The gestational age at the time of initial exposure was first trimester. It was reported that the subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. However, it was also reported that during the pregnancy, the subject's partner smoked (10 per day) and drank alcohol (20 units per week) with no usage of illicit drugs. The subject was discontinued from the study intervention on 20 Oct 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	54.25 kg	15.3 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Syncope	Syncope	15AUG2020 (1)	15:40	15AUG2020 (1)	15:41	1	2
2	GASTR	Vomiting	vomits	15AUG2020 (1)	15:30	15AUG2020 (1)	15:40	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN/P/W	N	Resolved (15AUG2020)	NOT RELATED/OTHER: post phlebotomy			Y
2	TCN/P/W	N	Resolved (15AUG2020)	NOT RELATED/OTHER: post sincopal recovery			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15AUG2020	
	VACCINATION		
Withdrawn	FOLLOW-UP	25SEP2020	WITHDRAWAL BY SUBJECT

Narrative Comment

Subject C4591001 1231 12311409, a 38-year-old white male with no reported medical history, experienced syncope and vomiting after the prevaccination phlebotomy on 15 Aug 2020 (Day 1), which resolved on the same day. Study vaccination was not administered.
The subject requested withdrawal from the study on 25 Sep 2020 because of the syncope and vomiting.
In the opinion of the investigator, there was no reasonable possibility that the syncope and vomiting were related to the study intervention, but rather they were related to the phlebotomy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	77 kg	25.4 kg/m2	18AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Syncope	Syncope	18AUG2020 (1)	10:25	18AUG2020 (1)	13:30	1

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	W	N	Resolved (18AUG2020)	NOT RELATED/OTHER: Post blood extraction			Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
	VACCINATION		
Withdrawn	FOLLOW-UP	18AUG2020	ADVERSE EVENT

Narrative Comment

Subject C4591001 1231 12311926, a 32-year-old white male with no reported medical history, reported syncope during the prevaccination blood sample collection on 18 Aug 2020 (Day 1); the syncope resolved on the same day.
The subject was withdrawn from the study before study vaccination on 18 Aug 2020 because of the syncope.
In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, but rather it was related to blood sample collection.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	91 kg	32.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lung adenocarcinoma	Lung adenocarcinoma	01JUL2019	Past
Depressive syndrome	Depression	01OCT2019	Present
Hypothyroidism	Hypothyroidism	13DEC2019	Present
Thyroidectomy	Thyroidectomy	13DEC2019	Past
Left Lobectomy	Exeresis	07JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	14:58

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Metastases to central nervous system	Brain metastasis	28AUG2020 (9)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/P	Y	Yes	NOT RELATED/OTHER: history of primary lung adenocarcinoma	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	28AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312577, a 46-year-old white female with a medical history of lung adenocarcinoma (from 01 Jul 2019 to 07 Jan 2020; left lobectomy on 07 Jan 2020), depression (since 01 Oct 2019), hypothyroidism (since 13 Dec 2019), and thyroidectomy (benign nodule; on 13 Dec 2019), received Dose 1 on 20 Aug 2020. The subject was diagnosed with brain metastasis on 28 Aug 2020, 8 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the brain metastasis included quetiapine (since 01 Oct 2019) for depressive disorder, and levothyroxine (since 13 Dec 2019) for hypothyroidism. The subject was discontinued from the study intervention on 28 Aug 2020 because of the brain metastasis due to lung adenocarcinoma and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 10 Sep 2020 (Day 22), during Visit 2 at the study site, the subject reported that a routine brain computerized tomogram performed on 28 Aug 2020 (Day 9) revealed an abnormal brain image finding; however, the details of the imaging were not available at that time. On 18 Sep 2020 (Day 30), the subinvestigator contacted the subject for additional information, and the subject confirmed that a gadolinium magnetic resonance imaging (MRI) - spectroscopy that was performed on 08 Sep 2020 (Day 20) revealed 2 focal images in the right hemisphere and 1 in the right cerebellum hemisphere that were not present in the previous MRI. These lesions were considered as a secondary proliferative etiology of the primary tumor (lung adenocarcinoma in Jul 2019). The subject's oncologist suggested brain radiosurgery for the treatment of the brain metastasis. During a follow-up call by the subinvestigator on 06 Oct 2020 (Day 48), the subject reported that he received radiosurgery therapy (daily course) and dexamethasone treatment 8 mg once daily (QD) on 05 Oct 2020 (Day 47), followed by 4 mg QD until 09 Oct 2020 (Day 51) for the brain metastasis. The subject tolerated the procedure well. The subject remained asymptomatic and the brain metastasis was ongoing at the time of the last available report. The investigator considered the brain metastasis to be a medically significant event. In the opinion of the investigator, there was no reasonable possibility that the brain metastasis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was suspected to be related to secondary disease from lung adenocarcinoma diagnosed in Jul 2019. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	83.5 kg	25.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	18:50
2	BNT162b2	09SEP2020 (20)	14:00

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	PSYCH	Anxiety	severe anxiety	23SEP2020 (34)	23:00	14OCT2020 (55)	15:30	22
2	GENRL	Injection site pain	mild pain at the injection site	23AUG2020 (3)	11:17	25AUG2020 (5)	14:47	3
3	INFEC	Suspected COVID-19	Suspected COVID-19 Illness	09SEP2020 (20)	21:00	14SEP2020 (25)	11:00	6

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	W	N	Resolved (14OCT2020)	NOT RELATED/OTHER: constitutive features	2	15	Y
2	1	N	N	Resolved (25AUG2020)	Study Treatment	1	3	N
3	3	TC	Y	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown	2	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	23SEP2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	23SEP2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1231 12312982, a 36-year-old white male with no reported medical history, received Dose 1 on 21 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 20). The subject reported severe anxiety on 23 Sep 2020, 14 days after receiving Dose 2. On 09 Sep 2020 (Day 20), the subject presented to the emergency room (ER) with fever (body temperature of 39.3˚centigrade [C]), malaise, myalgias, headache and nausea. The subject had a serious adverse event of suspected COVID-19 reported on 09 Sep 2020 (Day 20) and was treated with clonixin lysinate/pargeverine hydrochloride 10 mg/125 mg for nausea since 09 Sep 2020 (Day 20). On the same day night (Day 20), the subject presented again to the ER afebrile (body temperature of 39˚C), eupneic and had normal oxygen saturation with persistent moderate malaise, nausea and headache. On 10 Sep 2020 (Day 21), the subject remained subfebrile, with nausea and reported dizziness and darker urine colour. In the context of the severe acute respiratory syndrome (SARS) CoV2 pandemic, the physician decided to evaluate whether these symptoms were associated with SARS CoV2 infection and requested a SARS CoV2 reverse transcription polymerase chain reaction test, which was negative; laboratory tests results were normal and unremarkable except for mild increase in creatinine of 1.21 (unit and normal range not reported), abdominal ultrasound showed no significant findings and was unremarkable, and chest x-ray showed right paracardiac opacity and a possible right lung consolidation. On 12 Sep 2020 (Day 23), a chest x-ray showed bilateral pneumonia and the subject was hospitalized. A chest computerized tomogram scan was unremarkable and urine analysis reports were normal. On 13 Sep 2020 (Day 24), the symptoms fever, myalgia, headache, fatigue and nausea resolved during hospitalization. The COVID disease and pneumonia were ruled out and there were no other etiological causes identified for the symptoms that the subject had. The subject remained isolated in-house for suspected COVID-19 despite presenting no further fever and improving symptoms. On 14 Sep 2020 (Day 25), the suspected COVID-19 resolved and the subject was discharged from the hospital. The anxiety occurred after this hospitalization. On 14 Oct 2020 (Day 55), the anxiety resolved. The subject requested withdrawal from the study on 23 Sep 2020. In the opinion of the investigator, there was no reasonable possibility that the anxiety and suspected COVID-19 were related to the study intervention; anxiety was considered related to constitutive features and COVID-19 was suspected as a reactogenic systemic event. Pfizer concurred with the investigator's causality assessment for suspected COVID-19

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	54 kg	22.2 kg/m2	30AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	10:34

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	pain at injection site	30AUG2020 (1)	10:34	16SEP2020 (18)	09:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	18	2	TC/P/W	N	Resolved (16SEP2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Withdrawn	VACCINATION	05OCT2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	05OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1231 12315429, a 37-year-old white female with no reported medical history, received Dose 1 on 30 Aug 2020. The subject reported moderate injection site pain on 30 Aug 2020, after Dose 1 administration. The injection site pain resolved on 16 Sep 2020 (Day 18). The subject was withdrawn from the study on 05 Oct 2020 because of the injection site pain. In the opinion of the investigator, there was a reasonable possibility that the injection site pain was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	50 kg	19.1 kg/m2	30AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 Diabetes	Type 2 diabetes mellitus	30AUG2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	11:32

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	PSYCH	Depression	depressive syndrome	10SEP2020 (12)	13:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/P	N	Yes	NOT RELATED/OTHER: unknown	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Withdrawn	VACCINATION	22OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315441, a 34-year-old white female with no pertinent medical history, received Dose 1 on 30 Aug 2020. The subject reported depression on 10 Sep 2020, 11 days after receiving Dose 1. The subject was discontinued from the study intervention on 22 Oct 2020 because of the depression that was ongoing as of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the depression was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	23	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	108.18 kg	43.5 kg/m2	09SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	11:46

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	01OCT2020 (23)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	30OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1232 12321213, a 23-year-old black or African American female with a pertinent obstetrical history of 2 previous pregnancies resulting in 2 live births, received Dose 1 on 09 Sep 2020. The subject's pregnancy was confirmed on 01 Oct 2020, 22 days after receiving Dose 1. On 01 Oct 2020 (Day 23), at Visit 2, the subject's urine pregnancy test was positive. The information available at the time of this report was that the father did not take any medications during the mother's pregnancy. The pregnancy was considered an important medical event by the investigator. The subject was discontinued from the study intervention on 30 Oct 2020 because of the pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	95.45 kg	34.9 kg/m2	01OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01OCT2020 (1)	12:36

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	22OCT2020 (22)	15:19	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: pregnancy	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01OCT2020	
Withdrawn	VACCINATION	22OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1232 12321293, a 32-year-old black or African American female with no reported medical history, received Dose 1 on 01 Oct 2020. The subject reported an exposure during pregnancy on 22 Oct 2020 (Day 22). On 22 Oct 2020 (Day 22), during Visit 2, the subject's pregnancy test was positive. The subject's first day of her last menstrual period was on an unspecified date in Sep 2020. The gestational age at the time of initial exposure was unknown. The subject reported no previous pregnancies. It was reported that the subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. The subject was discontinued from the study intervention on 22 Oct 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	76.5 kg	27.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic low back pain	Back pain	2013	Present
Bariatric surgery	Metabolic surgery	05JAN2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:25

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	10SEP2020 (23)		14OCT2020 (57)		35
2	PREG	Retained products of conception	RETAINED PRODUCTS OF CONCEPTION	14OCT2020 (57)		14OCT2020 (57)		1
3	REPRO	Vaginal haemorrhage	Vaginal bleeding	05OCT2020 (48)		14OCT2020 (57)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		P	N	Resolved (14OCT2020)	NOT RELATED/OTHER: Pregnancy	1	23	Y
2	3	TC	Y	Resolved (14OCT2020)	NOT RELATED/OTHER: Vaginal bleeding	1	57	N
3	1	TC	N	Resolved (14OCT2020)	NOT RELATED/OTHER: threat of abortion	1	48	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	10SEP2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411279, a 35-year-old black or African American female with a pertinent medical history of 3 prior pregnancies complicated by gestational hypertension with the first and ectopic pregnancy with the second, received Dose 1 on 19 Aug 2020. The subject reported an exposure during pregnancy on 10 Sep 2020, 22 days after receiving Dose 1. Concomitant medication reported 2 weeks prior to the onset of exposure during pregnancy included ketoprofen (from 09 Sep 2020 to 10 Sep 2020) for back pain. The date of the subject's last menstrual period was 09 Aug 2020, and the estimated date of conception was 22 Aug 2020. On 10 Sep 2020 (Day 23), at Visit 2, the subject's urine and serum (β-human chorionic gonadotropin) pregnancy tests were positive. The gestational age at time of initial exposure was first trimester. The subject denied smoking, alcohol use, or use of illicit drugs during the pregnancy. It was reported that during the pregnancy, the subject's partner drank alcohol (socially). The subject was discontinued from the study intervention on 10 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 05 Oct 2020 (Day 48), the subject experienced vaginal hemorrhage. On 07 Oct 2020 (Day 50), the subject received scopolamine butylbromide and metamizole sodium both for colic. On 14 Oct 2020 (Day 57), the serious adverse event of retained products of conception was reported resulting in hospitalization. The investigator considered retained products of conception as an important medical event. The subject presented to the emergency room and a transvaginal ultrasonography showed a gestational age of approximately 7 weeks and 5 days. The subject underwent uterine curettage and had a spontaneous abortion. The procedure was performed without intercurrences. The subject received metamizole sodium, ferrous sulfate, and general anesthesia during this procedure. On 14 Oct 2020 (Day 57), the retained products of conception and vaginal hemorrhage were considered resolved. On 16 Oct 2020 (Day 59), the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	81.3 kg	27.2 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	18:21

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	09OCT2020 (24)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	24	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Withdrawn	VACCINATION	09OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1241 12411766, a 34-year-old white female with a pertinent medical history of 1 previous pregnancy and miscarriage in Aug 2019, received Dose 1 on 16 Sep 2020. The subject reported maternal exposure during pregnancy on 09 Oct 2020, 23 days after receiving Dose 1.

Concomitant medication reported 2 weeks prior to the onset of the maternal exposure during pregnancy included folic acid (since 04 Oct 2020) as a vitamin supplement.

On 09 Oct 2020 (Day 24), at Visit 2, the subject's urine and serum pregnancy tests were positive. The β-human chorionic gonadotropin was 9157.8 MiU/mL (normal range: 5.0-25.0 MiU/mL). The date of the subject's last menstrual period was 03 Sep 2020 and the estimated date of conception was 17 Sep 2020 (Day 2). The gestational age at the time of initial exposure was first trimester. On 21 Oct 2020 (Day 36), an obstetric ultrasonography dated the pregnancy at 6 weeks and 5 days. The subject denied smoking, alcohol use, or use of illicit drugs during this pregnancy. The subject's partner had no relevant history and did not take any drugs (over the counter or medical prescription) during this pregnancy. It was reported the subject received vitamin D during this pregnancy (since 21 Oct 2020).

The subject was discontinued from the study intervention on 09 Oct 2020 because of the maternal exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

In the opinion of the investigator, there was no reasonable possibility that the maternal exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	62 kg	21 kg/m2	28SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1998	Past
Asthma	Asthma	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28SEP2020 (1)	10:30

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Urticaria	Intermittent urticaria generalised.	07OCT2020 (10)		02NOV2020 (36)	
2	SKIN	Urticaria	urticaria generalized	29SEP2020 (2)	00:01	02OCT2020 (5)	18:15

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	27	2	TC/P	N	Resolved (02NOV2020)	Study Treatment	1	10	Y
2	4	3	TC	N	Resolved (02OCT2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28SEP2020	
Withdrawn	VACCINATION	19OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1246 12461025, a 45-year-old white female with pertinent medical history of asthma (in 2015), received Dose 1 on 28 Sep 2020. The subject reported urticaria on 2 occasions after receiving Dose 1. The subject had an initial episode on 29 Sep 2020 (Day 2) lasting until 02 Oct 2020 (Day 5). The second episode took place on 07 Oct 2020 (Day 10) lasting until 02 Nov 2020 (Day 36). The subject was discontinued from the study intervention on 19 Oct 2020 because of the additional episode of urticaria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2001	19	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	88 kg	26.3 kg/m2	30SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	11:24
2	Placebo	21OCT2020 (22)	10:17

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	Flail chest	Flail Chest	30OCT2020 (31)		13NOV2020 (45)		15	3	TC/TCN/W
2	INJ&P	Road traffic accident	Motorcyle accident	30OCT2020 (31)		30OCT2020 (31)		1	4	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (13NOV2020)	NOT RELATED/OTHER: Flail chest secondary to motorcycle accident	2	10	Y
2	N	Resolved (30OCT2020)	NOT RELATED/OTHER: Motorcycle accident	2	10	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30SEP2020	
Withdrawn	VACCINATION	30OCT2020	WITHDRAWAL BY SUBJECT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1247 12471121, a 19-year-old white female with no reported medical history, received Dose 1 on 30 Sep 2020 and Dose 2 on 21 Oct 2020 (Day 22). The subject had a flail chest on 30 Oct 2020, 9 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the flail chest included paracetamol (from 21 Oct 2020 to 29 Oct 2020) and diclofenac potassium (from 24 Oct 2020 to 29 Oct 2020), both for fever related to expected reactogenicity. On 30 Oct 2020 (Day 31), the subject had a motorcycle accident resulting in a flail chest. The subject went to the emergency room and was subsequently hospitalized. On 31 Oct 2020 (Day 32), the subject underwent surgery for rib fractures, which included open reduction and internal fixation (with plates and screws). On 01 Nov 2020 (Day 33), the subject was discharged from the hospital on tramadol 50 mg 3 times a day and paracetamol 1 g 4 times a day, and was advised strict rest for 8 to 12 weeks. On 13 Nov 2020 (Day 45), the subject recovered from the flail chest. The subject requested withdrawal from the study on 30 Oct 2020. In the opinion of the investigator, there was no reasonable possibility that the flail chest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was secondary to a motor vehicle accident. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.9 cm	43 kg	16.4 kg/m2	30SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1991	Present
Post Menopausal	Postmenopause	2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	13:39

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	NERV	Cerebellar infarction	Chronic cerebelar infarcts	23OCT2020 (24)	11:34	ONGOING			1	N	N
2	NERV	Cerebral atrophy	Cerebral atrophy	23OCT2020 (24)	11:34	ONGOING			1	N	N
3	NERV	Cerebral infarction	Left Middle Cerebral Artery Infarct	21OCT2020 (22)		ONGOING			3	TC/TCN/P	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: CT finding	1	24	N
2	Yes	NOT RELATED/OTHER: CT Findings	1	24	N
3	Yes	NOT RELATED/OTHER: Pt.68 years old; and 50 pack year history of smoking as risk factors for event.	1	22	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30SEP2020	
Withdrawn	VACCINATION	21OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1247 12471135, a 69-year-old white female with no pertinent medical history, received Dose 1 on 30 Sep 2020. The subject had a history of smoking since 1962 (50 packs a year). The subject was diagnosed with cerebral infarction on 21 Oct 2020, 21 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of cerebral infarction included salbutamol and budesonide (both since 1991) for asthma; and ibuprofen, paracetamol, and tramadol (all since 28 May 2020) for chronic left arm pain. On 21 Oct 2020 (Day 22), the subject had slurred speech and presented to the emergency department. The clinical examination revealed expressive aphasia and a left facial droop. That same day (Day22), the vital signs showed a blood pressure of 134/57 mmHg, heart rate of 119 beats per minutes, body temperature of 35.7C°, respiratory rate of 20 breaths per minute, and oxygen saturation of 96% on room air. An electrocardiogram showed p-pulmonale, which was not clinically significant. Laboratory test results showed a high urea level of 8.4 mmol/L, platelet count of 290 × 109/L (normal ranges [NR] not reported), and glucose of 5.5 (unit and NR not reported) with all other laboratory test results within normal limits. A computerized tomogram on 23 Oct 2020 (Day 24) revealed acute infarct in the middle cerebral artery distribution on the left side, along with chronic cerebellar infarcts and cerebral atrophy. The subject was diagnosed with cerebral infarction (left middle cerebral artery infarct) with an onset date of 21 Oct 2020 (Day 22) and was subsequently hospitalized. The subject was treated with simvastatin 20 mg and aspirin 150 mg, both orally once daily since 21 Oct 2020 (Day 22). She also received physiotherapy, occupational therapy, and speech therapy. The subject's clinical condition improved and speech was also improving. The subject was discharged on 28 Oct 2020 (Day 29) and was advised to follow-up with speech therapy. The cerebral atrophy and chronic cerebellar infarction were ongoing at the time of the last available report. The subject was discontinued from the study intervention on 21 Oct 2020 because of the cerebral infarction that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the cerebral infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather related to the age of the subject and history of smoking. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the cerebral infarction was most likely coincidental and associated with underlying clinical conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	69.4 kg	22.8 kg/m2	20SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Syncope	vasovagal syncope	20SEP2020 (1)	13:54	20SEP2020 (1)	14:52	1	2
2	GASTR	Vomiting	Vomiting	20SEP2020 (1)	14:52	21SEP2020 (2)	14:53	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	N	Resolved (20SEP2020)	NOT RELATED/OTHER: Study Procedure (phlebotomy)			Y
2	TCN	N	Resolved (21SEP2020)	NOT RELATED/OTHER: unknown			N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20SEP2020	
Withdrawn	VACCINATION	21SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	21SEP2020	ADVERSE EVENT

Narrative Comment

Subject C4591001 1248 12481218, a 26-year-old white male with no reported medical history, reported syncope during the prevaccination blood sample collection on 20 Sep 2020 (Day 1), which resolved on the same day.
On 20 Sep 2020 (Day 1), the subject also reported vomiting, which resolved on 21 Sep 2020 (Day 2).
The subject was withdrawn from the study before study vaccination on 21 Sep 2020 because of the syncope.
In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, but rather it was related to the study procedure (phlebotomy).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	21	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	63.05 kg	23.8 kg/m2	12SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2015	Present
Recurrent Miscarriage	Abortion spontaneous	2016	Past
Seasonal Allergies	Seasonal allergy	2017	Present
Benedryl Allergy	Drug hypersensitivity	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12SEP2020 (1)	13:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	stomach pain	15SEP2020 (4)	09:00	15SEP2020 (4)	14:00	1	2
2	SKIN	Alopecia	hair loss	OCT2020 ()		ONGOING			1
3	INV	Body temperature increased	elevated body temperature at 100.0F	13SEP2020 (2)	07:30	14SEP2020 (3)	04:00	2	1
4	INV	Body temperature increased	elevated body temperature at 100.0F	14SEP2020 (3)	10:00	15SEP2020 (4)		2	2
5	GENRL	Chills	intermittent chills	12SEP2020 (1)	22:00	25SEP2020 (14)		14	1
6	EYE	Eye irritation	left eye irritation	12SEP2020 (1)	16:00	14SEP2020 (3)		3	1
7	NERV	Headache	headache intermittent	15SEP2020 (4)		25SEP2020 (14)		11	2
8	INJ&P	Maternal exposure during pregnancy	Maternal Exposure During Pregnancy	12SEP2020 (1)	13:13	ONGOING			
9	GASTR	Nausea	Nausea	26SEP2020 (15)		ONGOING			1
10	EYE	Ocular hyperaemia	left eye redness	12SEP2020 (1)	16:00	14SEP2020 (3)		3	1
11	GENRL	Pyrexia	fever at 102.0F	14SEP2020 (3)	04:00	14SEP2020 (3)	08:00	1	2
12	INV	Weight decreased	weight loss	OCT2020 ()		ONGOING			1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (15SEP2020)	NOT RELATED/OTHER: unknown etiology but due to gas	1	4	N
2	N	N	Yes	NOT RELATED/OTHER: pregnancy			N
3	N	N	Resolved (14SEP2020)	Study Treatment	1	2	N
4	TC	N	Resolved (15SEP2020)	Study Treatment	1	3	N
5	N	N	Resolved (25SEP2020)	Study Treatment	1	1	N
6	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown etiology	1	1	N
7	TC	N	Resolved (25SEP2020)	Study Treatment	1	4	N
8	P	N	Yes	NOT RELATED/OTHER: pregnancy	1	1	Y
9	N	N	Yes	NOT RELATED/OTHER: Likely From Pregnancy	1	15	N
10	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown etiology	1	1	N
11	TC	N	Resolved (14SEP2020)	Study Treatment	1	3	N
12	N	N	Yes	NOT RELATED/OTHER: pregnancy			N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12SEP2020	
Withdrawn	VACCINATION	07OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1254 12541142, a 21-year-old white female with a pertinent obstetrical history of spontaneous abortion (in 2016), and 4 previous pregnancies that resulted in 2 spontaneous abortions in 2018 and 2019, 1 therapeutic abortion in 2018, and 1 live birth in May 2020, received Dose 1 on 12 Sep 2020. The subject was confirmed to have a positive pregnancy test on 02 Oct 2020 (Day 21). During Visit 1 on 11 Sep 2020 (Day -1), the subject had reported using contraceptives and her urine pregnancy test was negative. The first day of her last menstrual period was 12 Sep 2019. On 02 Oct 2020 (Day 21), the subject contacted the site to reschedule Visit 2 because of ongoing nausea, which started on 26 Sep 2020 (Day 15). That same day, she visited her personal physician for discomfort not specified and ongoing nausea. An evaluation including blood work was performed to evaluate her condition. The study coordinator suggested that she attend Visit 2 on 03 Oct 2020 (Day 22) for the study investigator to perform a physical examination. Although the subject agreed to attend Visit 2, she did not keep the appointment. Since the subject failed to attend Visit 2, the study site obtained medical records from her doctor's office on 07 Oct 2020 (Day 26). According to the medical records, the subject visited her doctor because of unprotected sex and vaginal spotting. The subject had a positive urine pregnancy test on 02 Oct 2020 (Day 21). On 03 Oct 2020 (Day 22), the subject returned to her doctor's office and had a transvaginal ultrasound scan, which showed 7 weeks and 2 days of pregnancy, with fetal cardiac activity noted. The subject had previously delivered a baby about 4 months before Visit 1. The estimated date of conception was considered as 29 Aug 2020 (Day -14). The subject did not smoke, drink alcohol, or use illicit drugs before the positive pregnancy test. The investigator considered the pregnancy to be an important medical event. The subject was discontinued from the study intervention on 07 Oct 2020 because of the pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the pregnancy was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	91.5 kg	28.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	05JAN2011	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	05JUN2011	Present
Chronic Deep Vein Thrombosis of bilateral legs	Deep vein thrombosis	06JUL2011	Present
Factor V Leiden Mutation, heterozygous	Factor V Leiden mutation	06JUL2011	Present
Hyperlipidemia	Hyperlipidaemia	06JUL2011	Present
Diabetes Mellitus 2	Type 2 diabetes mellitus	06JUL2011	Present
Spinal stenosis of lumbar spine with neurogenic claudication	Lumbar spinal stenosis	28JUL2011	Present
Erectile dysfunction	Erectile dysfunction	21NOV2016	Present
Peripheral neuropathy	Neuropathy peripheral	21NOV2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Actinic keratosis	Actinic keratosis	20SEP2017	Present
Insomnia	Insomnia	20SEP2017	Present
Anxiety	Anxiety	18DEC2017	Present
Lumbar radiculopathy	Lumbar radiculopathy	11MAY2018	Present
Arthritis of bilateral hips	Arthritis	27FEB2019	Present
Osteoarthritis of right knee	Osteoarthritis	27FEB2019	Present
Chronic pain syndrome	Pain	07MAR2019	Present
Allergy to Tramadol	Drug hypersensitivity	30MAY2019	Present
Genital Herpes Simplex	Genital herpes simplex	03APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	11:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary embolism	Pulmonary embolism	23SEP2020 (21)		ONGOING		

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/P	Y	Yes	NOT RELATED/OTHER: Factor V Leiden Mutation	1	21	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Withdrawn	VACCINATION	02NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1270 12701057, a 65-year-old white male with a pertinent medical history of deep vein thrombosis (DVT; bilateral legs), factor V Leiden mutation, hyperlipidemia, and type 2 diabetes mellitus (all since 06 Jul 2011), received Dose 1 on 03 Sep 2020. The subject was diagnosed with a pulmonary embolism on 23 Sep 2020, 20 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the pulmonary embolism included metformin (since 25 Dec 2015) for type 2 diabetes mellitus, acyclovir (since 03 Apr 2020) for genital herpes simplex, famotidine (since 03 Apr 2020) for gastroesophageal reflux disease, ciclesonide (since 20 Aug 2020) for asthma, albuterol (since 30 Mar 2015) for asthma, lovastatin (since 30 Aug 2019) for hyperlipidemia, and dabigatran etexilate mesylate (from 25 Jul 2018 to 25 Sep 2020) for recurrent DVT. On 24 Sep 2020 (Day 22), the subject presented to the emergency department (ED) because of shortness of breath and cough starting on 04 Sep 2020 (Day 2) and chest tightness since 23 Sep 2020 (Day 21). The subject thought these symptoms were related to the smoke in the air and his inhalers were not helping. The SARS-CoV-2 test result was negative and troponin I was <0.02 ng/mL (normal range [NR]: 0.00 - 0.04 ng/mL). The subject received albuterol inhaler once, acetylsalicylic acid 325 mg once orally, and normal saline bolus once intravenously. On 24 Sep 2020 (Day 22), the subject went home against medical advice as he was admitted to the COVID-19 area of the emergency room. After he was back home, the symptoms improved but were still present; therefore, the subject went back to the ED on 25 Sep 2020 (Day 23). A computed tomography angiogram of chest performed on 25 Sep 2020 (Day 23) was positive for acute pulmonary embolism, which was reported to be life-threatening and medically significant. On 25 Sep 2020 (Day 23), troponin I was <0.02 ng/mL, prothrombin time (PT) was 15.5 seconds (NR: 11.7 - 14.3 seconds), and international normalized ratio (INR) was 1.3 (NR: 2.0 - 3.0). The subject discontinued treatment with dabigatran etexilate mesylate and received enoxaparin 80 mg subcutaneously. The subject was discharged home on the same day (Day 23) in stable condition with a prescription for enoxaparin and warfarin and was referred to hematology/oncology. The subject continued to experience shortness of breath since 26 Sep 2020 (Day 24) and chest tightness since 27 Sep 2020 (Day 25). The subject was advised to postpone travel for 6 weeks, continue anticoagulant therapy with enoxaparin and warfarin, and monitor PT/INR levels. On 29 Sep 2020 (Day 27), the PT was 21.7 seconds and the INR level was 2.0. On 01 Oct 2020 (Day 29), the PT was 23.6 seconds and the INR level was in therapeutic range at 2.2, and the subject was advised to discontinue treatment with enoxaparin and continue warfarin. The subject continued to have shortness of breath, fatigue, and mild cough on 02 Oct 2020 (Day 30). On 05 Oct 2020 (Day 33), a repeat SARS-CoV-2 NAAT result was negative and PT was 33.2 seconds and INR was above therapeutic range at 3.3. On 09 Oct 2020 (Day 37), the PT was 32.9 seconds and the INR was 3.3, and warfarin doses were titrated. On 15 Oct 2020 (Day 43), the INR was therapeutic (value not reported), and a trial weekly dose of warfarin was recommended. On 21 Oct 2020 (Day 49), the PT was 22.6 seconds and the INR was in therapeutic range at 2.1. On 28 Oct 2020 (Day 56), the PT was 19.9 seconds and the INR was sub-therapeutic at 1.8, and the subject was instructed to increase the dose of warfarin and recheck the INR in 1 week. The subject was discontinued from the study intervention on 02 Nov 2020 because of the pulmonary embolism that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to factor V Leiden mutation. Pfizer concurred with the investigator's assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	77.9 kg	27.9 kg/m2	25SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	16:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	05SEP2020 (-20)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: not applicable			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	15OCT2020	PREGNANCY
Withdrawn	FOLLOW-UP	11NOV2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 4444 44441979, a 29-year-old white female with an obstetrical history of 1 previous pregnancy that resulted in a live birth via a cesarean section because of polyhydramnios, received Dose 1 on 25 Sep 2020 (Day 1). On 09 Oct 2020 (Day 15), the subject informed the site that she had a positive urine pregnancy test that day. The first day of her last menstrual period was 05 Sep 2020 (Day -20) and the estimated date of conception was 05 Sep 2020 (Day -20). The gestational at the time of initial exposure was 1st trimester. The subject smoked; however, she did not drink alcohol or use illicit drugs before the positive pregnancy test. The father smoked; however, he did not drink alcohol or use illicit drugs. The subject was discontinued from the study intervention on 15 Oct 2020 because of the pregnancy and decided to withdraw from the study on 11 Nov 2020. In the opinion of the investigator, there was no reasonable possibility that the pregnancy was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	70 kg	24.1 kg/m2	12JUN2020 (-12)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Wears Glasses	Corrective lens user	1982	Present
Deviated Septum - Nasal Surgery	Nasal septal operation	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24JUN2020 (1)	11:32
2	BNT162b2	15JUL2020 (22)	09:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Neuritis	neuritis right arm	29JUL2020 (36)		ONGOING		
2	MUSC	Pain in extremity	right arm pain	29JUL2020 (36)	09:40	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Yes	NOT RELATED/OTHER: related to study blood draw	2	15	Y
2	2	N	N	Yes	NOT RELATED/OTHER: unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12JUN2020	
Completed	VACCINATION	19AUG2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1003 10031065, a 52-year-old white female with no pertinent medical history, received Dose 1 on 24 Jun 2020 and Dose 2 on 15 Jul 2020 (Day 22). The subject developed neuritis on 29 Jul 2020, 14 days after receiving Dose 2.

On 22 Oct 2020 (Day 121), the subject visited the investigator with complaints of persistent right arm weakness and pain. The subject stated that she began experiencing intermittent right arm weakness and pain (pain in extremity; reported as nonserious adverse event) after undergoing the blood draw from the right antecubital fossa at Visit 6 on 29 Jul 2020 (Day 36). The subject described that the symptoms originated in the antecubital fossa at the site of the blood draw and radiated to the right thumb, fifth finger, and upward to the biceps. She described the pain as an aching sensation, which was worse with movement, even causing difficulty with putting on her jacket. She also felt that the arm was weak; however, it was difficult to differentiate this from the pain. Per review of the Visit 6 medical record, there was no mention of problems with the blood draw. Prior to the onset of these symptoms, the blood was drawn on 24 Jun 2020, on 01 Jul 2020, on 15 Jul 2020, and on 20 Jul 2020 without any concerns. On 22 Oct 2020 (Day 121), on examination, there was no swelling, bruise, or nodule felt in the antecubital fossa, and no tenderness on palpation. Her muscle strength was normal and equal to the right arm in the shoulder joint, the elbow (both flexion and extension), wrist, fingers, and with grasp; however, the subject looked distressed and anxious during the examination. The investigator concluded that no objective finding could be detected that might indicate injury to a nerve, muscle, or tendon; however, there was a possibility that the pain might be emanating from a subtle needle induced traumatic injury of either a tendon or a nerve bundle resulting in neuritic pain. The subject stated that despite intermittent pain throughout the day, the symptoms were not improving with time and she was concerned that her daily activities were compromised. After 2 subsequent follow-up phone calls with the subject, on 10 Nov 2020, the investigator reported the neuritis as a serious adverse event as it caused persistent/significant disability/incapacity.

The right arm pain and neuritis were ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the neuritis was related to the study intervention or concomitant medications, but rather it was related to clinical trial procedures (study-related blood draw). Pfizer concurred with the investigator's causality assessment for the study intervention. The neuritis was assessed by Pfizer as not related to the blood draw based on the absence of evidence.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	71.82 kg	22 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2000	Present
Osteoarthritis	Osteoarthritis	2000	Present
Interstitial Lung Disease	Interstitial lung disease	2017	Present
Seasonal Allergies	Seasonal allergy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30JUL2020 (1)	13:55
2	Placebo	20AUG2020 (22)	13:04

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Interstitial lung disease	worsening of interstitial lung disease	17OCT2020 (80)		ONGOING		
2	MUSC	Scleroderma	possible scleroderma	20OCT2020 (83)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Yes	NOT RELATED/OTHER: worsening of interstitial lung disease	2	59	Y
2	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: possible scleroderma	2	62	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	21SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1003 10031113, a 73-year-old white male with a pertinent medical history of interstitial lung disease and seasonal allergies (both since 2017), received Dose 1 on 30 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 22). The subject developed worsening of interstitial lung disease on 17 Oct 2020, 58 days after receiving Dose 2 and scleroderma on 20 Oct 2020, 61 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the worsening of interstitial lung disease and scleroderma included fluoxetine hydrochloride (since 2000) for anxiety and cetirizine hydrochloride (since 2017) for seasonal allergies. On 14 Oct 2020 (Day 77), the subject suddenly fell ill and experienced rigors lasting 45 minutes. He felt tired but had no other specific symptoms except moderate low back pain. The subject went to the emergency department immediately, where he was found to have a body temperature of 37.2°C, pulse rate of 76 beats per minute, respiratory rate of 18 breaths per minute, blood pressure (BP) of 113/58 mmHg, and oxygen saturation of 96%. An initial white blood cell (WBC) count was 4500 with 11 bands (normal range [NR] and unit not provided). Later, the subject's BP dropped to 80/53 mmHg; however, he responded to intravenous (IV) fluids and was started on vancomycin and piperacillin sodium/tazobactam sodium. His condition rapidly improved; the back pain resolved but he developed diarrhea transiently. That same day (Day 77), a computerized tomogram (CT) of the abdomen was normal and a viral diagnostic panel, SARS CoV-2 test, and legionella urine antigen test were all negative. A blood culture showed no bacteria or yeast isolated. A chest x-ray showed possible left lower lobe infiltrate. The subject's C-reactive protein was 14.1 mg/L (NR: 0.0 - 10.0 mg/L), neutrophil percentage was 85% (NR: 45% - 75%), lymphocyte count was 0.2 × 109/L (NR: 1.0 - 4.8 × 109/L), and lymphocyte percentage was 4% (NR: 15% - 45%). On 16 Oct 2020 (Day 79), the subject was discharged from the hospital. On 17 Oct 2020 (Day 80), the subject felt better and he was on oral amoxicillin/clavulanic acid (Augmentin) for possible community acquired pneumonia. However, later on the same day (Day 80), he had chills and weakness and returned to the hospital. Laboratory test results showed a WBC count of 12200 (unit and NR not provided) and a negative SARS CoV-2 test. An initial chest x-ray showed diffuse pneumonia; however, a repeat chest x-ray showed pulmonary edema. The subject's blood cultures were negative, and D-dimer was elevated at 3341 (NR: <500; unit not provided). On 18 Oct 2020 (Day 81), a CT of the chest with contrast did not demonstrate pulmonary embolus. The subject was restarted on piperacillin sodium/tazobactam sodium along with doxycycline. The subject's condition slowly improved. On 22 Oct 2020 (Day 85), the subject had a bronchoscopy to assess the etiology of lung disease, and the result showed normal airways. Bronchoalveolar lavage (BAL) fluid was negative for all viruses, including human rhinovirus, parainfluenza viruses, meta-pneumovirus, respiratory syncytial virus, Flu A and B, adenovirus, SARS-CoV-2, mycoplasma, and chlamydia. Bacterial cultures, acid-fast bacillus and final stain, and antinuclear antibody were also negative. Pneumocystis stain was negative and no malignancy was noted. However, SCL-70 antibody was positive. The subject was diagnosed with interstitial lung disease possibly due to scleroderma and was started on glucocorticosteroids. The subject was treated with intravenous methylprednisolone sodium succinate 60 mg twice a day (from 22 Oct 2020 to 24 Oct 2020), which was later increased to 250 mg twice a day (from 24 Oct 2020 to 26 Oct 2020). The subject improved clinically with furosemide. On 26 Oct 2020 (Day 89), the subject was discharged from the hospital. On 27 Oct 2020 (Day 90), the subject continued on prednisone 20 mg 3 tablets for 7 days and followed by 2.5 tablets daily until 17 Nov 2020 (Day 111), at which time he was scheduled to follow up with a pulmonologist as an outpatient. The worsening of interstitial lung disease and scleroderma were ongoing at the time of last available report. In the opinion of the investigator, there was no reasonable possibility that the worsening of interstitial lung disease and scleroderma were related to the study intervention, concomitant medications, or clinical trial procedures. The worsening of interstitial lung disease was related to the subject's medical history of interstitial lung disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	86.82 kg	26.6 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	1959	Past
appendicitis	Appendicitis	1959	Past
high blood pressure	Hypertension	2009	Present
gastrointestinal reflux disorder	Duodenogastric reflux	2013	Present
benign prostatic hypertrophy	Benign prostatic hyperplasia	2017	Present
environmental allergies - hives	Urticaria	2019	Present
right eye cataract	Cataract	FEB2019	Past
right eye cataract removal	Cataract operation	FEB2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	15:19
2	Placebo	26AUG2020 (22)	14:57

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Small intestinal obstruction	small bowel obstruction	08AUG2020 (4)	00:17	10AUG2020 (6)	00:13	3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (10AUG2020)	NOT RELATED/OTHER: SAE - unplanned bowel obstruction	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1003 10031149, a 70-year-old white male with a pertinent medical history of appendicitis and appendectomy (both in 1959), and duodenogastric reflux (since 2013), received Dose 1 on 05 Aug 2020 and Dose 2 on 26 Aug 2020 (Day 22). The subject was diagnosed with a small intestinal obstruction on 08 Aug 2020, 3 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the small intestinal obstruction included atorvastatin (since 2009) for high cholesterol, lisinopril and amlodipine (both since 2009) for hypertension, omeprazole (since 2013) for gastroesophageal reflux disease, and finasteride (since 2017) for benign prostatic hyperplasia. On 08 Aug 2020 (Day 4), the subject presented to the emergency room with acute abdominal pain with distention. It was reported that the subject was afebrile and normotensive. A computerized tomogram of the abdomen showed dilated loops of small bowel, stomach, possibly infectious or ileus, suggestive of small bowel obstruction, and the subject was hospitalized. A nasogastric (NG) tube was placed and the subject was treated with famotidine 20 mg intravenously (IV) 1 dose, morphine 4 mg IV 2 doses, and ondansetron 4 mg IV 1 dose. On 08 Aug 2020 (Day 4), the laboratory test results showed an elevated blood urea nitrogen of 31 mg/dL (normal range: 8 – 20 mg/dL) and other laboratory test results were within normal limits. The subject's condition improved rapidly and the NG tube was removed on 09 Aug 2020 (Day 5). On 10 Aug 2020 (Day 6), the small intestinal obstruction resolved and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the small intestinal obstruction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to bowel obstruction. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	137.55 kg	48.8 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HIGH BLOOD PRESSURE	Hypertension	1980	Present
DEPRESSION	Depression	1985	Present
MORPHINE ALLERGY	Drug hypersensitivity	1985	Present
ANXIETY	Anxiety	2004	Present
HYSTERECTOMY	Hysterectomy	2008	Past
UTERINE FIBROIDS	Uterine leiomyoma	2008	Past
MENOPAUSE	Menopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	12:04
2	BNT162b2	04SEP2020 (23)	10:58

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Non-cardiac chest pain	INTERMITTENT NON CARDIAC CHEST PAIN	09SEP2020 (28)		17SEP2020 (36)		9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	Y	Resolved (17SEP2020)	NOT RELATED/OTHER: IDIOPATHIC	2	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1005 10051054, a 54-year-old black/African American female with a pertinent medical history of hypertension (since 1980), anxiety (since 2004), menopause (since 2017), and family medical history of chest pain (mother, father, and brother), received Dose 1 on 13 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 23). The subject experienced non-cardiac chest pain on 09 Sep 2020, 5 days after receiving Dose 2.

Concomitant medications reported within 2 weeks prior to the onset of the non-cardiac chest pain included verapamil hydrochloride and metoprolol succinate (both since 01 Jan 1995) and lisinopril (since 01 Jan 2005) for high blood pressure; and escitalopram oxalate (since 01 Dec 2019) for anxiety.

On 09 Sep 2020 (Day 28), the subject presented to the emergency room with intermittent non-cardiac chest pain resulting in hospitalization for 1 day. On 16 Sep 2020 (Day 35), the subject was hospitalized again with intermittent non-cardiac chest pain and relevant laboratory tests showed normal troponin level of <0.01 ng/mL (normal range: 0.00-0.09 ng/mL) and a repeat troponin after 6 hours was also normal (<0.01 ng/mL). A stress echocardiogram showed nonischemic heart rate (response to exercise) without chest pain, hypertensive blood pressure, and an average exercise capacity. The SARS-CoV-2 real time-polymerase chain reaction test result was negative. On 17 Sep 2020 (Day 36), the non-cardiac chest pain resolved and the subject was discharged from the hospital.

In the opinion of the investigator, there was no reasonable possibility that the non-cardiac chest pain was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was idiopathic. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the non-cardiac chest pain was most likely related to the subject's underlying clinical conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	64.55 kg	26.8 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
controlled squamous cell carcinoma skin on chin	Squamous cell carcinoma of skin	1993	Present
MENOPAUSE	Menopause	2002	Present
HIGH BLOOD PRESSURE	Hypertension	2004	Present
LEFT BREAST CANCER	Breast cancer	2005	Past
LEFT BREAST LUMPECTOMY	Breast conserving surgery	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	09:34
2	Placebo	02SEP2020 (20)	15:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Breast cancer	LEFT BREAST CANCER	04SEP2020 (22)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: PRE-EXISTING OCCULT MALIGNANCY	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1005 10051069, a 68-year-old white female with a pertinent medical history of menopause (since 2002) and left breast cancer (2005 to 2010) treated with lumpectomy (in 2010) and radiation, received Dose 1 on 14 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 20). The subject was diagnosed with left breast cancer on 04 Sep 2020, 2 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the breast cancer included doxycycline hydrochloride (since Jan 2000) for gum disease, valsartan (since 01 Jan 2008) and metoprolol succinate (since 01 Jan 2010) for high blood pressure, retinol (since 01 Jan 2014) for skin cancer, and erythromycin ethyl succinate (since 01 Jan 2016) for rosacea. On 04 Sep 2020 (Day 22), the subject's routine mammogram showed a small lump, sub-centimeter spiculated mass in the upper outer quadrant of the left breast. On 14 Sep 2020 (Day 32), the left breast lump biopsy findings revealed invasive ductal carcinoma. On the same day (Day 32), the left breast ultrasound showed a 5 mm irregular hypoechoic mass with associated architectural distortion at the 1:30 position of the left breast. On 21 Sep 2020 (Day 39), a magnetic resonance imaging showed an irregular sub-centimeter enhancing mass in the superior left breast measuring 6 × 4 × 4 mm. An appointment with a surgeon was scheduled on 30 Sep 2020 (Day 48) to discuss further treatment plan; however, no further details are available at this time. The breast cancer was considered medically significant by the investigator and was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the left breast cancer was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the pre-existing occult malignancy. Pfizer concurred with the investigator's causality assessment and considered the breast cancer as most likely related to the subject's underlying clinical conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183.64 cm	93.91 kg	27.8 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VASECTOMY	Vasectomy	2005	Past
CERVICAL FUSION	Spinal fusion surgery	2013	Past
RIGHT INGUINAL HERNIA REPAIR	Inguinal hernia repair	2016	Past
OSTEOARTHRITIS	Osteoarthritis	2017	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2018	Present
HIGH CHOLESTEROL	Blood cholesterol increased	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19OCT2020 (1)	08:47

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RESP	Acute respiratory failure	Acute Respiratory Failure	08NOV2020 (21)	00:43	ONGOING			4	N	Y
2	CARD	Cardiac arrest	CARDIAC ARREST	08NOV2020 (21)	00:43	08NOV2020 (21)		1	4	TC	Y
3	INJ&P	Overdose	Overdose	08NOV2020 (21)	00:43	08NOV2020 (21)		1	4	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: unknown	1	21	Y
2	Resolved (08NOV2020)	NOT RELATED/OTHER: possible intentional overdose, or. poor choice of alcohol and drug abuse.	1	21	Y
3	Resolved (08NOV2020)	NOT RELATED/OTHER: unknown	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1005 10051293, a 60-year-old white male with a pertinent medical history of increased blood cholesterol (since Jan 2020), received Dose 1 on 19 Oct 2020. The subject had an overdose and was diagnosed with cardiac arrest and acute respiratory failure on 08 Nov 2020, 20 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the overdose, cardiac arrest, and acute respiratory failure included sildenafil citrate (since 23 Mar 2019) for erectile dysfunction, omeprazole (since Jan 2020) for gastroesophageal reflux disease, meloxicam (since 01 Jul 2020) and gabapentin (since an unknown date) for osteoarthritis, atorvastatin (since 01 Jul 2020) for hypercholesterolemia, and hydrocodone bitartrate/paracetamol for an unspecified indication (since an unknown date). On 08 Nov 2020 (Day 21), the subject's partner found him unresponsive. After a successful emergency medical service (EMS) resuscitation, the subject was transferred to an intensive care unit incubator. On the same day (Day 21), the subject's laboratory test results showed a white blood cell count of 11.2 ×103/mm3 (normal range [NR]: 4.2 - 9.1 × 103/mm3), high hemoglobin of 15 g/dL, normal blood sodium of 138 mmol/L (NRs not available), high glucose of 240 mg/dL (NR: 60-99 mg/dL); urine toxicity screening was positive for cocaine; a chest x-ray showed bilateral perihilar airspace and interstitial opacities, suggestive of possible pulmonary edema vs infection; a computerized tomogram of the head was normal; and SARS CoV-2 polymerase chain reaction test result is pending. The troponin test at 1100 hours was high at 62 ng/L (NR: <21 ng/mL) and a repeat troponin test at 1430 hours was 53 ng/L. Additionally, it was reported that the subject had taken gabapentin, hydrocodone bitartrate/paracetamol, and 8 beers; however, it was unclear if this was intentional. The overdose, cardiac arrest, and acute respiratory failure were considered to be life-threatening by the investigator. On 08 Nov 2020 (Day 21), as part of cardiac arrest and overdose management, the subject was treated with 1 dose of naloxone hydrochloride and one dose of epinephrine 1 mg. On the same day (Day 21), the overdose and cardiac arrest were considered resolved. On 10 Nov 2020 (Day 23), the subject's glucose remained high at 117 mg/dL. The acute respiratory failure was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the overdose, cardiac arrest, and acute respiratory failure were related to the study intervention or clinical trial procedures, but rather due to overdose or poor choice of alcohol and drug abuse complicated by concomitant gabapentin use. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.01 cm	60.55 kg	21.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ehlers-Danlos Syndrome	Ehlers-Danlos syndrome	1966	Present
Postural Orthostatic Tachycardia Syndrome	Postural orthostatic tachycardia syndrome	1966	Present
Environmental Allergies	Hypersensitivity	1969	Present
Recurrent Urinary Tract Infection	Urinary tract infection	1974	Present
Migraines with Aura	Migraine with aura	1979	Present
Recurrent Sinusitis	Sinusitis	1980	Past
Asthma (Moderate)	Asthma	1985	Present
Complete Hysterectomy	Hysterectomy	1989	Past
Postmenopausal	Postmenopause	1989	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post Partum Hemorrhage	Postpartum haemorrhage	1989	Past
Premarin Allergy (Hives)	Urticaria	1989	Present
Attention Deficit Hyperactivity Disorder	Attention deficit hyperactivity disorder	01FEB1989	Present
Macrodantin Allergy (Hives)	Urticaria	1990	Present
Restless Leg Syndrome	Restless legs syndrome	2000	Present
History of Recurrent Actinic Keratosis	Actinic keratosis	06SEP2011	Present
Basal Cell Carcinoma (Forehead)	Basal cell carcinoma	11SEP2011	Past
Rosacea (mild)	Rosacea	12SEP2011	Present
Chronic Fatigue Syndrome	Chronic fatigue syndrome	14AUG2012	Present
Insomnia	Insomnia	13SEP2013	Present
Mild Anxiety	Anxiety	19MAY2014	Present
Lumbar Disc Degeneration	Intervertebral disc degeneration	14AUG2014	Present
Tinnitus Left Ear	Tinnitus	12MAR2015	Present
Bilateral Eye Cataracts	Cataract	20OCT2016	Past
Recurrent Muscle Spasms (Whole Body)	Muscle spasms	10MAR2017	Present
Gastrointestinal Bleed	Gastrointestinal haemorrhage	27NOV2017	Past
Urethral Sling	Urinary bladder suspension	2018	Present
Osteoporosis	Osteoporosis	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	13:34
2	BNT162b2	15SEP2020 (23)	15:51

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	ATRIAL FIBRILLATION INTERMITTENT	06OCT2020 (44)		12OCT2020 (50)		7	2
2	NERV	Headache	Headache	24AUG2020 (1)	14:30	25AUG2020 (2)	07:00	2	2
3	INFEC	Urinary tract infection	URINARY TRACT INFECTION	03OCT2020 (41)		12OCT2020 (50)		10	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (12OCT2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	22	Y
2	TC	N	Resolved (25AUG2020)	Study Treatment	1	1	N
3	TC	N	Resolved (12OCT2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	2	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	02OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061098, a 66-year-old white female with a pertinent medical history of Ehlers-Danlos syndrome and postural orthostatic tachycardia syndrome (both since 1966), hypersensitivity (environmental allergies, since 1969), postmenopause (since 1989), restless legs syndrome (since 2000), chronic fatigue syndrome (since Aug 2012), insomnia (since Sep 2013), and anxiety (since May 2014), received Dose 1 on 24 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 23). The subject was diagnosed with intermittent atrial fibrillation on 06 Oct 2020, 21 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the atrial fibrillation included gabapentin (since 03 Oct 2020) for restless legs syndrome and sulfamethoxazole/trimethoprim (from 03 Oct 2020 to 06 Oct 2020) and ciprofloxacin (from 06 Oct 2020 to 12 Oct 2020) for urinary tract infection (UTI). She also received influenza vaccine (on 02 Oct 2020). On 03 Oct 2020 (Day 41), the subject was diagnosed with a nonserious adverse event of UTI that was treated with sulfamethoxazole/trimethoprim; however, the UTI did not subside after this treatment and she was started on ciprofloxacin. On 06 Oct 2020 (Day 44), following treatment with ciprofloxacin for the UTI, the subject experienced intermittent atrial fibrillation that was detected by her apple watch. On the same day, she went to a cardiologist and an electrocardiogram also showed atrial fibrillation, for which diltiazem 120 mg (from 09 Oct 2020 to 16 Oct 2020) was prescribed. The atrial fibrillation was considered medically significant by the investigator, and the subject was monitored. It was reported that the subject's apple watch identified tracings consistent with atrial fibrillation. She had intermittent atrial fibrillation for several hours every day from 07 Oct 2020 (Day 45) to 12 Oct 2020 (Day 50). Treatment with ciprofloxacin was discontinued on 12 Oct 2020 (Day 50) and the atrial fibrillation resolved on the same day. In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention or clinical trial procedures, but rather it was related to the ciprofloxacin. Pfizer did not concur with the investigator's causality assessment of the concomitant medication and considered that the atrial fibrillation as most likely coincidental and associated with the subject's underlying cardiovascular conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187 cm	91.4 kg	26.1 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergy	Seasonal allergy	1987	Present
Asthma	Asthma	1990	Present
Vasectomy	Vasectomy	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	15:11
2	Placebo	17SEP2020 (23)	14:33

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Chronic myeloid leukaemia	chronic myelogenous leukemia	24SEP2020 (30)		ONGOING			4
2	BLOOD	Leukocytosis	leukocytosis	24SEP2020 (30)		19OCT2020 (55)		26	3
3	BLOOD	Thrombocytosis	thrombocytosis	24SEP2020 (30)		26OCT2020 (62)		33	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Genetic change in stem cells	2	8	Y
2	N	N	Resolved (19OCT2020)	NOT RELATED/OTHER: Chronic myelogenous leukemia	2	8	N
3	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: Chronic myelogenous leukemia	2	8	N

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Dasatinib	DASATINIB	06OCT2020	ONGOING	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1007 10071276, a 43-year-old white male with no pertinent medical history, received Dose 1 on 26 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 23). The subject was diagnosed with chronic myeloid leukemia on 24 Sep 2020, 7 days after receiving Dose 2. On 25 Sep 2020 (Day 31), the subject notified the study site that his routine laboratory tests performed on 24 Sep 2020 (Day 30) were abnormal with a white blood cell (WBC) count of 168,500, platelets of 955,000, hemoglobin of 12.0, and hematocrit of 38.5 (units and normal ranges not provided) consistent with a diagnosis of leukocytosis and thrombocytosis (reported as nonserious adverse events). The subject's physician ordered a repeat complete and differential blood count on 25 Sep 2020 (Day 31), which showed a platelet count of 1092 × 103/mm3 (normal range [NR]: 140-400 × 103/mm3), WBC count of 183.6 × 103/mm3 (NR: 3.8-10.8 × 103/mm3), lactate dehydrogenase of 912 U/L (NR: 110-270 U/L), hemoglobin of 11.5 g/dL (NR: 13.2-17.1 g/dL), and hematocrit of 35.5% (NR: 38.5% - 50%); consistent with the previous day's report. On the same day (Day 31), the subject visited the hematology/oncology unit for further work-up. He had no signs or symptoms of illness, fever, or fatigue. He was treated with Hydrea 1000 mg orally (PO) twice a day, allopurinol 300 mg PO daily, and baby aspirin 1 tablet PO daily. On 28 Sep 2020 (Day 34), a bone marrow biopsy was performed, which showed myeloproliferative neoplasm; cytogenic analysis showed an abnormal male karyotype; all cells showed translocation between chromosomes 9 and 22, resulting in formation of the Philadelphia chromosome consistent with chronic myeloid leukemia. The subject was additionally treated with dasatinib 100 mg PO once daily (from 06 Oct 2020). He was initially advised to undergo weekly tests for complete and differential blood count, comprehensive metabolic panel, and baseline thyroid stimulating hormone, which was later spaced out to monthly. On 19 Oct 2020 (Day 55), the leukocytosis was considered resolved and on 26 Oct 2020 (Day 62), the thrombocytosis resolved. The chronic myeloid leukemia was ongoing at the time of last available report and considered to be life threatening by the investigator. In addition, the subject reported COVID-19 symptoms that began on 05 Oct 2020 (Day 41), for which a SARS-CoV-2 polymerase chain reaction test was done on 07 Oct 2020 (Day 43); the test result was negative. In the opinion of the investigator, there was no reasonable possibility that the chronic myeloid leukemia was related to the study intervention or clinical trial procedures, but rather it was related to a genetic change in stem cells. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	92 kg	28.4 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to food - shellfish	Food allergy	1952	Present
drug allergy Penicillin	Drug hypersensitivity	1958	Present
drug allergy sulfa	Drug hypersensitivity	1958	Present
Hepatitis B	Hepatitis B	1970	Past
Tobacco use disorder, continuous use	Tobacco abuse	1975	Present
Hypertension	Hypertension	1980	Present
Reflux esophagitis	Gastrooesophageal reflux disease	1989	Present
Fundoplication	Oesophagogastric fundoplasty	1989	Past
Asthma	Asthma	1990	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hepatitis C	Hepatitis C	1999	Past
COPD	Chronic obstructive pulmonary disease	2000	Present
Cardiac surgery	Cardiac operation	2006	Past
Coronary artery disease	Coronary artery disease	2006	Present
Iodine allergy	Iodine allergy	2006	Present
Enlarged prostate (benign)	Benign prostatic hyperplasia	25APR2011	Present
Hypercholesterolemia	Hypercholesterolaemia	25NOV2011	Present
Depression	Depression	2016	Present
Post-traumatic stress disorder	Post-traumatic stress disorder	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	14:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	atrial fibrillation	25OCT2020 (11)	11:30	26OCT2020 (12)		2	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: history of coronary artery disease	1	11	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
Withdrawn	VACCINATION	05NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1007 10071347, a 68-year-old white male with a pertinent medical history of food allergy (allergy to shellfish, since 1952), drug hypersensitivity (allergy to penicillin and sulfa, since 1958), tobacco abuse (smoking for 45 years [22.5 pack years], since 1975), hypertension (since 1980), asthma (in 1990), chronic obstructive pulmonary disease (COPD, since 2000), cardiac operation (cardiac stents in 2006), coronary artery disease and iodine allergy (both since 2006), hypercholesterolemia (since 25 Nov 2011), post-traumatic stress disorder (in 2016), and depression (since 2016), received Dose 1 on 15 Oct 2020. The subject was diagnosed with atrial fibrillation on 25 Oct 2020, 10 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the atrial fibrillation included tiotropium bromide (since an unknown date) for COPD, hydrochlorothiazide/lisinopril and metoprolol tartrate (both since unknown dates), both for hypertension, acetylsalicylic acid (since an unknown date) as a prophylaxis for coronary artery disease, trazodone (since an unknown date) for depression, atorvastatin (since Oct 2019) for hypercholesterolemia, and sildenafil (since Feb 2020) for erectile dysfunction. On 15 Oct 2020 (Day 1), the subject reported that his medical conditions were stable. On 25 Oct 2020 (Day 11), the subject experienced palpitations and atrial fibrillation requiring an emergency room visit. He denied dizziness, shortness of breath, chest pain, syncope, nausea, vomiting, diarrhea, or any previous episodes of palpitations or history of atrial fibrillation; he was feeling well with no recent illnesses or changes in his health. The subject was hospitalized and an electrocardiogram (ECG) showed atrial fibrillation. The subject was treated with diltiazem 125 mg/125 mL intravenous (IV) infusion at 2.5-15 mg/hour and heparin 25,000 units/250 mL IV infusion at 18 units/kg/hour. On 25 Oct 2020 (Day 11), troponin I was <0.015 ng/mL (normal range [NR]: 0-0.045 ng/mL); a chest x-ray was normal, and the SARS-CoV-2 test result was negative. On 26 Oct 2020 (Day 12), the laboratory test results showed thyroid stimulating hormone of 1.280 µIU/mL (NR: 0.358-3.74 µIU/mL) and troponin I was <0.015 ng/mL; an echocardiogram was also normal; an ECG result showed sinus rhythm with an incomplete right bundle branch block and inferior infarct. On the same day (Day 12), the atrial fibrillation resolved, and the treatment with heparin and diltiazem were discontinued after the subject achieved normal cardiac sinus rhythm. On 27 Oct 2020 (Day 13), the subject was discharged from the hospital. The subject was started on oral apixaban with a follow-up cardiology appointment scheduled on 19 Nov 2020 (Day 36). The subject was discontinued from the study intervention on 05 Nov 2020 (Day 22) since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of coronary artery disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	109.55 kg	38.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Thimerosal allergy	Drug hypersensitivity	1974	Present
High cholesterol	Blood cholesterol increased	2019	Present
Elevated PSA	Prostatic specific antigen increased	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	14:32
2	Placebo	24SEP2020 (22)	10:57

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Prostate cancer	Prostate cancer	30SEP2020 (28)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: Unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flucelvax influenza prophylaxis intramuscular vaccine 0.5 ml once	INFLUENZA VACCINE INACT SAG 3V	19OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081184, a 62-year-old white male with a pertinent medical history of increased prostatic specific antigen (PSA) (since 2019), received Dose 1 on 03 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 22). The subject was diagnosed with prostate cancer on 30 Sep 2020, 6 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the diagnosis of the prostate cancer included atorvastatin (since 2019) for hypercholesterolemia. The subject reported that he had a repeat elevated PSA (PSA value and normal range were not reported) on 01 Sep 2020 (Day -2). On 30 Sep 2020 (Day 28), a prostate biopsy was performed and the results obtained on 07 Oct 2020 (Day 35) revealed prostate cancer. A bone scan was planned on 26 Oct 2020 (Day 54) to determine staging. It was confirmed that the subject had no previous diagnosis of prostate cancer prior to the biopsy on 30 Sep 2020 (Day 28). The prostate cancer was considered medically significant by the investigator. The prostate cancer was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the prostate cancer was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	92.09 kg	30.4 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	1980	Present
Diabetes type II	Type 2 diabetes mellitus	2000	Present
High cholesterol	Blood cholesterol increased	2014	Present
Coronary artery disease	Coronary artery disease	2015	Present
Sebaceous cyst of scalp	Dermal cyst	SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	11:44
2	Placebo	05NOV2020 (23)	15:06

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cellulitis	CELLULITIS UPPER BACK	26OCT2020 (13)		02NOV2020 (20)		8	3
2	INFEC	Sepsis	SEPSIS	26OCT2020 (13)		02NOV2020 (20)		8	3
3	INFEC	Subcutaneous abscess	SCALP ABCESS	26OCT2020 (13)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (02NOV2020)	NOT RELATED/OTHER: SCALP ABCESS	1	13	Y
2	TC	Y	Resolved (02NOV2020)	NOT RELATED/OTHER: SCALP ABCESS	1	13	Y
3	TC/TCN	N	Yes	NOT RELATED/OTHER: HISTORY SCALP CYST	1	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081603, a 65-year-old black/African American male with a pertinent medical history of type 2 diabetes mellitus (since 2000) and dermal cyst (sebaceous cyst of scalp) (since Sep 2020), received Dose 1 on 14 Oct 2020 and Dose 2 on 05 Nov 2020 (Day 23). The subject developed cellulitis on the upper back and sepsis on 26 Oct 2020, 12 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the cellulitis on the upper back and sepsis included amlodipine and benazepril (both since 2014) for hypertension, atorvastatin (since 2014) for hypercholesterolemia, carvedilol and isosorbide (both since 2015) for hypertension, acetylsalicylic acid (since 2015) for cardiac prophylaxis, insulin detemir (since 2016) pioglitazone (from 12 Oct 2020 to 26 Oct 2020), and metformin (since 12 Oct 2020) for type 2 diabetes mellitus, sulfamethoxazole/trimethoprim (from Sep 2020 to 26 Oct 2020) for scalp cyst. On 05 Nov 2020 (Day 23), during Visit 2 the subject reported that he developed a scalp abscess (reported as a nonserious adverse event), cellulitis on the upper back, and sepsis on 26 Oct 2020 (Day 13), and presented to the emergency room. On the same day (Day 13), he was hospitalized for sepsis due to the abscess on the scalp that progressed to cellulitis on the upper back. The abscess was drained on 27 Oct 2020 (Day 14), and the subject was treated with intravenous (IV) ampicillin sodium/sulbactam sodium. On 31 Oct 2020 (Day 18), the laboratory results showed an elevated white blood cell (WBC) count of 10.8 × 109/L (normal range: 4.4-10.7 × 109/L). On 01 Nov 2020 (Day 19), the WBC count was further elevated at 11.5 × 109/L, and on 02 Nov 2020 (Day 20), the subject's WBC count returned to normal (8.8 × 109/L). While in the hospital, a computerized tomogram of the head performed on an unknown date showed no acute findings. On 02 Nov 2020 (Day 20), the cellulitis on the upper back and sepsis resolved. The subject was discharged from the hospital in stable condition on the same day (Day 20) and instructed to continue IV ampicillin sodium/sulbactam sodium at home for an additional 2 weeks. The diabetic medications were changed (stopped pioglitazone, metformin was increased from 850 mg twice a day [BID] to 1000 mg BID, added glipizide 5 mg daily and dapagliflozin propanediol monohydrate 10 mg daily) for improved glucose control, and stopped sulfamethoxazole/trimethoprim, which the subject was initially taking for the scalp cyst. The scalp abscess was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the cellulitis on the upper back and sepsis were related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to the scalp abscess. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	110.55 kg	41.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MTHFR GENE MUTATION	Methylenetetrahydrofolate reductase gene mutation	(b) (6) 1957	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	1958	Present
LACTOSE INTOLERANCE	Lactose intolerance	1970	Present
ASPIRIN INTOLERANCE	Drug intolerance	1986	Present
MORPHINE INTOLERANCE	Drug intolerance	1986	Present
HYSTERECTOMY	Hysterectomy	1986	Past
GLUTEN INTOLERANCE	Gluten sensitivity	2003	Present
ANXIETY	Anxiety	JUN2011	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	JUN2011	Present
HYPOTHYROIDISM	Hypothyroidism	JUN2011	Present
MILD ASTHMA	Asthma	2018	Present
OSTEOARTHRITIS (GENERALIZED)	Osteoarthritis	JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	13:44
2	Placebo	22SEP2020 (23)	16:22

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	REPRO	Breast mass	right breast lump	02SEP2020 (3)		ONGOING	
2	NEOPL	Intraductal proliferative breast lesion	Right Breast Ductal Carcinoma In Situ	02SEP2020 (3)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		1	N	N	Yes	NOT RELATED/OTHER: cancer	1	3	N
2		1	N	Y	Yes	NOT RELATED/OTHER: spontaneous onset	1	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1009 10091135, a 63-year-old white female with a pertinent medical history of methylenetetrahydrofolate reductase gene mutation (since (b) (6) 1957), hysterectomy (in 1986), and hypothyroidism (since Jun 2011), received Dose 1 on 31 Aug 2020 and Dose 2 on 22 Sep 2020 (Day 23). The subject was diagnosed with a right-sided intraductal proliferative breast lesion (ductal carcinoma in situ) on 02 Sep 2020, 2 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the right-sided intraductal proliferative breast lesion included Armour thyroid (since Jun 2011) for hypothyroidism, citalopram (since Jun 2011) for depression, estradiol/progesterone (since Jun 2011) for hormone replacement, salbutamol (since Sep 2012) for asthma, naproxen (since Jun 2019) for generalized osteoarthritis, celecoxib (since Jun 2019) for generalized osteoarthritis, and montelukast (since May 2020) for environmental allergies. On 02 Sep 2020 (Day 3), the subject noted a lump in her right breast (reported as nonserious adverse event). On 21 Sep 2020 (Day 22), the subject had her lump biopsied and the results obtained on 24 Sep 2020 (Day 25) revealed ductal carcinoma in situ of the right breast. The right breast ductal carcinoma in situ was considered an important medical event by the investigator. A lumpectomy was planned; however, the surgery was not yet scheduled. The right-sided intraductal proliferative breast lesion was ongoing at the time of last available report. In the opinion of the investigator, there was no reasonable possibility that the right-sided intraductal proliferative breast lesion was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	75.82 kg	28.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Postmenopausal	Postmenopause	1994	Present
Dilation and Curettage	Uterine dilation and curettage	1998	Past
Uterine Bleeding	Uterine haemorrhage	1998	Past
Facelift	Face lift	2001	Past
Insomnia	Insomnia	2015	Present
Overactive Bladder	Hypertonic bladder	2018	Present
Shingles	Herpes zoster	01APR2020	Past
Post Herpetic Neuralgia	Post herpetic neuralgia	10APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	16:47
2	Placebo	31AUG2020 (19)	14:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis perforated	Perforated Appendicitis	12SEP2020 (31)	08:00	15SEP2020 (34)		4	3
2	INFEC	Peritonitis	Feculant Peritonitis	14SEP2020 (33)		18SEP2020 (37)		5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: Appendicitis	2	13	Y
2	TC/TCN	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: Perforated Appendicitis	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1011 10111029, a 77-year-old white female with no pertinent medical history, received Dose 1 on 13 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 19). The subject was diagnosed with perforated appendicitis on 12 Sep 2020, 12 days after receiving Dose 2 and peritonitis on 14 Sep 2020, 14 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the perforated appendicitis and peritonitis included mirabegron (since 2019) for overactive bladder and pregabalin (since 10 Apr 2020) for post herpetic neuralgia. On 12 Sep 2020 (Day 31), the subject experienced abdominal pain and fever (body temperature was not reported) and was diagnosed with perforated appendicitis. On 14 Sep 2020 (Day 33), the subject presented to the emergency room with right lower quadrant pain and was hospitalized. The subject underwent a laparoscopic appendectomy on the same day and was found to have feculent peritonitis. A surgical drain was placed and she was treated with intravenous antibiotics (unspecified). On 14 Sep 2020 (Day 33), a SARS-CoV-2 nasal swab test was negative. On 15 Sep 2020 (Day 34), the perforated appendicitis was considered resolved. On 17 Sep 2020 (Day 36), the subject had diarrhea and a clostridium test was negative. The subject was discharged from the hospital on 17 Sep 2020 (Day 36) with the following medications: metronidazole 500 mg 3 times a day and ceftriaxone sodium for 9 days following discharge, along with acetaminophen 650 mg 4 times a day, cefuroxime 500 mg twice a day, lactobacillus acidophilus 1 capsule once daily, tramadol 50 mg as needed (PRN), and zolpidem 5 mg at bedtime PRN. On 18 Sep 2020 (Day 37), the peritonitis resolved. In the opinion of the investigator, there was no reasonable possibility that the perforated appendicitis and peritonitis were related to the study intervention, concomitant medications, or clinical trial procedures, but the peritonitis was related to the perforated appendicitis. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	57.6 kg	23.4 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT RENAL STENT INSERTION	Renal surgery	FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	10:40
2	BNT162b2	26AUG2020 (22)	15:05

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Vascular stent occlusion	OBSTRUCTED RENAL STENT (ARTERY)	01SEP2020 (28)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: RENAL STENT	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1013 10131084, a 49-year-old white female with a pertinent medical history of right renal aneurysm and right renal stent insertion (both in Feb 2020), received Dose 1 on 05 Aug 2020 and Dose 2 on 26 Aug 2020 (Day 22). The subject was diagnosed with vascular stent occlusion (obstructed renal artery stent) on 01 Sep 2020, 6 days after receiving Dose 2. On 31 Aug 2020 (Day 27), the subject presented to the emergency room (ER) with vomiting and abdominal pain. A computerized tomogram was performed which revealed a 'clogged' stent. The subject was given fluids (unspecified) and observed in the ER, and later, was sent home. On 01 Sep 2020 (Day 28), the subject was diagnosed with an obstructed renal artery stent. On 03 Sep 2020 (Day 30), the subject developed fever (body temperature was not reported) and went to the ER again and the subject had symptoms consistent with urinary tract infection. Subsequently, she was hospitalized and was given antibiotics (unspecified). The subject was discharged home on 05 Sep 2020 (Day 32). The vascular stent occlusion was ongoing at the time of last available report. In the opinion of the investigator, there was no reasonable possibility that the vascular stent occlusion was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the renal stent. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.9 cm	72.2 kg	23.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
LEFT KNEE OSTEOARTHRITIS	Osteoarthritis	1990	Past
RIGHT KNEE OSTEOARTHRITIS	Osteoarthritis	1990	Past
LEFT KNEE REPLACEMENT	Knee arthroplasty	2000	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2005	Present
HIATAL HERNIA	Hiatus hernia	2005	Present
RIGHT KNEE REPLACEMENT	Knee arthroplasty	2009	Past
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2014	Present
HYPERTENSION	Hypertension	2015	Present
INGUINAL HERNIA	Inguinal hernia	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SMALL BOWEL PERFORATION	Small intestinal perforation	2016	Past
SMALL BOWEL RESECTION	Small intestinal resection	2016	Past
INGUINAL HERNIA REPAIR	Inguinal hernia repair	2017	Past
CONSTIPATION	Constipation	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	12:35
2	BNT162b2	07OCT2020 (56)	15:10

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	GASTR	Abdominal adhesions	abdominal adhesions	29AUG2020 (17)		30AUG2020 (18)		2	3	TC
2	RENAL	Acute kidney injury	acute renal failure	29AUG2020 (17)		16SEP2020 (35)		19	3	N
3	RESP	Acute respiratory failure	acute hypoxic respiratory failure	30AUG2020 (18)		11SEP2020 (30)		13	3	N
4	BLOOD	Anaemia	anemia	30AUG2020 (18)		16SEP2020 (35)		18	3	N
5	CARD	Cardiac failure congestive	CONGESTIVE HEART FAILURE	30AUG2020 (18)		16SEP2020 (35)		18	3	N
6	METAB	Hypokalaemia	hypokalemia	30AUG2020 (18)		16SEP2020 (35)		18	3	N

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
7	METAB	Hyponatraemia	HYPONATREMIA	29AUG2020 (17)		07SEP2020 (26)		10	2	TC
8	CARD	Left ventricular hypertrophy	MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY	16SEP2020 (35)		ONGOING			1	N
9	BLOOD	Leukopenia	LEUKOPENIA	29AUG2020 (17)		07SEP2020 (26)		10	2	TCN
10	PSYCH	Mental status changes	altered mental status	29AUG2020 (17)		16SEP2020 (35)		19	3	N
11	RESP	Pneumonia aspiration	ASPIRATION PNEUMONIA	30AUG2020 (18)		16SEP2020 (35)		18	2	TCN
12	INFEC	Sepsis	sepsis	29AUG2020 (17)		16SEP2020 (35)		19	3	N
13	GASTR	Small intestinal obstruction	SMALL BOWEL OBSTRUCTION	29AUG2020 (17)		30AUG2020 (18)		2	2	TCN

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: PREVIOUS SURGERY	1	17	Y
2	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	17	N
3	Y	Resolved (11SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	Y
4	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
5	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
6	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
7	N	Resolved (07SEP2020)	NOT RELATED/OTHER: BOWEL OBSTRUCTION	1	17	N
8	N	Yes	NOT RELATED/OTHER: UNKNOWN	1	35	N
9	N	Resolved (07SEP2020)	NOT RELATED/OTHER: BOWEL OBSTRUCTION	1	17	N
10	N	Resolved (16SEP2020)	NOT RELATED/CONCOMITANT NON-DRUG TREATMENT	1	17	N
11	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: ADHESIONS	1	18	Y

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
12	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	17	N
13	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: ADHESIONS	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1013 10131176, a 75-year-old white male with a pertinent medical history of hiatus hernia (since 2005); inguinal hernia, small intestinal perforation, and small intestinal resection (all in 2016); inguinal hernia repair (in 2017); and constipation (since 2018), received Dose 1 on 13 Aug 2020 and Dose 2 on 07 Oct 2020 (Day 56). The subject was diagnosed with abdominal adhesions and small intestinal obstruction on 29 Aug 2020, 16 days after receiving Dose 1; acute respiratory failure and pneumonia aspiration on 30 Aug 2020, 17 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the abdominal adhesions, small intestinal obstruction, acute respiratory failure, and pneumonia aspiration included simvastatin (since 2014) for hypercholesterolemia, omeprazole (since 2016) for gastroesophageal reflux disease, amlodipine (since 2016) for hypertension, and linaclotide (since Jul 2020) for constipation. The subject presented to the emergency room with back pain, chronic nausea, and epigastric pain and was hospitalized on 29 Aug 2020 (Day 17). On admission, it was noted that the subject was unable to urinate or tolerate an oral diet because of nausea and vomiting; therefore, he was treated with normal saline and intravenous fluids. An abdominal x-ray showed a large hiatal hernia, patchy opacity area in the perihilar area on the left side, nonspecific bowel gas pattern with some distention of small bowel loops in mid abdomen consistent with a diagnosis of abdominal adhesions and small intestinal obstruction. His laboratory results showed blood potassium of 3.1 mmol/L, creatinine of 2.79 mg/dL, and sodium of 126 mmol/L (normal ranges not reported). The subject was diagnosed with sepsis, acute kidney injury, leukopenia, mental status changes, and hyponatremia (reported as nonserious adverse events). The subject underwent surgery for the small bowel obstruction with pneumatosis and portal venous air with sepsis. The subject was intubated postoperation and noted to have lower creatinine levels and drained urine into Foley. On 30 Aug 2020 (Day 18), the abdominal adhesions and small intestinal obstruction were considered resolved. While in the hospital, the subject was also diagnosed with acute respiratory failure and pneumonia aspiration on 30 Aug 2020 (Day 18) and the laboratory results showed a white blood cell (WBC) count of 1.9 × 103/mm3; a chest x-ray revealed moderate to severe airspace disease in medial aspect of left lung. On the same day (Day 18), the subject was diagnosed with anemia, congestive cardiac failure, and hypokalemia (reported as nonserious adverse events). On 31 Aug 2020 (Day 19), a chest x-ray showed unchanged bilateral infiltrates. The subject was treated with piperacillin sodium/tazobactam sodium and was extubated on 03 Sep 2020 (Day 22). On 05 Sep 2020 (Day 24), a chest x-ray showed cardiomegaly with mild interstitial pulmonary edema. On 06 Sep 2020 (Day 25), an echocardiogram showed ejection fraction of 55%-60% with mild concentric left ventricular hypertrophy and mild diastolic dysfunction. Blood and urine cultures showed no growth. Additionally, the subject received the following medications during hospitalization: enoxaparin sodium, potassium chloride as needed (PRN), cefoxitin (×2), dicycloverine hydrochloride 4 times a day (QID) for 7 days, tramadol PRN, paracetamol PRN, salbutamol QID and PRN, furosemide twice a day (BID) for 3 days then daily for 3 days, hydralazine PRN, simethicone BID, norepinephrine, pantoprazole sodium sesquihydrate, and zolpidem PRN. On 07 Sep 2020 (Day 26), the subject's sodium level was 137 mmol/L and WBC count was 9.4 × 103/mm3 and hyponatremia and leukopenia were considered resolved. On 08 Sep 2020 (Day 27), the subject was discharged from the hospital. On 11 Sep 2020 (Day 30), the acute respiratory failure resolved. On 16 Sep 2020 (Day 35), the pneumonia aspiration, acute kidney injury, anemia, cardiac failure congestive, sepsis, mental status changes, and hypokalemia resolved. In the opinion of the investigator, there was no reasonable possibility that the abdominal adhesions, small intestinal obstruction, pneumonia aspiration, and acute respiratory failure were related to the study intervention, concomitant medications, or clinical trial procedures, but were rather likely related to subject's previous surgery. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.8 cm	77.1 kg	23.1 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	1951	Present
VITILIGO	Vitiligo	1978	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2005	Present
HYPOTHYROIDISM	Hypothyroidism	2016	Present
STENT CARDIAC INSERTION	Coronary arterial stent insertion	14FEB2016	Past
MYOCARDIAL INFARCTION	Myocardial infarction	14FEB2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	13:05
2	BNT162b2	30SEP2020 (21)	14:36

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	FATIGUE	11SEP2020 (2)	07:00	11SEP2020 (2)	19:00	1	1
2	GENRL	Injection site pain	INJECTION SITE PAIN TO LEFT ARM	10SEP2020 (1)	07:00	11SEP2020 (2)	08:00	2	1
3	CARD	Myocardial infarction	MYOCARDIAL INFARCTION	08NOV2020 (60)		10NOV2020 (62)		3	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (11SEP2020)	Study Treatment	1	2	N
2	N	N	Resolved (11SEP2020)	Study Treatment	1	1	N
3	N	Y	Resolved (10NOV2020)	NOT RELATED/OTHER: MYOCARDIAL INFARCTION	2	40	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1013 10131517, a 70-year-old white male with a pertinent medical history of coronary artery disease (since 2005); and myocardial infarction, balloon angioplasty, and coronary arterial stent insertion (all on 14 Feb 2016), received Dose 1 on 10 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 21). The subject was diagnosed with myocardial infarction on 08 Nov 2020, 39 days after receiving Dose 2. On 08 Nov 2020 (Day 60), the subject was hospitalized because of the myocardial infarction. No relevant tests and treatment were reported. On 10 Nov 2020 (Day 62), the myocardial infarction was considered resolved and the subject was discharged from the hospital on the same day. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.01 cm	103.64 kg	37.1 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	JUN1985	Present
depression	Depression	JUN1987	Present
polycystic ovary syndrome	Polycystic ovaries	JUN1987	Present
hypothyroidism	Hypothyroidism	JUN1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	09:48
2	Placebo	02OCT2020 (22)	10:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	atrial fibrillation	09OCT2020 (29)	13:00	12OCT2020 (32)	10:00	4	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (12OCT2020)	NOT RELATED/OTHER: cardiac dysrhythmia	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1016 10161277, a 47-year-old white female with a pertinent medical history of hypothyroidism (since Jun 1995) and mild mitral regurgitation (since 2012), received Dose 1 on 11 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 22). The subject was diagnosed with atrial fibrillation on 09 Oct 2020, 7 days after receiving Dose 2.

On 09 Oct 2020 (Day 29), the subject experienced shortness of breath, and reported to have chest pain along with gastroesophageal reflux disease-like symptoms. On 11 Oct 2020 (Day 31), the subject presented to the emergency room with a sudden onset of tachycardia, weakness, and heart palpitations, and was hospitalized overnight. An electrocardiogram showed atrial fibrillation with rapid ventricular response and nonspecific ST abnormality, with rate of 142, QRS interval of 20, QRSD interval of 80, QT interval of 300, and QTc interval of 461 (units not reported). Laboratory results included troponin <0.001 ng/mL (normal range [NR]: 0.001-0.013 ng/mL), brain natriuretic peptide of 41.5 pg/mL (NR: 10-100 pg/mL), and fibrin D dimer of 0.44 FEU µg/mL (normal range: ≤0.49 FEU µg/mL). Treatment with diltiazem (drip) was initiated and within 7 hours, the subject's heart rate returned to normal sinus rhythm. On 12 Oct 2020 (Day 32), an echocardiogram showed normal heart size and wall thickness of the left ventricle, ejection fraction of 60%-65%, and normal atrial contribution to ventricular filling. Additional laboratory results included blood cholesterol of 161 mg/dL (NR: 7-200 mg/dL), blood triglycerides of 95 mg/dL (NR: 7-150 mg/dL), high density lipoprotein of 33 mg/dL (NR not reported), and low density lipoprotein of 109 mg/dL (NR: ≤100 mg/dL). On 12 Oct 2020 (Day 32), the atrial fibrillation resolved and the subject was discharged with oral diltiazem at 20 mg extended release once daily. The subject had a follow-up appointment with a cardiologist on 21 Oct 2020 (Day 41).

In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2002	17	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.58 cm	60.18 kg	22.4 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	MAY2008	Present
asthma	Asthma	30JUN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	10:00
2	BNT162b2	07OCT2020 (20)	09:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	chills	18SEP2020 (1)	20:30	20SEP2020 (3)	11:30	3	2
2	INJ&P	Concussion	concussion	31OCT2020 (44)		ONGOING			2
3	INJ&P	Facial bones fracture	facial fractures	31OCT2020 (44)		ONGOING			3
4	GENRL	Pyrexia	fever	18SEP2020 (1)	20:30	20SEP2020 (3)	11:30	3	1
5	INJ&P	Road traffic accident	motor vehicle accident	31OCT2020 (44)		31OCT2020 (44)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (20SEP2020)	Study Treatment	1	1	N
2	N	N	Yes	NOT RELATED/OTHER: motor vehicle accident	2	25	N
3	TC	Y	Yes	NOT RELATED/OTHER: motor vehicle accident	2	25	Y
4	TC	N	Resolved (20SEP2020)	Study Treatment	1	1	N
5	N	N	Resolved (31OCT2020)	NOT RELATED/OTHER: motor vehicle accident	2	25	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161289, a 17-year-old multiracial male with no pertinent medical history, received Dose 1 on 18 Sep 2020 and Dose 2 on 07 Oct 2020 (Day 20). The subject was diagnosed with facial bone fractures on 31 Oct 2020, 24 days after receiving Dose 2. On 31 Oct 2020 (Day 44), the subject had a motor vehicle accident, and was taken to a hospital for blunt trauma injuries to the face. A computerized tomogram of the head showed multiple facial bone fractures. On the same day, the subject was hospitalized for observation and pain control for multiple facial bone fractures and a concussion. The subject was discharged on 01 Nov 2020 (Day 45) in a stable condition. The subject was evaluated by a plastic surgeon on 09 Nov 2020 (Day 53). The surgeon will re-evaluate in 3 weeks if the subject requires surgical intervention during the follow-up. The facial bone fractures and concussion were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the facial bone fractures was related to the study intervention or clinical trial procedures, but rather were related to the motor vehicle accident. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	70.73 kg	28.5 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Iodine Allergy	Iodine allergy	1970	Present
Codeine Allergy	Drug hypersensitivity	1988	Present
Facial injuries	Face injury	1988	Past
Jaw surgery	Jaw operation	1988	Past
Nasal surgery	Nasal operation	1988	Past
Generalized Osteoarthritis	Osteoarthritis	1988	Present
Seasonal Allergic Rhinitis	Seasonal allergy	1988	Present
Vertigo	Vertigo	1988	Present
Asthma	Asthma	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1990	Past
Postmenopausal	Postmenopause	1990	Present
Uterine fibroids	Uterine leiomyoma	1990	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1994	Past
Hypothyroidism	Hypothyroidism	1994	Present
Hypertension	Hypertension	1999	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Barrett's esophagus	Barrett's oesophagus	2004	Present
Nissen fundoplication - Surgery	Oesophagogastric fundoplasty	2004	Past
Acquired deformities of second toe of right foot	Foot deformity	2007	Present
Partial Left knee replacement	Knee arthroplasty	14MAY2007	Past
Sleep apnea	Sleep apnoea syndrome	2008	Present
Osteoporosis	Osteoporosis	JUN2008	Present
Vitamin D deficiency	Vitamin D deficiency	2009	Present
Lumbar radiculopathy	Lumbar radiculopathy	2010	Present
Fatigue	Fatigue	2012	Present
Prediabetes	Glucose tolerance impaired	2012	Past
Intermittent lower extremities edema	Oedema peripheral	2016	Present
Telangiectasias on lower extremities	Telangiectasia	2016	Present
Vitamin B12 deficiency	Vitamin B12 deficiency	2016	Present
Right trigger finger release	Tendon sheath incision	09DEC2016	Past
Right stenosing tenosynovitis	Tenosynovitis stenosans	09DEC2016	Past
Acute bronchitis	Bronchitis	15DEC2016	Past
Foot fracture	Foot fracture	2017	Past
Surgery - Foot fracture repair	Fracture treatment	2017	Past
Colonic polyps	Large intestine polyp	28APR2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Neck strain	Muscle strain	14JUN2017	Past
Right Jaw pain	Pain in jaw	14JUN2017	Past
Penicillin Allergy	Drug hypersensitivity	2018	Present
Pre-syncope	Presyncope	2018	Past
Acute rhinitis	Rhinitis	11DEC2018	Past
Left hand inflammatory arthropathy	Arthropathy	MAR2019	Past
Acute bronchitis	Bronchitis	19MAR2019	Past
Concussion	Concussion	28MAY2019	Past
Frontal Scalp contusion	Contusion	28MAY2019	Past
Closed nasal bone fracture	Facial bones fracture	28MAY2019	Past
Periorbital hematoma	Periorbital haematoma	28MAY2019	Past
Urinary tract infection	Urinary tract infection	14AUG2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	11:09
2	BNT162b2	01SEP2020 (21)	12:18

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INV	Cardiac stress test abnormal	CARDIAC STRESS TEST ABNORMAL, HOSPITALIZED	08SEP2020 (28)		ONGOING			3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Believed related to chronic conditions including hypertension and hyperlipidemia	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1018 10181132, a 71-year-old black/African American female with pertinent medical history of asthma and postmenopause (both since 1990), hypothyroidism (since 1994), hypertension (since 1999), hyperlipidemia (since 2000), sleep apnea syndrome (since 2008), and peripheral edema and telangiectasia (both since 2016), received Dose 1 on 12 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 21). The subject reported an abnormal cardiac stress test on 08 Sep 2020, 7 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the abnormal cardiac stress test included meclizine (since 1988) for vertigo, salbutamol (since 1990) for asthma, estradiol (since 1996) for postmenopause, losartan potassium/hydrochlorothiazide (since 1999) for hypertension, potassium (since 1999) as a supplement, levothyroxine (since 1999) for hypothyroidism, lansoprazole (since 1999) for gastroesophageal reflux disease, ezetimibe (since 2000) for hypercholesterolemia, celecoxib (since 2000) for osteoarthritis, azelastine (since 2005) for seasonal allergic rhinitis, and acetylsalicylic acid (since 2006) as a supplement. On 08 Sep 2020 (Day 28), the subject had a routine cardiac stress test, which was reported to be abnormal. It was reported that the subject was asymptomatic. She was hospitalized and her primary care physician informed the study site that the subject might need cardiac bypass surgery. The abnormal cardiac stress test was ongoing and the subject remained hospitalized at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the abnormal cardiac stress test was related to the study intervention, concomitant medications, or clinical trial procedures. The investigator believed that the abnormal cardiac stress test was related to sequelae of chronic conditions, including hypertension and hyperlipidemia; as well as age. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	80	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	86.23 kg	34.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Drug allergy - macrodantin	Drug hypersensitivity	1950	Present
Drug allergy - penicillin	Drug hypersensitivity	1950	Present
Endometriosis	Endometriosis	1960	Past
Tonsillectomy	Tonsillectomy	1961	Past
Tonsillitis	Tonsillitis	1961	Past
Allergic rhinitis	Rhinitis allergic	1972	Present
Familial tremors	Familial tremor	1974	Present
Recurrent joint pain, neck, shoulders, ankles, elbows, hips, knees, wrists	Arthralgia	1980	Present
Arthroscopy left knee	Arthroscopy	1980	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anal fistula	Anal fistula	1981	Past
Anal fistulectomy	Anal fistula repair	1981	Past
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	1984	Present
Myopia - bilateral	Myopia	1984	Present
Presbyopia	Presbyopia	1984	Present
Obesity	Obesity	1985	Present
CPAP	Continuous positive airway pressure	1989	Present
Sleep apnea	Sleep apnoea syndrome	1989	Present
duodenal ulcer	Duodenal ulcer	1990	Past
heartburn	Dyspepsia	1990	Present
esophageal ulcer	Oesophageal ulcer	1990	Past
Tension headaches	Tension headache	1993	Present
Cholecystectomy	Cholecystectomy	1994	Past
cholelithiasis	Cholelithiasis	1994	Past
Hypercholesterolemia	Hypercholesterolaemia	1994	Present
Carpal tunnel release surgery, bilateral	Carpal tunnel decompression	1996	Past
Carpal tunnel syndrome, bilateral	Carpal tunnel syndrome	1996	Past
Osteoarthritis, bilateral hands and knees	Osteoarthritis	1997	Present
Tennis elbow	Epicondylitis	1998	Past
Gout	Gout	1998	Present
Trigger release surgery, left fourth finger	Tendon sheath incision	1999	Past
Left fourth trigger finger	Trigger finger	1999	Past
Diabetic neuropathy bilateral hands	Diabetic neuropathy	2000	Present
Diabetic neuropathy, bilateral lower extremities	Diabetic neuropathy	2000	Present
Anxiety	Anxiety	2001	Present
Depression	Depression	2001	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Rosacea	Rosacea	26NOV2001	Present
Psoriasis	Psoriasis	2002	Present
Diabetes mellitus type 2	Type 2 diabetes mellitus	2002	Present
Urinary incontinence	Urinary incontinence	2002	Present
Fracture L. 5th toe	Foot fracture	2003	Past
Recurrent back pain - lumbar	Back pain	2004	Present
Heart murmur	Cardiac murmur	2004	Present
Hypertension	Hypertension	2004	Present
Hypothyroidism	Hypothyroidism	2004	Present
mitral valve regurgitation	Mitral valve incompetence	2005	Present
Uterine lesion - benign	Uterine disorder	2005	Past
Excision, uterine lesion	Uterine operation	2006	Past
Tendonitis, left wrist	Tendonitis	JAN2006	Past
Left wrist tendonitis repair	Tenoplasty	JAN2006	Past
Left knee arthroplasty	Knee arthroplasty	2007	Past
cyst, right ankle, benign	Arthropathy	2009	Past
Pneumonia	Pneumonia	MAR2009	Past
Fracture, right foot	Foot fracture	2010	Past
External hemorrhoids	Haemorrhoids	2010	Present
chronic constipation	Constipation	APR2010	Present
Cyst excision, right ankle	Ankle operation	JUL2010	Past
Fracture, right shoulder	Upper limb fracture	JUL2010	Past
Stress fracture, right ankle	Stress fracture	AUG2010	Past
Iron deficiency anemia	Iron deficiency anaemia	SEP2010	Past
bronchitis	Bronchitis	12NOV2010	Past
Dry mouth	Dry mouth	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteopenia	Osteopenia	2012	Present
Shoulder implant, right - insertion	Shoulder arthroplasty	2013	Past
Shoulder implant infection, right	Device related infection	2014	Past
Insomnia	Insomnia	2014	Present
Fibromyalgia	Fibromyalgia	APR2014	Present
Shoulder implant removal, right	Shoulder arthroplasty	APR2014	Past
Cataracts - bilateral	Cataract	2016	Past
Osteoporosis	Osteoporosis	2016	Present
atrial fibrillation	Atrial fibrillation	01NOV2017	Present
implantable loop recorder	Implantable cardiac monitor insertion	01NOV2017	Present
Chest Pain	Chest pain	2018	Present
Left rotator cuff tear	Rotator cuff syndrome	JAN2018	Past
Left rotator cuff repair surgery	Rotator cuff repair	01MAR2018	Past
Bilateral leg cramps	Muscle spasms	APR2018	Present
Chronic kidney disease stage III	Chronic kidney disease	25APR2018	Present
edema- bilateral lower extremities	Oedema peripheral	25APR2018	Present
nasal polyps	Nasal polyps	MAY2018	Present
Peripheral Vascular Disease	Peripheral vascular disorder	MAY2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	10:15
2	BNT162b2	01SEP2020 (22)	08:18

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Diarrhoea	Diarrhea	17AUG2020 (7)	00:00	27AUG2020 (17)	00:00	11	2
2	GASTR	Diarrhoea	Diarrhea	27AUG2020 (17)		29AUG2020 (19)		3	4
3	PSYCH	Mental status changes	Mental State Status Change	02OCT2020 (53)		02OCT2020 (53)		1	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (27AUG2020)	NOT RELATED/OTHER: Pre-Existing conditions	1	7	N
2	N	Y	Resolved (29AUG2020)	NOT RELATED/OTHER: Unknown	1	17	Y
3	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: unknown	2	32	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1019 10191010, an 80-year-old white female with a pertinent medical history of esophageal ulcer and duodenal ulcer (both in 1990), dyspepsia (since 1990), cholelithiasis and cholecystectomy (both in 1994), hemorrhoids (since 2010), and constipation (since Apr 2010), received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject had diarrhea on 27 Aug 2020, 16 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the diarrhea included montelukast (since 1998) and guaifenesin (since 2010) for allergic rhinitis; allopurinol (since 1998) for gout; sitagliptin (since 2001), glimepiride (since 2012), and dulaglutide (since 08 Mar 2020) for diabetes; tiotropium (since 2004), fluticasone propionate/salmeterol xinafoate (since 2012) and salbutamol (nebulizer) (since 2012) for chronic obstructive pulmonary disease; propranolol (since 2004), furosemide (since 2006), and losartan (since 23 Jun 2020) for hypertension; tolterodine tartrate (since 2004) for urinary incontinence; omeprazole (since 2007) and ranitidine (since 2019) for gastroesophageal reflux disease; gabapentin (since 2010) for diabetic neuropathy; levothyroxine sodium (since 2010) for hypothyroidism; acetaminophen (since 2010) and tramadol (since Apr 2014) for back pain; duloxetine (since 2011) and oxitriptan (since 2019) for depression; pilocarpine (since 2012) for dry mouth; calcium/vitamin D NOS (since 2012) for osteopenia; macrogol (since 2012) for constipation; vitamin D3 (since 2012) for osteopenia; chondroitin sulfate/glucosamine hydrochloride/methylsulfonylmethane (since 2012), ubidecarenone and potassium chloride (both since 2018), and folic acid (since 2019) as a supplement; eszopiclone (since 2014) for insomnia; fish oil (omega 3) and atorvastatin (both since 2015) for hypercholesterolemia; apixaban (since 01 Nov 2017) for atrial fibrillation; and acetylsalicylic acid (since 2018) as cardiac prophylaxis. On 17 Aug 2020 (Day 7), the subject had diarrhea (reported as a nonserious adverse event) but was not treated because of her normal vital signs. On 27 Aug 2020 (Day 17), diarrhea persisted, and the subject presented to the emergency room with symptoms of confusion, left side abdominal pain, and debility. The subject was hospitalized and underwent a computerized tomogram (CT), which showed bronchiolitis of bilateral lung bases with several nodules. A CT of the head, abdomen, and pelvis were normal with no acute abnormalities. The subject's electrocardiogram and vital signs were normal, but the blood glucose was elevated at 107 mg/dL (normal range: 70–99 mg/dL). The diarrhea along with symptoms of confusion, left side abdominal pain, and debility resolved on 29 Aug 2020 (Day 19) and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the diarrhea was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	87.27 kg	25.3 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gastric reflux	Gastrooesophageal reflux disease	1975	Present
Presbyopia	Presbyopia	1997	Present
Prostate Cancer	Prostate cancer	2004	Past
Radical prostatectomy	Radical prostatectomy	2004	Past
vasectomy	Vasectomy	2004	Past
Coronary stent placement	Coronary arterial stent insertion	2008	Past
Coronary artery disease	Coronary artery disease	2008	Present
Hypercholesterolemia	Hypercholesterolaemia	2008	Present
Implantable Cardioverter Defibrillator		2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cardiac arrest	Cardiac arrest	2015	Past
Coronary stent placement	Coronary arterial stent insertion	2015	Past
Coronary Artery Occlusion	Coronary artery occlusion	2015	Past
cholecystectomy	Cholecystectomy	2017	Past
Cholelithiasis	Cholelithiasis	2017	Past
Bladder Cancer	Bladder cancer	2019	Past
Cystoscopy	Cystoscopy	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	08:37
2	BNT162b2	04SEP2020 (22)	06:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Asthenia	Weakness	27OCT2020 (75)		ONGOING			2
2	SURG	Cardioversion	Defibrillator Discharge	15OCT2020 (63)		15OCT2020 (63)		1	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Yes	NOT RELATED/OTHER: Medical History of Heart Issues	2	54	Y
2	N	N	Resolved (15OCT2020)	NOT RELATED/OTHER: Implanted Defibrillator	2	42	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1019 10191037, a 72-year-old white male with a pertinent medical history of prostate cancer and radical prostatectomy (both in 2004), coronary arterial stent insertion (in 2008 and 2015), coronary artery disease and hypercholesterolemia (both since 2008), coronary artery occlusion and cardiac arrest (both in 2015), implantable cardioverter defibrillator (since 2015), and bladder cancer (in 2019), received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). The subject experienced asthenia on 27 Oct 2020, 53 days after receiving Dose 2. On 27 Oct 2020 (Day 75), the subject was hospitalized because of weakness. The subject did not report chest pain or fever, and his SARS-CoV-2 test was negative. A chest x-ray showed a stable exam with no active disease and clear lungs. The subject's hemoglobin was mildly increased (value not provided), which was probably due to volume depletion. An echocardiogram was planned for the subject, to evaluate the need for cardiac catheterization. The subject was discharged from the hospital on 29 Oct 2020 (Day 77) and the asthenia was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the asthenia was related to the study intervention or clinical trial procedures, but rather it was related to the subject's medical history of heart disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.82 cm	116.18 kg	39.7 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1960	Present
Leg Cramps	Muscle spasms	1972	Present
asthma	Asthma	1985	Present
Allergic Rhinitis	Rhinitis allergic	1986	Present
Hemorrhoids	Haemorrhoids	1990	Present
Gastric Reflux	Gastrooesophageal reflux disease	2000	Present
Hypercholesterolemia	Hypercholesterolaemia	2002	Present
Recurrent Back pain	Back pain	2010	Present
Osteoarthritis- knees	Osteoarthritis	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2016	Present
Atrial Fibrillation	Atrial fibrillation	30OCT2019	Present
sleep apnea	Sleep apnoea syndrome	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	14:40
2	Placebo	22SEP2020 (22)	07:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Hepatic cancer metastatic	poorly differentiated carcinoma metastatic to liver, unknown primary	27OCT2020 (57)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Unknown	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1019 10191146, a 67-year-old white male with a pertinent medical history of asthma (since 1985), gastroesophageal reflux disease (since 2000), hypercholesterolemia (since 2002), hypertension (since 2016), and sleep apnea syndrome (since Nov 2019), received Dose 1 on 01 Sep 2020 and Dose 2 on 22 Sep 2020 (Day 22). The subject was diagnosed with metastatic hepatic cancer (poorly differentiated carcinoma metastatic to liver, unknown primary) on 27 Oct 2020, 35 days after receiving Dose 2. On 16 Oct 2020 (Day 46), a liver biopsy was performed which revealed carcinoma. On 29 Oct 2020 (Day 59), the subject underwent a positron emission tomogram scan, which showed no other cancer beside liver and the subject was scheduled for an oncology consultation on 16 Nov 2020 (Day 77) for further evaluation. It was reported that there were no predisposing factors. The metastatic hepatic cancer was considered to be an important medical event by the investigator and it was ongoing at the time of the last available report. Follow-up on 19 Nov 2020 (Day 80), revealed that the primary source of the malignancy was biliary carcinoma with metastases to the liver. In the opinion of the investigator, there was no reasonable possibility that the metastatic hepatic cancer was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	53.5 kg	21.2 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1988	Present
Osteoarthritis - knees	Osteoarthritis	1995	Present
Allergic rhinitis	Rhinitis allergic	1995	Present
Hemorrhoids	Haemorrhoids	1998	Present
Anxiety	Anxiety	2001	Present
Cyst - bilateral breasts	Breast cyst	2001	Past
Cystectomy - bilateral breasts	Breast cyst excision	2001	Past
Insomnia	Insomnia	2005	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2006	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Recurrent lumbar pain	Back pain	2010	Present
Recurrent abdominal pain	Abdominal pain	2012	Present
Chronic constipation	Constipation	2012	Past
Asthma	Asthma	2013	Present
Osteoporosis	Osteoporosis	2013	Present
Septal deviation - nasal	Nasal septum deviation	AUG2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	13:40
2	Placebo	15OCT2020 (22)	11:09

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Road traffic accident	Motor Vehicle Collision	05NOV2020 (43)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	N	Y	Yes	NOT RELATED/OTHER: Vehicle Collision	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1019 10191229, a 63-year-old black/African American female with a pertinent medical history of anxiety (since 2001) and insomnia (since 2005), received Dose 1 on 24 Sep 2020 and Dose 2 on 15 Oct 2020 (Day 22). The subject was involved in a road traffic accident on 05 Nov 2020, 21 days after receiving Dose 2. On 05 Nov 2020 (Day 43), the subject had a road traffic accident and was hospitalized. The investigator considered the road traffic accident to be life-threatening. The subject remained hospitalized and had not recovered from the road traffic accident at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the road traffic accident was related to the study intervention. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	79.64 kg	28.7 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1995	Present
Recurrent back pain lumbar	Back pain	1998	Present
Polycystic Kidney Disease	Congenital cystic kidney disease	1999	Present
Migraine	Migraine	2000	Present
allergic rhinitis	Rhinitis allergic	2010	Present
Biliary Colic	Biliary colic	2012	Past
cholecystectomy	Cholecystectomy	2012	Past
bilateral tubal ligation	Female sterilisation	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05OCT2020 (1)	15:26

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Benign pancreatic neoplasm	Serous cystadenoma of Pancreas	24OCT2020 (20)		ONGOING			1
2	INFEC	Urinary tract infection	Urinary Tract Infection	15OCT2020 (11)		24OCT2020 (20)		10	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: unknown	1	20	N
2	N	Y	Resolved (24OCT2020)	NOT RELATED/OTHER: Pancreatic Mass Found	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1019 10191254, a 39-year-old white female with a pertinent medical history of congenital cystic kidney disease (since 1999) and biliary colic (in 2012), received Dose 1 on 05 Oct 2020. The subject was diagnosed with a urinary tract infection on 15 Oct 2020, 10 days after receiving Dose 1. The subject was hospitalized on 24 Oct 2020 (Day 20) because of the urinary tract infection. No culture was performed. During the inpatient evaluation, there was an incidental finding of a benign pancreatic neoplasm (serous cystadenoma of pancreas; reported as a nonserious adverse event). On 24 Oct 2020 (Day 20), the urinary tract infection resolved. It was reported that a SARS CoV-2 test was negative on 14 Oct 2020 (Day 10) prior to this hospitalization. The subject was discharged from the hospital on 27 Oct 2020 (Day 23). The serous cystadenoma of the pancreas was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the urinary tract infection was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	67.7 kg	28.5 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1959	Past
Tonsillitis	Tonsillitis	1959	Past
Seasonal Allergic Rhinitis	Seasonal allergy	1979	Present
Post Menopausal	Postmenopause	2000	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	16:44
2	BNT162b2	01OCT2020 (22)	15:06

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Cerebrovascular accident	Stroke (CVA)	02NOV2020 (54)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: not related to drug or non-drug treatment	2	33	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1021 10211190, a 66-year-old white female with no pertinent medical history, received Dose 1 on 10 Sep 2020 and Dose 2 on 01 Oct 2020 (Day 22). The subject was diagnosed with a cerebrovascular accident on 02 Nov 2020, 32 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the cerebrovascular accident included ranitidine hydrochloride and calcium carbonate (both since 2018) for gastrointestinal reflux disease. On 02 Nov 2020 (Day 54), the subject presented to the emergency room and was subsequently hospitalized because of a cerebrovascular accident. Relevant tests were unknown. It was unknown whether a COVID-19 test was performed during the hospital stay. The subject remained hospitalized at the time of this report and the discharge information was not available. The cerebrovascular accident was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the cerebrovascular accident was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	66.45 kg	25.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DRUG ALLERGY TO CODEINE SULFATE	Drug hypersensitivity	1961	Present
NICOTINE DEPENDENCE	Nicotine dependence	1980	Past
DRUG ALLERGY TO ZESTRIL	Drug hypersensitivity	1996	Present
HYPERTENSION	Hypertension	1996	Present
POSTMENOPAUSAL	Postmenopause	1996	Present
DRUG ALLERGY TO LOPRESSOR	Drug hypersensitivity	1998	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2000	Present
OSTEOPOROSIS	Osteoporosis	2008	Present
DRUG ALLERGY TO FOSAMAX	Drug hypersensitivity	2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
LEFT BUNDLE BRANCH BLOCK	Bundle branch block left	2010	Present
PALPITATIONS	Palpitations	2010	Present
SHORTNESS OF BREATH	Dyspnoea	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:28
2	BNT162b2	12SEP2020 (24)	10:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Acute myeloid leukaemia	Acute Myeloid Leukemia	08NOV2020 (81)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Unknown	2	58	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1027 10271054, a 77-year-old white female with a pertinent medical history of drug hypersensitivity (allergic to codeine sulfate since 1961, to zestril since 1996, to Lopressor since 1998, to Fosamax since 2009); nicotine dependence (in 1980); hypertension (since 1996); and osteoporosis (since 2008), received Dose 1 on 20 Aug 2020 and Dose 2 on 12 Sep 2020 (Day 24). The subject was diagnosed with acute myeloid leukemia on 08 Nov 2020, 57 days after receiving Dose 2. On 08 Nov 2020 (Day 81), the subject went to the emergency room because of abnormal laboratory test consistent with acute myeloid leukemia resulting in hospitalization. The subject's primary care physician reported to the investigator that the subject's laboratory values performed on 06 Nov 2020 were abnormal with a high white blood cell (WBC) count of 58.9 × 103/mm3, low neutrophil count of 0, low lymphocyte count of 6, and high blasts/blast like cell count of 93 (normal ranges and units for these were not reported) and therefore, she was sent to the hospital for additional testing. On 08 Nov 2020 (Day 81), a repeat laboratory test showed elevated WBC count (value not reported). On admission, the physical examination showed tenderness and edema over the left ankle and plantar arch. On 09 Nov 2020 (Day 82), the subject underwent a bone marrow biopsy, which showed a cellularity more than 95% with Auer rods and decreased trilineage hematopoiesis. Flow cytometry showed 95% blasts positivity for CD117 and CD34, consistent with acute myeloid leukemia. The subject's laboratory tests results showed a high WBC count of 60.7 × 103/mm3, low neutrophil count of 2%, low lymphocyte count of 6%, and high blasts/blast like cell count of 91% (normal ranges were not provided). On 10 Nov 2020 (Day 83), the subject was treated with decitabine and venetoclax. On 11 Nov 2020 (Day 84), a venous Doppler of the left lower extremity showed totally occlusive deep vein thrombosis of the left posterior tibial and peroneal veins. The subject received enoxaparin sodium twice a day, and intravenous fluids until 13 Nov 2020 (Day 86) and allopurinol until 14 Nov 2020 (Day 87) to prevent tumor lysis syndrome. The subject tolerated the chemotherapy without complications. On 14 Nov 2020 (Day 87), the subject was discharged with a peripherally inserted central catheter line in place for chemotherapy. The site was not informed if SARS-CoV-2 test was done. The follow-up visit with the hematology oncology clinic was scheduled for 16 Nov 2020 (Day 89). The acute myeloid leukemia was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the acute myeloid leukemia was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	68.36 kg	25.2 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1985	Present
Asthma, Allergy Induced	Asthma	1992	Present
Amoxicillin Allergy	Drug hypersensitivity	1992	Present
Wisdom Teeth Extraction	Wisdom teeth removal	1994	Past
Ceftin Allergy	Drug hypersensitivity	1998	Present
Polycystic Ovarian Disease	Polycystic ovaries	2003	Present
Hyperlipidemia	Hyperlipidaemia	2015	Present
GERD	Gastrooesophageal reflux disease	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	AUG2016	Past
Hypothyroidism	Hypothyroidism	30AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	10:01
2	Placebo	16SEP2020 (22)	10:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	Breast mass	left breast lump	27AUG2020 (2)		29SEP2020 (35)		34
2	GASTR	Diarrhoea	diarrhea	01SEP2020 (7)		01SEP2020 (7)		1
3	GENRL	Injection site pain	left arm soreness at injection site.	27AUG2020 (2)		29AUG2020 (4)		3
4	NEOPL	Invasive ductal breast carcinoma	invasive ductal carcinoma stage 1B, left breast	30SEP2020 (36)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (29SEP2020)	NOT RELATED/OTHER: breast lump	1	2	N

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	2	N	N	Resolved (01SEP2020)	Study Treatment	1	7	N
3	2	N	N	Resolved (29AUG2020)	Study Treatment	1	2	N
4	2	N	Y	Yes	NOT RELATED/OTHER: breast cancer	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1028 10281059, a 48-year-old white female with a pertinent medical history of polycystic ovaries (since 2003); hyperlipidemia (since 2015); hypothyroidism (since 30 Aug 2019); family history of breast cancer (maternal great aunt), leukemia (paternal grandmother), stomach cancer (maternal grandmother), lung cancer (paternal grandfather), and Hodgkin's lymphoma (maternal side), received Dose 1 on 26 Aug 2020 in the left deltoid and Dose 2 on 16 Sep 2020 (Day 22). The subject was diagnosed with invasive ductal breast carcinoma on 30 Sep 2020 of the left breast, 14 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of invasive ductal breast carcinoma included fluconazole (since 2005); levonorgestrel (since 2007) as birth control; cetirizine hydrochloride (since 2018) for seasonal allergies; nature thyroid (since 30 Aug 2019) for hypothyroidism; and metformin (since 10 Jul 2020) for polycystic ovarian disease, and phentermine (since 10 Jul 2020) for weight loss. On 13 Oct 2020 (Day 49), during the study visit reminder call, the subject stated that she had been diagnosed with breast cancer. When queried, she reported that she noted soreness in the left arm at the injection site on 27 Aug 2020 (Day 2), a day after receiving Dose 1. She found a lump in her left breast (breast mass; reported as a non-serious adverse event) at that time. She reported that 2 mammograms and an ultrasound were done and the results were not provided. On 30 Sep 2020 (Day 36) a biopsy showed invasive ductal carcinoma Stage 1B which was triple negative. The invasive ductal breast carcinoma was considered as medically significant by the investigator. The subject did not report any of this until 13 Oct 2020 (Day 49). The subject stated that she would undergo chemotherapy for 20 weeks, a lumpectomy, and 4 weeks of radiation following the lumpectomy. The invasive ductal breast carcinoma was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the invasive ductal breast carcinoma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.04 cm	83 kg	31.9 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
environmental allergy	Hypersensitivity	1980	Present
asthma	Asthma	1984	Present
chronic back pain	Back pain	1989	Present
herpes simplex, genital	Genital herpes simplex	1990	Present
irritable bowel syndrome-constipation	Irritable bowel syndrome	1990	Present
drug abuse	Drug abuse	1999	Past
anxiety	Anxiety	2000	Present
depression	Depression	2000	Present
chronic vaginitis	Vaginal infection	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lumbar facet syndrome	Facet joint syndrome	2013	Present
degenerative disc disease	Intervertebral disc degeneration	2013	Present
herniated disc	Intervertebral disc protrusion	2013	Present
cervical spondylosis	Spinal osteoarthritis	2014	Present
lumbar spondylosis	Spinal osteoarthritis	2014	Present
bilateral sacro-iliac joint dysfunction	Spondyloarthropathy	2014	Present
dyspareunia	Dyspareunia	2015	Present
hot flashes	Hot flush	2015	Present
insomnia	Insomnia	2015	Present
osteoarthritis	Osteoarthritis	2015	Present
obesity	Obesity	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	11:50
2	BNT162b2	17SEP2020 (23)	16:03

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Fatigue	Fatigue	27AUG2020 (2)		03SEP2020 (9)		8
2	INJ&P	Upper limb fracture	Closed fracture of right elbow	28OCT2020 (64)	19:35	29OCT2020 (65)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (03SEP2020)	Study Treatment	1	2	N
2	2	TC/TCN	Y	Resolved (29OCT2020)	NOT RELATED/OTHER: fall trauma	2	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1028 10281060, a 48-year-old white female with a pertinent medical history of back pain (since 1989); intervertebral disc degeneration, intervertebral disc protrusion and facet joint syndrome (all since 2013); spinal osteoarthritis (cervical and lumbar) and bilateral sacroiliac joint dysfunction (both since 2014); and insomnia and osteoarthritis (both since 2015), received Dose 1 on 26 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 23). The subject was diagnosed with an upper limb fracture on 28 Oct 2020, 41 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the upper limb fracture included valaciclovir hydrochloride (since 1990) for genital herpes; salbutamol (since 1991) for asthma; fluticasone propionate (since 2005) and benzonatate (since 2016) for environmental allergy; cyclobenzaprine (since 2013), duloxetine and nabumetone (both since 2016), and ketorolac (since 2019) for chronic back pain; and a multivitamin (since 2015) as a health supplement. On 28 Oct 2020 (Day 64), the subject accidentally fell at work and reported bilateral elbow pain and went to an emergency room at 1935 hours, resulting in hospitalization for 1 day. An x-ray revealed a closed fracture of the right elbow that required surgery. The subject underwent open reduction and internal fixation surgery. The upper limb fracture was considered to be resolved on 29 Oct 2020 (Day 65) and she was discharged from the hospital on the same day. In the opinion of the investigator, there was no reasonable possibility that the upper limb fracture was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to fall/trauma. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195.58 cm	123.18 kg	32.1 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
old sport injury R knee	Sports injury	1963	Past
Allergic rhinitis	Rhinitis allergic	2000	Present
Surgery on R knee	Knee operation	2006	Past
Hypertension	Hypertension	14MAR2009	Present
Male erective disorder	Erectile dysfunction	2010	Present
Lumbar radiculopathy	Lumbar radiculopathy	22DEC2015	Present
Impingement syndrome of R shoulder	Rotator cuff syndrome	23FEB2017	Present
Bursitis of R shoulder	Bursitis	20JUN2017	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	20DEC2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hyperlipidemia	Hyperlipidaemia	27DEC2018	Present
Obesity	Obesity	2019	Present
Cataract surgery L eye	Cataract operation	MAR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	09:41
2	BNT162b2	28SEP2020 (21)	09:07

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Fatigue	fatigue	09SEP2020 (2)	07:00	11SEP2020 (4)		3
2	GENRL	Injection site pain	Injection site tenderness	08SEP2020 (1)	12:00	11SEP2020 (4)		4
3	NERV	Ischaemic stroke	Acute Ischemic Stroke	04OCT2020 (27)	13:00	06OCT2020 (29)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (11SEP2020)	Study Treatment	1	2	N

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	1	N	N	Resolved (11SEP2020)	Study Treatment	1	1	N
3	2	N	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1038 10381101, a 69-year-old white male with a pertinent medical history of hypertension (since 14 Mar 2009), hyperlipidemia (since 27 Dec 2018), and obesity (since 2019), received Dose 1 on 08 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 21). The subject experienced an ischemic stroke on 04 Oct 2020, 6 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the ischemic stroke included olmesartan medoxomil (since 22 Jan 2020) for hypertension. On 05 Oct 2020 (Day 28), the site had a telephone contact with the subject, during which it was reported that he went to the emergency room on 04 Oct 2020(Day 27) because of an acute ischemic attack and was admitted to the hospital at 01:00 PM. An echocardiogram and computed tomography angiography of neck performed on 05 Oct 2020 (Day 28) were unremarkable. On 06 Oct 2020 (Day 29), a magnetic resonance imaging showed an acute ischemic stroke. On 06 Oct 2020 (Day 29), the ischemic stroke was considered resolved and the subject was discharged from the hospital on the same day. A COVID-19 testing was not performed during this hospitalization. In the opinion of the investigator, there was no reasonable possibility that the ischemic stroke was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	72.73 kg	25.8 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
ROTATOR CUFF REPAIR RIGHT SIDE	Rotator cuff repair	2012	Past
TORN ROTATOR CUFF RIGHT SIDE	Rotator cuff syndrome	2012	Past
ROTATOR CUFF REPAIR LEFT SIDE	Rotator cuff repair	2015	Past
TORN ROTATOR CUFF LEFT SIDE	Rotator cuff syndrome	2015	Past
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	2017	Present
HYPOTHYROIDISM	Hypothyroidism	2017	Present
ARTHROSCOPIC REPAIR LEFT SIDE	Arthroscopic surgery	2019	Past
TORN MENISCUS LEFT SIDE	Meniscus injury	DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	18:17
2	BNT162b2	02OCT2020 (38)	09:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	Acute Pain hip right side	03SEP2020 (9)		02OCT2020 (38)		30
2	MUSC	Arthralgia	Right Shoulder Pain	03SEP2020 (9)		20OCT2020 (56)		48
3	INJ&P	Brain contusion	Left frontal lobe contusion	03SEP2020 (9)		02OCT2020 (38)		30
4	INJ&P	Fall	FALL	03SEP2020 (9)		03SEP2020 (9)		1
5	MUSC	Mobility decreased	Decreased Mobility	03SEP2020 (9)		20OCT2020 (56)		48
6	MUSC	Muscle spasms	Muscle Spasm	03SEP2020 (9)		02OCT2020 (38)		30
7	INJ&P	Pelvic fracture	Closed Fracture of Rt Interior Pubic Ramus	03SEP2020 (9)		02OCT2020 (38)		30
8	INJ&P	Rib fracture	Closed Fracture of Four Ribs	03SEP2020 (9)		02OCT2020 (38)		30
9	INJ&P	Scapula fracture	Closed Displaced Fracture of body Right Scapula	03SEP2020 (9)		20OCT2020 (56)		48
10	NERV	Subarachnoid haemorrhage	SUBARACHNOID HEMORRAGE	03SEP2020 (9)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
2	1	TC	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
3	1	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: fall from bicycle	1	9	N
4	1	TC	N	Resolved (03SEP2020)	NOT RELATED/OTHER: fall from bicycle	1	9	N
5	1	N	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
6	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
7	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
8	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
9	2	N	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
10	3	TC	Y	Yes	NOT RELATED/OTHER: FALL	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1042 10421166, a 69-year-old white male with a pertinent medical history of hypercholesterolemia (since 2010), received Dose 1 on 26 Aug 2020 and Dose 2 on 02 Oct 2020 (Day 38). The subject was diagnosed with a subarachnoid hemorrhage on 03 Sep 2020, 8 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the subarachnoid hemorrhage included atorvastatin (since 2010) for hypercholesterolemia, levothyroxine (since 2017) for hypothyroidism, and tamsulosin (since 2017) for benign prostatic hyperplasia. On 03 Sep 2020 (Day 9), the subject hit his head after an accident while riding his bicycle and went to the emergency room. A computerized tomogram scan showed a small brain bleed and the subject required hospitalization for 4 days. During this hospitalization, the subject also experienced nonserious adverse events of arthralgia (acute pain hip [right side], right shoulder pain), left frontal lobe contusion, decreased mobility, muscle spasms, pelvic fracture (closed fracture of right interior pubic ramus), rib fracture (closed fracture of 4 ribs), and scapula fracture (closed displaced fracture of body right scapula) on 03 Sep 2020 (Day 9). The subject was discharged on 08 Sep 2020 (Day 14). The acute pain hip (right side), left frontal lobe contusion, muscle spasm, pelvic fracture, and rib fracture were considered resolved on 02 Oct 2020 (Day 38) and the right shoulder pain, decreased mobility and scapula fracture were considered resolved on 20 Oct 2020 (Day 56). The subarachnoid hemorrhage was ongoing at the time of last available report. In the opinion of the investigator, there was no reasonable possibility that the subarachnoid hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the fall from his bicycle. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	71.8 kg	23.4 kg/m2	08SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	13:15
2	BNT162b2	28SEP2020 (21)	15:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Hypokalaemia	Hypokalemia	23OCT2020 (46)		24OCT2020 (47)		2
2	METAB	Hypomagnesaemia	Hypomagnesemia	23OCT2020 (46)		24OCT2020 (47)		2
3	INJ&P	Muscle injury	Muscle Sprain (Right Leg)	23SEP2020 (16)		ONGOING		
4	INJ&P	Overdose	Heroin Overdose	23OCT2020 (46)		24OCT2020 (47)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	N
2	2	TC	N	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	N
3	1	TC	N	Yes	NOT RELATED/OTHER: unk	1	16	N
4	4	TC	Y	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1044 10441093, a 59-year-old white male with no pertinent medical history, received Dose 1 on 08 Sep 2020 and Dose 2 on 28 Sep 2020(Day 21). The subject had an overdose (heroin overdose) on 23 Oct 2020, 25 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the overdose included acetylsalicylic acid/caffeine/salicylamide (since 23 Sep 2020) for muscle sprain. On 23 Oct 2020 (Day 46), the subject went to the emergency room (ER) in the evening after an accidental heroin overdose associated with hypokalemia and hypomagnesemia. The subject was treated with naloxone hydrochloride for the overdose and potassium intravenously. The hypokalemia, hypomagnesemia, and overdose were considered resolved on 24 Oct 2020(Day 47) and the subject was discharged from the ER on the same day. The event was considered as life-threatening by the investigator. In the opinion of the investigator, there was no reasonable possibility that the overdose (heroin overdose) was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	100 kg	32.5 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral broken Knees	Lower limb fracture	1953	Past
Bilateral Hip Replacement	Hip arthroplasty	1990	Past
Hypothyroidism	Hypothyroidism	1999	Present
Angioplasty	Angioplasty	2000	Past
Joint Pain	Arthralgia	2000	Present
High Cholestrol	Blood cholesterol increased	2000	Present
Congestive Heart Failure	Cardiac failure congestive	2000	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2000	Present
Hypertension	Hypertension	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	2000	Present
Tinnitis	Tinnitus	2000	Present
Left Eye Vision Loss	Blindness unilateral	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	15:25
2	BNT162b2	23SEP2020 (22)	14:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Cerebrovascular accident	Stroke	18OCT2020 (47)		ONGOING			3	N	Y
2	GASTR	Diarrhoea	diarrhea	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N
3	GASTR	Nausea	nausea	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N
4	GASTR	Vomiting	vomiting	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: medical history of hypertension and congestive heart failure	2	26	Y
2	Resolved (24SEP2020)	Study Treatment	2	2	N
3	Resolved (24SEP2020)	Study Treatment	2	2	N
4	Resolved (24SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1047 10471114, a 76-year-old white male with a pertinent medical history of congestive cardiac failure (since 2000 and angioplasty in 2000), blood cholesterol increased and hypertension (both since 2000); and coronary artery disease (unspecified onset date), received Dose 1 on 02 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 22). The subject was diagnosed with a cerebrovascular accident on 18 Oct 2020, 25 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of cerebrovascular accident included acetylsalicylic acid (since 1990) for heart health; atorvastatin calcium for hypercholesterolemia, diltiazem and furosemide for hypertension, levothyroxine for hypothyroidism, and esomeprazole for gastrointestinal reflux disease (all medications since 2000). On 18 Oct 2020 (Day 47), the subject presented to the emergency room with increased weakness and pain for several days and was hospitalized. He fell the night before this visit and was seen in another hospital, where it was reported that the subject had a cervical fracture because of the fall. On the same day (Day 47), a computerized tomography (CT) of the head without contrast showed cerebral and cerebellar hemispheres with no acute intracranial abnormality, hemorrhage mass, or abnormal extra-axial fluid collections. The density within the dual venous sinuses was within normal limits. Gray white matter differentiation was preserved and there were no focal areas of hypoattenuation within a vascular distribution to suggest acute transcortical ischemia. The basilar cisterns were patent. Ventricles were normal in size and configured for age. Osseous structures and paranasal sinuses showed no significant abnormality. On the same day (Day 47), the subject was diagnosed with a cerebrovascular accident. On 19 Oct 2020 (Day 48), a magnetic resonance imaging (MRI) of the brain without contrast showed multifocal acute to subacute infarcts within the bilateral cerebral and right cerebellar hemispheres, suspicious for underlying embolic phenomenon. A repeat CT scan showed acute and subacute infarct and an MRI of the cervical spine showed an acute fracture only in the anterior inferior corner of C4. The subject also reported headache, slight chest pain, and slurred speech. An echocardiogram showed mobile echogenic calcified annulus and ejection fraction of 45%. Carotid Doppler showed no hemodynamically significant stenosis. The subject was started on antibiotics (unspecified dates) for possible culture negative endocarditis. Cervical collar was placed. No immediate intervention was planned due to acute stroke. The subject failed a swallow test and had a gastric tube placed. The subject had a peripherally inserted central catheter line placed for long-term antibiotics. Cefepime was discontinued because of concerns of medication encephalopathy. A SARS-CoV-2 test performed on 05 Nov 2020 (Day 65), was negative. The subject was discharged to a rehabilitation center on an unspecified date. The cerebrovascular accident was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the cerebrovascular accident was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to hypertension and congestive heart failure. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	88.64 kg	29.7 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	MAY2005	Past
appendicitis	Appendicitis	MAY2005	Past
abdominal scar	Scar	MAY2005	Present
bilateral lower legs edema 1+	Oedema peripheral	2015	Present
bilateral fungus toenails	Onychomycosis	2015	Present
nerve pain, cervical spine	Neuralgia	11SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	11:50
2	Placebo	09OCT2020 (22)	11:22

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Aortic valve incompetence	acute severe aortic insufficiency	28OCT2020 (41)		ONGOING			4	TC/TCN	Y
2	CARD	Atrial fibrillation	intermittent atrial fibrillation	06NOV2020 (50)		ONGOING			2	TC	N
3	INFEC	Endocarditis bacterial	bacterial endocarditis	28OCT2020 (41)		ONGOING			2	TC	N
4	MUSC	Myalgia	pain L hamstring muscles	28OCT2020 (41)		ONGOING			2	TC	N
5	NERV	Subarachnoid haemorrhage	subarachnoid hemorrhage	05NOV2020 (49)		ONGOING			3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: gram positive cocci bacterial endocarditis, source unknown	2	20	Y
2	Yes	NOT RELATED/OTHER: bacterial endocarditis	2	29	N
3	Yes	NOT RELATED/OTHER: infection	2	20	N
4	Yes	NOT RELATED/OTHER: heavy lifting	2	20	N
5	Yes	NOT RELATED/OTHER: possibly secondary to underlying bacterial endocarditis (mycotic aneurysm)	2	28	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1054 10541173, a 58-year-old white male with a pertinent medical history of peripheral edema (bilateral lower legs edema 1+, since 2015), received Dose 1 on 18 Sep 2020 and Dose 2 on 09 Oct 2020 (Day 22). The subject was diagnosed with acute aortic valve insufficiency on 28 Oct 2020, 19 days after receiving Dose 2 and subarachnoid hemorrhage on 05 Nov 2020, 27 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the aortic valve incompetence and subarachnoid hemorrhage included ibuprofen (since 11 Sep 2020) for neck nerve pain. On 28 Oct 2020 (Day 41), the subject went to the emergency room (ER) because of pain in the left hamstring muscles (myalgia; reported as a nonserious adverse event), that worsened during the day. During the ER evaluation, the laboratory test results showed a borderline increase in troponin (value not reported), blood sodium of 124, total white blood cell count of 17000, and neutrophils of 79% (normal ranges and units not reported). The subject's initial systolic blood pressure was noted to be low at 95 mmHg. He was hypoxemic with a partial pressure of oxygen at 84 mmHg on 2 liters per minute via nasal cannula and a partial pressure of carbon dioxide at 23 mmHg. On 28 Oct 2020 (Day 41), a chest x-ray revealed bilateral lobe infiltrate and pulmonary edema. Subsequently, the subject was hospitalized because of aortic valve incompetence and the investigator considered it to be life-threatening. He was started on intravenous (IV) fluids, and was empirically treated with azithromycin 500 mg IV once daily (QD) and ceftriaxone 1 g IV QD. A SARS-CoV-2 polymerase chain reaction test performed on the same day (Day 41) was negative. On 29 Oct 2020 (Day 42), an echocardiogram showed a good ejection fraction (value not reported). Later that same day, a repeat echocardiogram showed wide open aortic insufficiency. The subject's oxygen saturation was low and he was transferred to the intensive care unit (ICU) because of increased hypoxemia requiring intubation. Low dose of IV norepinephrine bitartrate was initiated to maintain blood pressure. On 30 Oct 2020 (Day 43), a chest computerized tomogram (CT) scan revealed bilateral pleural effusion associated with pulmonary edema of cardiac origin. The subject remained in the ICU on ventilator support and continued to receive antibiotics for possible pneumonia. On 02 Nov 2020 (Day 46), the subject was reported to be stable. On an unspecified date, a chest x-ray showed pulmonary edema as a result of acute severe aortic insufficiency and haziness in both lung bases consistent with pneumonia; a CT scan of the thorax showed pulmonary edema and bilateral pleural effusion as a result of acute severe aortic insufficiency. The decreased oxygen saturation was attributed to pulmonary edema. The subject was transferred to another hospital for aortic valve replacement surgery. During the course of the assessments, a CT scan of the head showed a central nervous system bleed secondary to an aneurysm. A cerebral angiogram showed a small aneurysm, which was treated with an embolization procedure on 05 Nov 2020 (Day 49). He was also treated with levetiracetam as a prophylaxis for subarachnoid hemorrhage. The subject had intermittent atrial fibrillation (reported as a nonserious adverse event) since 06 Nov 2020 (Day 50), and was treated with amiodarone. He was currently in sinus rhythm. He was treated with ceftriaxone 2 g IV daily, metoprolol, and diuretics as needed. There was no further bleeding nor evidence of neurological sequelae. On 09 Nov 2020 (Day 53), following aortic valve replacement surgery (open procedure the pulmonary edema was resolving. After the surgery, a diagnosis of bacterial endocarditis was confirmed. Postoperatively, the subject was clinically stable. On 12 Nov 2020 (Day 56), the subject was extubated, his oxygen saturation was 98% on room air. The aortic valve incompetence, myalgia, atrial fibrillation, bacterial endocarditis, and subarachnoid hemorrhage were ongoing at the time of the last available report. In the opinion of the investigator, there was no a reasonable possibility that the aortic valve incompetence and subarachnoid hemorrhage were related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to gram positive cocci bacterial endocarditis (specimen source unknown). Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.8 cm	68.8 kg	22.8 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	2005	Present
Diabetic neuropathy	Diabetic neuropathy	FEB2005	Present
Hyperlipidemia	Hyperlipidaemia	2010	Present
Hypertension	Hypertension	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	13:30
2	BNT162b2	21SEP2020 (22)	12:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis perforated	Perforated appendicitis	31AUG2020 (1)	19:00	16SEP2020 (17)		17
2	GENRL	Fatigue	Fatigue	21SEP2020 (22)	16:00	21SEP2020 (22)	20:00	1
3	GENRL	Injection site pain	Injection Site Pain	31AUG2020 (1)	18:00	03SEP2020 (4)	08:00	4
4	GENRL	Injection site pain	Injection site pain	22SEP2020 (23)	08:00	24SEP2020 (25)	08:00	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: bacterial infection	1	1	Y
2	1	N	N	Resolved (21SEP2020)	Study Treatment	2	1	N
3	1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	N
4	1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1055 10551153, a 63-year-old Asian male with a pertinent medical history of type 2 diabetes mellitus (since 2005) and hypertension (since 2010), received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject was diagnosed with perforated appendicitis on 31 Aug 2020, approximately 5 hours after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the perforated appendicitis included atorvastatin (since 2010) for hyperlipidemia; acetylsalicylic acid (since 2010) as prophylaxis; losartan (since 2010) for hypertension; liraglutide (since 2010), metformin hydrochloride/sitagliptin (since 2015), and human insulin (since 2017), all for type 2 diabetes; and simethicone (since 29 Aug 2020), for gastroesophageal reflux disease. On 31 Aug 2020 (Day 1), in the evening following Dose 1, the subject visited the emergency room (ER) with abdominal pain and fever with a body temperature of 101.4 F°. A COVID-19 test performed in the ER was negative. An abdominal computerized tomogram scan revealed a perforated appendix, which was a complication of appendicitis and surgery was scheduled. The subject was hospitalized and was treated with intravenous (IV) piperacillin sodium/tazobactam sodium and a single dose of IV metronidazole. It was unknown if a culture was performed. On 01 Sep 2020 (Day 2), the subject underwent a laparoscopic appendectomy without complications. Surgical pathology results revealed acute appendicitis and gross features consistent with a perforated appendix. On 03 Sep 2020 (Day 4), the subject was discharged on oral amoxicillin/clavulanic acid for 2 weeks. On 16 Sep 2020 (Day 17), the perforated appendicitis resolved. In the opinion of the investigator, there was no reasonable possibility that the perforated appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a bacterial infection. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	104.3 kg	36.1 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	01APR1982	Present
Hypertension	Hypertension	01OCT2000	Present
Anomalous coronary artery	Congenital coronary artery malformation	2010	Present
Coronary artery bypass graft	Coronary artery bypass	2010	Past
Angina	Angina pectoris	24MAR2010	Past
Coronary vasospasm	Arteriospasm coronary	24MAR2010	Past
Hypertriglyceridemia	Hypertriglyceridaemia	01APR2010	Present
Redo of coronary bypass graft with re-implantation RCA and unroofing of LAD bridge	Coronary artery bypass	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sinus tachycardia	Sinus tachycardia	01APR2019	Present
Type 2 diabetes	Type 2 diabetes mellitus	01FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	12:14
2	Placebo	23SEP2020 (21)	10:18

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Arteriospasm coronary	Coronary vasospasm	25SEP2020 (23)		26SEP2020 (24)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (26SEP2020)	NOT RELATED/OTHER: underlying cardiac disease	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1055 10551176, a 50-year-old white female with a pertinent medical history of congenital coronary artery malformation (diagnosed in 2010), angina pectoris and arteriospasm coronary (both in Mar 2010), hypertriglyceridemia (since Apr 2010), coronary artery bypass (in 2010 and in 2016), sinus tachycardia (since Apr 2019), type 2 diabetes mellitus (since Feb 2020), received Dose 1 on 03 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 21). The subject was diagnosed with coronary arteriospasm on 25 Sep 2020, 2 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the coronary arteriospasm included acetylsalicylic acid (since 2010) as a prophylaxis, losartan (since 2018) for hypertension, fenofibrate (since Mar 2019) and cholestyramine (since Sep 2020)for hypertriglyceridemia, ivabradine (since Aug 2019) for angina, and metformin (since 01 Feb 2020) for type 2 diabetes. On 25 Sep 2020 (Day 23), the subject went to the emergency room for chest pain, and was subsequently hospitalized for observation. Myocardial infarction was ruled out and the chest pain was considered due to coronary vasospasm. The subject's troponin (values not reported) was normal; no acute electrocardiogram changes, no evidence of heart failure, or arrhythmia were noted. A computerized tomography angiography showed no evidence of obstructive coronary artery disease. Initiation of nebivolol as an outpatient for questionable endothelial dysfunction and vasospasm was discussed. A SARS-CoV-2 swab polymerase chain reaction test performed on the same day (Day 23) was negative. On 26 Sep 2020 (Day 24), the coronary arteriospasm was considered resolved, and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the coronary arteriospasm was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.5 cm	92.2 kg	34.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPOTHYROIDISM	Hypothyroidism	18MAR1993	Present
TYPE II DIABETES	Type 2 diabetes mellitus	18MAR1995	Present
OBESITY	Obesity	2000	Present
OSTEOARTHRITIS	Osteoarthritis	18MAR2003	Present
CHRONIC PAIN	Pain	18MAR2003	Present
POST MENOPAUSAL	Postmenopause	2008	Present
RIGHT HEMITHYROIDECTOMY	Thyroidectomy	2015	Past
CORONARY ARTERY BYPASS GRAFT	Coronary artery bypass	19AUG2018	Past
CORONARY ARTERY DISEASE	Coronary artery disease	19AUG2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	19AUG2018	Present
HYPERTENSION	Hypertension	19AUG2018	Present
MYOCARDIAL INFARCTION	Myocardial infarction	19AUG2018	Past
BILATERAL LEG EDEMA	Oedema peripheral	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:25
2	Placebo	09SEP2020 (22)	15:08

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Pneumonia	PNEUMONIA	20SEP2020 (33)		04OCT2020 (47)	08:00	15	2	TC

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (04OCT2020)	NOT RELATED/OTHER: COMMUNITY ACQUIRED PNEUMONIA	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1057 10571052, a 67-year-old black/African American female with a pertinent medical history of hypothyroidism (since Mar 1993), type 2 diabetes mellitus (since Mar 1995); coronary artery disease, hypercholesterolemia, and hypertension (all since Aug 2018); myocardial infarction and coronary artery bypass (in Aug 2018); and peripheral oedema (since 2019), received Dose 1 on 19 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 22). The subject was diagnosed with pneumonia on 20 Sep 2020, 11 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the pneumonia included levothyroxine (since Mar 1993) for hypothyroidism; duloxetine (since 2015) for chronic pain; furosemide, metoprolol, amlodipine and ramipril (all since Aug 2018) for hypertension; isosorbide mononitrate and clopidogrel (both since Aug 2018) for cardiac prophylaxis; and atorvastatin (since 01 Jan 2019) for hypercholesterolemia. On 20 Sep 2020 (Day 33), the subject had difficulty breathing, and she called for rescue. Subsequently, she was hospitalized because of pneumonia. On 23 Sep 2020 (Day 36), a SARS-CoV-2 swab polymerase chain reaction test was negative; laboratory test results showed low hemoglobin of 8.2 g/dL, high blood glucose of 420 mg/dL, high brain-natriuretic peptide of 202 pg/mL, and a white blood cell count of 11 K/mcL (normal ranges not reported); an electrocardiogram showed sinus tachycardia and probable left atrial enlargement. The subject was treated with ceftriaxone sodium 1 g intravenously (IV) every 24 hours, salbutamol 2.5 mg nebulization every 4 hours, and ranolazine 1000 mg orally twice a day. On 24 Sep 2020 (Day 37), an echocardiogram showed ejection fraction of 55%-60%; a chest x-ray showed atelectasis versus pneumonia; a computed tomography-angiogram showed scar, atelectasis versus infectious/inflammatory process or edema. On 26 Sep 2020 (Day 39), a portable chest x-ray showed a stable cardio-mediastinal silhouette, stable bilateral airspace opacities, small bilateral pleural effusions, and no pneumothorax. A stress echocardiography test on 28 Sep 2020 (Day 41) was negative for ischemia, and the subject was discharged from the hospital on 29 Sep 2020 (Day 41). The subject denied fever, and the pneumonia was considered resolved on 04 Oct 2020 (Day 47). A SARS-CoV-2 test performed on 05 Oct 2020 (Day 48) was negative; however, she was isolated for 14 days in a rehabilitation center. The subject was discharged from the rehabilitation center on 13 Oct 2020 (Day 56) on oxygen therapy as needed. In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	44	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	128.4 kg	41.8 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	1980	Present
PENICILLIN ALLERGY	Drug hypersensitivity	1985	Present
MIGRAINE HEADACHES	Migraine	1994	Present
CESAREAN SECTION	Caesarean section	20MAY1994	Past
CESAREAN SECTION	Caesarean section	24MAY1996	Past
BILATERAL TUBAL LIGATION	Female sterilisation	1999	Past
CESAREAN SECTION	Caesarean section	29NOV1999	Past
OBESITY	Obesity	2000	Present
UTERINE FIBROIDS	Uterine leiomyoma	2000	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
BENIGN CARDIAC MASS	Benign cardiac neoplasm	NOV2008	Past
THORACTOMY WITH RESECTION OF BENIGN CARDIAC MASS	Cardiac operation	NOV2008	Past
OSTEOARTHRITIS BILATERAL KNEES	Osteoarthritis	2010	Present
GOITER	Goitre	2011	Past
HYPOTHYROIDISM	Hypothyroidism	2011	Present
THYROIDECTOMY	Thyroidectomy	2011	Past
MAJOR DEPRESSION	Major depression	2014	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	01SEP2020 (1)	11:47
2	Placebo	01OCT2020 (31)	13:41

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	NEOPL	Uterine leiomyoma	WORSENING OF UTERINE FIBROIDS	14SEP2020 (14)	08:00	19SEP2020 (19)	12:00	6	2	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19SEP2020)	NOT RELATED/OTHER: MEDICAL HISTORY OF UTERINE FIBROIDS	1	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1057 10571137, a 44-year-old black/African American female with a pertinent medical history of caesarean section (May 1994, May 1996, and Nov 1999); female sterilization (in 1999); obesity and uterine leiomyoma (both since 2000); and hypothyroidism (since 2011; thyroidectomy in 2011), received Dose 1 on 01 Sep 2020 and Dose 2 on 01 Oct 2020 (Day 31). The subject was diagnosed with uterine leiomyoma on 14 Sep 2020, 13 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the uterine leiomyoma included albuterol salbutamol inhaler (since 1980) for asthma; ibuprofen (since 2000) for bilateral knee osteoarthritis; tizanidine (since 2010) for osteoarthritis; levothyroxine (since 2011) for hypothyroidism; duloxetine (since 2011) for major depression; and topiramate (since 2011) for migraines. On 14 Sep 2020 (Day 14), the subject was hospitalized for worsening of uterine fibroids, and underwent total hysterectomy on the same day. On 19 Sep 2020 (Day 19), the uterine leiomyoma was considered resolved and she was discharged from the hospital on azithromycin 500 mg orally twice a day (from 19 Sep 2020 to 24 Sep 2020) and oxycodone hydrochloride/paracetamol 1-2 tablets orally as needed (since 19 Sep 2020). Prior to the surgery, a SARS-CoV-2 test performed on 12 Sep 2020 (Day 12) was negative. On 23 Sep 2020 (Day 23), the subject informed the site about her hysterectomy and reported that it was a preplanned procedure, which she failed to disclose prior to enrolling into the trial. In the opinion of the investigator, there was no reasonable possibility that the uterine leiomyoma was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a medical history of uterine fibroids. Pfizer concurred with the investigator's assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	88.6 kg	36.9 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1970	Present
Cholecystectomy	Cholecystectomy	1985	Past
Cholelithiasis	Cholelithiasis	1985	Past
Seasonal Allergies	Seasonal allergy	1990	Present
Cesarean Section	Caesarean section	27JUL1999	Past
Obesity	Obesity	2000	Present
Hypertension	Hypertension	2002	Present
Cesarean Section	Caesarean section	23SEP2002	Past
Depression	Depression	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type II Diabetes Mellitus	Type 2 diabetes mellitus	2010	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2011	Present
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	2014	Present
Post Menopausal	Postmenopause	2016	Present
Dyslipidemia	Dyslipidaemia	2017	Present
Coronary Artery Stent Placement	Coronary arterial stent insertion	28MAY2017	Past
Myocardial Infarction	Myocardial infarction	28MAY2017	Past
Bilateral Hands Carpal Tunnel Syndrome	Carpal tunnel syndrome	2019	Present
Left Wrist Carpal Tunnel Surgery	Carpal tunnel decompression	OCT2019	Past
Right Wrist Carpal Tunnel Surgery	Carpal tunnel decompression	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	11:17
2	Placebo	04NOV2020 (20)	14:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Peritonsillar abscess	PENTONSILLAR ABSESS	22OCT2020 (7)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown at this time, awaiting medical records	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1057 10571327, a 56-year-old white female with no pertinent medical history, received Dose 1 on 16 Oct 2020 and Dose 2 on 04 Nov 2020 (Day 20). The subject was diagnosed with a peritonsillar abscess on 22 Oct 2020, 6 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the peritonsillar abscess included salbutamol (since 1970) for asthma; spironolactone (since 2005) and losartan and isosorbide (both since 2010) for hypertension; insulin aspart (since 2009), metformin, insulin detemir, and empagliflozin (all since 2010) for type 2 diabetes mellitus; mirtazapine (since 2010) for depression; ipratropium bromide/salbutamol sulfate (since 2014), umeclidinium bromide (since 2015), and budesonide/formoterol fumarate (since 2016) for chronic obstructive pulmonary disease; acetylsalicylic acid (since 2017) as a cardiovascular prophylaxis; and rosuvastatin calcium (since 2018) for dyslipidemia. On 17 Oct 2020 (Day 2), the subject experienced fever, chills, sore throat, diarrhea, and fatigue. On 22 Oct 2020 (Day 7), the subject presented to the emergency room with severe sore throat, and was diagnosed with a peritonsillar abscess. On the same day, the subject was hospitalized; the abscess was drained and sent for culture, but the results were unknown. The subject was treated with intravenous antibiotic vancomycin (from 22 Oct 2020 to 26 Oct 2020) and an unspecified steroid. Per hospital orders, a tonsillectomy was scheduled. The subject was discharged from the hospital on 26 Oct 2020 (Day 11) on amoxicillin/clavulanic acid and doxycycline for 25 days. The peritonsillar abscess was ongoing at the time of the last available report. The subject reported that a SARS-CoV-2 test was performed in the hospital and the result was negative. In the opinion of the investigator, there was no reasonable possibility that the peritonsillar abscess was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	81.82 kg	30.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis	Osteoarthritis	2005	Present
Carotid Artery Disease	Carotid artery disease	2013	Present
Hypercholesterolemia	Hypercholesterolaemia	2013	Present
Hypertension	Hypertension	2013	Present
Heartburn	Dyspepsia	2015	Present
Hodgkin's Lymphoma	Hodgkin's disease	JUN2016	Past
Non-Hodgkins's Lymphoma	Non-Hodgkin's lymphoma	JUN2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	17:35
2	BNT162b2	23SEP2020 (38)	16:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Transient ischaemic attack	Transient Ischaemic Attack	04SEP2020 (19)		09SEP2020 (24)		6	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: carotid artery disease	1	19	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1072 10721007, a 71-year-old white male with a pertinent medical history of obstructive sleep apnea (since 2005), carotid artery disease, hypercholesterolemia, and hypertension (all since 2013), and Hodgkin's disease and Non-Hodgkin's lymphoma (both in Jun 2016), received Dose 1 on 17 Aug 2020 and Dose 2 on 23 Sep 2020 (Day 38). The subject was diagnosed with a transient ischemic attack on 04 Sep 2020, 18 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the transient ischemic attack included celecoxib (since 2005) for osteoarthritis, atorvastatin (since 2013) for hypercholesterolemia, losartan and amlodipine (both since 2013) for hypertension, and omeprazole (since 2015) for gastroesophageal reflux disease. On 04 Sep 2020 (Day 19), the subject reported the site that he missed his scheduled Visit 2 appointment because of a mild transient ischemic attack, which required a visit to the emergency room resulting in hospitalization on 05 Sep 2020 (Day 20). The subject underwent a left carotid endarterectomy with Xenosure biological patch implanted on 08 Sep 2020 (Day 23). The transient ischemic attack resolved on 09 Sep 2020 (Day 24), and the subject was discharged from the hospital on clopidogrel bisulfate 75 mg, once a day (from 10 Sep 2020). The subject reported that he was doing well and felt better than he had ever felt in a long while. The subject reported that the SARS-CoV-2 tests performed on 04 Sep 2020 (Day 19) and on 08 Sep 2020 (Day 23) were negative. In the opinion of the investigator, there was no reasonable possibility that the transient ischemic attack was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to carotid artery disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187 cm	100.9 kg	28.9 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Codeine	Drug hypersensitivity	1960	Present
Tonsillectomy	Tonsillectomy	1960	Past
Appendectomy	Appendicectomy	1964	Past
Hernia Repair	Hernia repair	1970	Past
Hernia Repair	Hernia repair	1978	Past
Testicular Cancer	Testis cancer	1982	Past
Low Testosterone	Blood testosterone decreased	1983	Present
Hypercholesterolemia	Hypercholesterolaemia	2000	Present
Hypertension	Hypertension	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 Diabetes	Type 2 diabetes mellitus	2005	Present
Deep Vein Thrombosis	Deep vein thrombosis	2010	Present
Depression	Depression	2010	Present
Pressure in Eyes	Ocular discomfort	2018	Present
Erectile Dysfunction	Erectile dysfunction	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	11:33
2	Placebo	29SEP2020 (28)	13:13

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	EYE	Retinal artery occlusion	Central Retinal Artery Occlusion	29SEP2020 (28)	15:30	ONGOING			1	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Pre-existing medical conditions,hypercoagulable state due to hypertension, TIID	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1079 10791228, a 66-year-old white male with a pertinent medical history of hypercoagulable state due to hypertension (unknown date), hypertension and hypercholesterolemia (both, since 2000), type 2 diabetes mellitus (since 2005), deep vein thrombosis (since 2010), and ocular discomfort (since 2018), received Dose 1 on 02 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 28). The subject was diagnosed with a central retinal artery occlusion on 29 Sep 2020, the same day of Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the central retinal artery occlusion included testosterone (since 1983) for low testosterone; pravastatin, fenofibrate, and ezetimibe (all since 2000) for hypercholesterolemia; hydrochlorothiazide, isradipine, and nebivolol hydrochloride (all since 2000) for hypertension; metformin, pioglitazone hydrochloride, and insulin degludec (all since 2005), insulin lispro (since 2010), and dulaglutide (since 2019) for type 2 diabetes mellitus; escitalopram oxalate (since 2005) for depression; rivaroxaban (since 2010) for deep vein thrombosis; and bimatoprost (since 2018) for eye pressure. On 29 Sep 2020 (Day 28), the subject had loss of vision in the left eye and visited the emergency room and was hospitalized for a day. On 01 Oct 2020 (Day 30), a computerized tomogram, ultrasound, magnetic resonance imaging of brain were unremarkable; a transthoracic echocardiogram with bubble showed normal systolic function; a carotid ultrasound showed no significant stenosis. The subject was diagnosed with central retinal artery occlusion with no changes to medications. The subject was discharged from the hospital the following day. The retinal artery occlusion was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the retinal artery occlusion was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	85.91 kg	29.6 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post Menopausal	Postmenopause	2000	Present
Seasonal Allergies	Seasonal allergy	2000	Present
Osteoarthritis, right knee	Osteoarthritis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	15:36
2	BNT162b2	25SEP2020 (22)	14:38

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Aphasia	Expressive Aphasia	22OCT2020 (49)		26OCT2020 (53)		5	2
2	NERV	Cerebrovascular accident	CVA	22OCT2020 (49)		26OCT2020 (53)		5	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: Pending medical records	2	28	N
2	N	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: PENDING MEDICAL RECORDS	2	28	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1079 10791246, a 73-year-old white female with no pertinent medical history, received Dose 1 on 04 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 22). The subject was diagnosed with a cerebrovascular accident on 22 Oct 2020, 27 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the cerebrovascular accident included vitamin D3 and a multivitamin (both since 2018) as supplement, stool softener (since 2018) as prophylaxis, and meloxicam (since 01 May 2020) for right knee pain. On 26 Oct 2020 (Day 53), the subject informed the site that she was hospitalized for a stroke on 22 Oct 2020 (Day 49). The subject presented to the emergency room after developing aphasia (reported as nonserious adverse event). A computed tomography angiography of the brain and neck and magnetic resonance imaging of brain were negative. The subject was discharged from the hospital the following day. The aphasia and cerebrovascular accident resolved on 26 Oct 2020 (Day 53). In the opinion of the investigator, there was no reasonable possibility that the cerebrovascular accident was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.5 cm	66.5 kg	27.2 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	1990	Present
Hypertension	Hypertension	1995	Present
Torn Meniscus	Meniscus injury	2005	Past
Bilateral Inguinal Hernia	Inguinal hernia	JUL2006	Present
Knee Replacement, Left Leg	Knee arthroplasty	JAN2011	Past
Upset Stomach	Abdominal discomfort	2012	Present
Insomnia	Insomnia	2012	Present
Dermatographia	Mechanical urticaria	2018	Present
Dry Eyes, Bilateral	Dry eye	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	13:42
2	Placebo	01SEP2020 (22)	12:20

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Gastrointestinal disorder	Bowel Problems	31OCT2020 (82)		ONGOING			3	TC/TCN	Y
2	MUSC	Osteoarthritis	Osteoarthritis of the knee	26OCT2020 (77)		26OCT2020 (77)		1	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: A confirmed possible etiology will be entered once it is known.	2	61	Y
2	Resolved (26OCT2020)	NOT RELATED/OTHER: Osteoarthritis of the knee which led to knee replacement	2	56	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1080 10801013, a 77-year-old white female with a pertinent medical history of fibromyalgia (since 1990), hypertension (since 1995), meniscus injury and meniscus repair (in 2005), inguinal hernia (since Jul 2006), hernia repair (in Jul 2006), knee arthroplasty (in Jan 2011), abdominal discomfort (since 2012), received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject was diagnosed with osteoarthritis (of right knee) on 26 Oct 2020, 55 days after receiving Dose 2 and gastrointestinal disorder (bowel problems) on 31 Oct 2020, 60 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the osteoarthritis and gastrointestinal disorder included bupropion and ibuprofen (both since 1990) for fibromyalgia, diltiazem and hydrochlorothiazide/quinapril hydrochloride (both since 1995) for hypertension, zolpidem tartrate (since 2012) for insomnia, ranitidine hydrochloride (since 2012) for abdominal discomfort, cetirizine (since 2018) for hives, lifitegrast (since 2019) for dry eyes, cannabidiol (since Dec 2019) for fibromyalgia, and clonazepam (since 2020) for an unspecified indication. On 26 Oct 2020 (Day 77), the subject experienced worsening of osteoarthritis of the right knee, and was hospitalized for 2 days. On the same day (Day 77), she underwent knee replacement and the osteoarthritis was considered resolved. The subject was treated with apixaban, celecoxib, and hydrocodone acetaminophen (all since Oct 2020). On 31 Oct 2020 (Day 82), the subject subsequently developed constipation and was hospitalized with a diagnosis of perforated colon/ischemic colitis due to constipation. At the time of the hospitalization, an electrocardiogram showed normal sinus rhythm and septal infarct; a computerized tomogram of the abdomen and pelvis without contrast showed mild gaseous distention of the proximal colon and a large amount of stool in the distal colon; an x-ray of the abdomen showed probable ileus with no evidence for small or large bowel obstruction or free air. This prompted an exploratory laparotomy and a diagnosis of perforated colon/ischemic colitis was confirmed. The subject also developed acute parotitis, and was treated with clindamycin (since Nov 2020). The subject also received furosemide (since 09 Nov 2020) for diuresis, and morphine (since 09 Nov 2020) for pain. The subject was still hospitalized at the time of this report. The gastrointestinal disorder was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the osteoarthritis and gastrointestinal disorder were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	135.4 kg	48.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Histerectomy	Hysterectomy	1974	Past
Growth on Thyroid	Thyroid neoplasm	1974	Past
Fibroids	Uterine leiomyoma	1974	Past
Partial Thyroidectomy	Thyroidectomy	1975	Past
Hypothyroid	Hypothyroidism	1984	Present
Obesity	Obesity	1990	Present
Arrhythmia- A-Fib	Atrial fibrillation	1996	Present
Acid Reflux	Gastrooesophageal reflux disease	1997	Present
Hiatal Hernia	Hiatus hernia	1997	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Left Knee Replacement Surgery	Knee arthroplasty	1998	Past
Seasonal Allergies	Seasonal allergy	2000	Present
Hypertension	Hypertension	2008	Present
Right Knee Replacement Surgery	Knee arthroplasty	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	09:46
2	BNT162b2	01OCT2020 (28)	08:28

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Fluid retention	Worsening of WATER RETENTION in lower extremities	16SEP2020 (13)		18SEP2020 (15)		3
2	VASC	Hypertension	Worsening of HYPERTENSION	16SEP2020 (13)		18SEP2020 (15)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	13	Y
2	3	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1080 10801152, a 76-year-old white female with a pertinent medical history of thyroid neoplasm, uterine leiomyoma, and hysterectomy (all in 1974), thyroidectomy (in 1975), hypothyroidism (since 1984), obesity (since 1990), atrial fibrillation (since 1996), hiatus hernia (since 1997), hypertension (since 2008), arrhythmia and fluid retention (date unknown), received Dose 1 on 04 Sep 2020 and Dose 2 on 01 Oct 2020 (Day 28). The subject was diagnosed with fluid retention (worsening of water retention in lower extremities) and hypertension (worsening of hypertension) on 16 Sep 2020, 12 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the fluid retention and hypertension included levothyroxine sodium (since 1974) for hypothyroidism, omeprazole (since 1995) for acid reflux, salbutamol sulfate (since 2000) for unspecified indication, acetylsalicylic acid (since 2000) as a cardiac prophylaxis, ergocalciferol (since 2008) as a supplement, metoprolol succinate (since 2008) and telmisartan (since Jan 2020) for hypertension, mupirocin (since Sep 2019) for nose sores, and nystatin (since 2019) for an unspecified indication. On 16 Sep 2020 (Day 13), the subject experienced worsening water retention in lower extremities due to worsening hypertension, which resulted in hospitalization. The subject was placed on a new hypertensive medication (not specified). On the same day (Day 13), an electrocardiogram showed normal sinus rhythm with incomplete right bundle branch block; a chest x-ray was normal with no pulmonary edema. On 16 Sep 2020 (Day 13), the subject's laboratory test results showed a white blood cell count of 5.6 × 103/mm3 (normal range [NR]: 3.6 - 11.2 × 103/mm3), red blood cell count of 3.86 × 106/mm3 (NR: 3.63 - 4.92 × 106/mm3), hemoglobin of 11.2 g/dL (NR: 11.4 - 15.0 g/dL), hematocrit of 34% (NR: 31% - 42%), mean cell volume of 87 fL (NR: 74 - 96 fL), mean cell hemoglobin of 29 pg (NR: 26 - 33 pg), mean cell hemoglobin concentration of 33 g/dL (NR: 33 - 36 g/dL), platelet count of 180 × 103/mm3 (NR: 150 - 450 × 103/mm3), neutrophils of 57 % (NR: 37% - 80%), lymphocytes of 32% (NR: 10% - 50%), monocytes of 8% (NR: 0% - 12%), eosinophils of 2% (NR: 0% - 7%), basophils of 1% (NR: 0% - 2%), sodium of 142 mmol/L (NR: 136 - 145 mmol/L), potassium of 4.5 mmol/L (NR: 3.5 - 5.1 mmol/L), chloride of 106 mmol/L (NR: 99 - 108 mmol/L), CO2 of 30 mmol/L (NR: 21 - 31 mmol/L), blood urea nitrogen of 24 mg/dL (NR: 7 - 25 mg/dL), creatinine of 1.13 mg/dL (NR: 0.51 - 1.00 mg/dL), random blood glucose of 105 mg/dL (NR: 70 - 199 mg/dL), total calcium of 8.6 mg/dL (NR: 8.8 - 10.6 mg/dL), osmolality 288 mosm/kg (NR: 270 - 295 mosm/kg), anion gap of 6 (NR: 3 - 11), troponin I of <0.03 ng/mL (NR: <0.05 ng/mL), brain natriuretic peptide of 247 pg/mL (NR: 0 - 100 pg/mL), thyroid-stimulating hormone of 0.70 IU/mL (NR: 0.45 - 5.33 IU/mL), magnesium of 1.5 mg/dL (NR: 1.6 - 2.7 mg/dL), and estimated glomerular filtration rate of 47 mL/minute/1.73m2. It was reported that the water retention and heart arrhythmia were pre-existing conditions. The fluid retention and hypertension resolved on 18 Sep 2020 (Day 15), and the subject was discharged from the hospital on the same day (Day 15) in stable condition. On 18 Sep 2020 (Day 15), the subject informed the site about her hospitalization. In the opinion of the investigator, there was no reasonable possibility that the fluid retention and hypertension were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	117.91 kg	41.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	1962	Present
Seasonal Allergies	Seasonal allergy	1972	Present
Hypothyroidism	Hypothyroidism	1984	Present
Hypertension	Hypertension	1987	Present
Adrenal Hyperplasia	Hyperplasia adrenal	1997	Present
Bilateral Carpal Tunnel Surgery	Carpal tunnel decompression	2002	Past
Carpal Tunnel Syndrome- Bilateral	Carpal tunnel syndrome	2002	Present
Dyslipidemia	Dyslipidaemia	2002	Present
Gallstones	Cholelithiasis	FEB2002	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	2003	Past
Total Knee Replacement Right Knee	Knee arthroplasty	2003	Past
Osteoarthritis of Right Thumb	Osteoarthritis	2003	Present
Osteoarthritis-Bilateral Knees	Osteoarthritis	2003	Present
Fracture-Bilateral Wrists	Wrist fracture	2007	Past
Squamous Cell Skin Cancer removed from Nose	Skin neoplasm excision	2010	Past
Skin Cancer-Squamous Cell on Nose	Squamous cell carcinoma of skin	2010	Past
Anemia	Anaemia	2011	Past
Colon Polyps- Benign	Large intestine polyp	2011	Past
Colonoscopy/Removal of Benign Colon Polyps	Large intestinal polypectomy	01DEC2011	Past
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	11:49
2	BNT162b2	02SEP2020 (22)	11:06

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Abdominal pain lower	lower abdominal pain	11OCT2020 (61)		16OCT2020 (66)		6	3	TC/TCN	N
2	BLOOD	Anaemia	Worsening of Anemia	11OCT2020 (61)		29OCT2020 (79)		19	3	N	N
3	NEOPL	Borderline serous tumour of ovary	Serous borderline tumor of left ovary	11OCT2020 (61)		16OCT2020 (66)		6	3	TC/TCN	Y
4	GASTR	Diarrhoea	Diarrhea	13AUG2020 (2)		17AUG2020 (6)		5	1	N	N
5	INFEC	Urinary tract infection	Urinary Tract Infection	05OCT2020 (55)		16OCT2020 (66)		12	1	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (16OCT2020)	NOT RELATED/OTHER: Neoplasm of uncertain behavior of left ovary	2	40	N
2	Resolved (29OCT2020)	NOT RELATED/OTHER: Tumor of left ovary	2	40	N
3	Resolved (16OCT2020)	NOT RELATED/OTHER: Cancerous	2	40	Y
4	Resolved (17AUG2020)	NOT RELATED/OTHER: idiopathic	1	2	N
5	Resolved (16OCT2020)	NOT RELATED/OTHER: Idiopathic	2	34	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1081 10811026, a 67-year-old white female with a pertinent medical history of obesity (since 1962), hypothyroidism (since 1984), hypertension (since 1987), adrenal hyperplasia (since 1997), anemia and large intestine polyp (both in 2011), large intestinal polypectomy (in Dec 2011), and type 2 diabetes mellitus (since 2016), received Dose 1 on 12 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 22). The subject was diagnosed with a serous borderline tumor of left ovary on 11 Oct 2020, 39 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the serous borderline tumor of left ovary included levothyroxine (since 1984) for hypothyroidism, simvastatin (since 2002) for dyslipidemia, spironolactone (since 2003) for hypertension, metformin hydrochloride/sitagliptin (since 2011) for diabetes, lisinopril (since 2011) for hypertension, and cephalexin (from 05 Oct 2020 to 07 Oct 2020) and sulfamethoxazole/trimethoprim (from 08 Oct 2020 to an unknown date in Oct 2020) for urinary tract infection. On 05 Oct 2020 (Day 55), the subject experienced abdominal symptoms (not specified) and a urinary tract infection confirmed by urinalysis. The subject was initially treated by her primary care physician for the urinary tract infection, but her symptoms persisted and the abdominal discomfort worsened. She experienced lower abdominal pain on 11 Oct 2020 (Day 61). On the same day, a computerized tomogram of the abdomen and pelvis with contrast showed a large intra-abdominal/intrapelvic mass lesion suspicious for ovarian neoplasm. The subject's hemoglobin was 9.8 g/dL (normal range: 11.2 - 15.7 g/dL), and a worsening of anemia was reported. On 12 Oct 2020 (Day 62), a pelvic ultrasound and transvaginal scan showed a large, complete right ovarian cystic mass measuring up to 18.3 cm, which was suspicious for ovarian cystic neoplasm. The subject was sent for an obstetrics and gynecology consultation and a surgical removal of the mass with total abdominal hysterectomy and bilateral salpingo-oopherectomy was scheduled. On 15 Oct 2020 (Day 65), the laboratory test results showed carbohydrate antigen-125 of 402.6 IU/mL (NR: 0 - 35 IU/mL) and carcinoembryonic antigen of 1.11 ng/mL. On 16 Oct 2020 (Day 66), the subject was subsequently hospitalized and underwent the hysterectomy and bilateral salpingo-oopherectomy. The postoperative diagnosis was neoplasm of uncertain behavior of the left ovary; the pelvic washing for nongynecological cytology was negative for malignant cells and benign mesothelial cells with chronic and acute inflammation were noted. The pathology report final diagnosis was serous borderline tumor measuring 22.8 cm in greatest dimension limited to the left ovary, pT1a; the capsule of the tumor was intact with no evidence of metastasis. The histological examination showed multicystic neoplasm with predominant hemorrhage and infarct type necrosis with no ovarian surface involvement; the left fallopian tube was negative for tumor. Biopsies of the diaphragm, omentum, left and right pelvis, right pelvic gutter, posterior cul-de-sac, uterus, cervix, right ovary, right fallopian tube, lymph nodes, and bladder were all negative for tumor. During hospitalization, a SARS-CoV-2 test performed was negative. On 16 Oct 2020 (Day 66), the lower abdominal pain, serous borderline tumor of the left ovary, and urinary tract infection were considered to be resolved. The subject was discharged from the hospital on 19 Oct 2020 (Day 69) with enoxaparin syringe 40 mg/0.4 mL twice a day and oxycodone 5 mg every 6 hours as needed. The anemia was considered resolved on 29 Oct 2020 (Day 79). In the opinion of the investigator, there was no reasonable possibility that the serous borderline tumor of left ovary was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	72.82 kg	28.8 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma-Stable, No change within 6 weeks of screening	Asthma	1980	Present
Seasonal Allergies	Seasonal allergy	1980	Present
C-Section	Caesarean section	1991	Past
Bilateral Tubal Ligation	Female sterilisation	1991	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	15:09
2	BNT162b2	03SEP2020 (22)	15:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Appendicitis	21AUG2020 (9)		23AUG2020 (11)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (23AUG2020)	NOT RELATED/OTHER: Acute Infection	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1081 10811036, a 51-year-old black/African American female with no pertinent medical history, received Dose 1 on 13 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 21 Aug 2020, 8 days after receiving Dose 1. On 21 Aug 2020 (Day 9), the subject was hospitalized for an emergency appendectomy. After appendectomy, she was treated with amoxicillin/clavulanic acid 875/125 mg orally (PO) daily, ondansetron 4 mg PO as needed (PRN) for nausea, and oxycodone 5 mg PO PRN for pain (all from 21 Aug 2020 to 02 Sep 2020). On 23 Aug 2020 (Day 11), the appendicitis resolved, and the subject was discharged from the hospital on the same day. On 24 Aug 2020 (Day 12), the pathology findings showed an appendix with mild focal inflammation. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to an unspecified acute infection. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	92.95 kg	34.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy-Sulfa	Drug hypersensitivity	1989	Present
Blood Transfusion	Transfusion	1989	Past
Allergy-Shellfish-Hives	Urticaria	1989	Present
Hysterectomy	Hysterectomy	1999	Past
Anxiety	Anxiety	2000	Present
Obesity	Obesity	2003	Present
Chronic Bronchitis-Stable	Bronchitis chronic	2005	Present
Hypertension	Hypertension	2008	Present
Insomnia	Insomnia	2008	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2009	Present
Allergy-Dilaudid-itching	Pruritus allergic	2010	Present
Pneumonia	Pneumonia	2011	Past
Abdominal Hernia	Abdominal hernia	2012	Past
Abdominal Hernia Repair	Abdominal hernia repair	2012	Past
Chronic Back Pain	Back pain	2014	Present
Osteoarthritis of Left Knee	Osteoarthritis	2014	Present
Pneumonia	Pneumonia	2014	Past
Sleep Apnea	Sleep apnoea syndrome	2014	Present
Osteoarthritis of Low Back	Spinal osteoarthritis	2014	Present
Dyslipidemia	Dyslipidaemia	2016	Present
Presbyopia	Presbyopia	2016	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2016	Present
Abdominal Hernia Repair	Abdominal hernia repair	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	11:32
2	BNT162b2	09SEP2020 (24)	10:49

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	METAB	Hyperglycaemia	Hyperglycemic episode	17SEP2020 (32)		18SEP2020 (33)		2	3	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: self-induced due to watermelon diet	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1081 10811046, a 55-year-old black/African American female with a pertinent medical history of obesity (since 2003), insomnia (since 2008), and type 2 diabetes mellitus (since 2016), received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject reported hyperglycemia on 17 Sep 2020, 8 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the hyperglycemia included lisinopril (since 01 Jan 2011) and amlodipine besilate (since 11 Dec 2014), both for hypertension; and metformin (since 12 Dec 2014) for type 2 diabetes mellitus. The subject informed the site that she had been hospitalized for 2 days because of hyperglycemia. On 17 Sep 2020 (Day 32), the subject was feeling very ill and went to the emergency room; she was on a watermelon diet at that time, which raised her blood glucose level (glucose value was not reported), and she was hospitalized on the same day (Day 32) for a hyperglycemic episode. The subject recovered from hyperglycemia on 18 Sep 2020 (Day 33). In the opinion of the investigator, there was no reasonable possibility that the hyperglycemia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1939	81	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	65.64 kg	22.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1957	Present
Osteopenia-stable since 2016	Osteopenia	1985	Present
Hysterectomy	Hysterectomy	1989	Past
Migraine	Migraine	1990	Present
Chronic Urinary Tract Infections	Urinary tract infection	2000	Present
Hypothyroidism	Hypothyroidism	AUG2009	Present
Osteoarthritis of bilateral hands	Osteoarthritis	2013	Present
Rosacea	Rosacea	2013	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2014	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Skin Cancer- Left Arm	Skin cancer	2014	Past
Skin Cancer-Right Leg	Skin cancer	2014	Past
Raynaud's Disease- No associated autoimmune conditions	Raynaud's phenomenon	2016	Present
Sleep Apnea	Sleep apnoea syndrome	APR2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	12:34
2	BNT162b2	16SEP2020 (22)	10:13

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INFEC	Empyema	loculated empyema	11OCT2020 (47)		ONGOING	
2	INFEC	Pneumonia	Right lower lobe pneumonia	11OCT2020 (47)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		3	TC	Y	Yes	NOT RELATED/OTHER: idiopathic	2	26	Y
2		3	TC	Y	Yes	NOT RELATED/OTHER: idiopathic	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1081 10811110, an 81-year-old white female with a pertinent medical history of seasonal allergy (since 1957), received Dose 1 on 26 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 22). The subject was diagnosed with right lower lobe pneumonia and loculated empyema on 11 Oct 2020, 25 days after receiving Dose 2. The subject had been suffering with upper respiratory symptoms since 26 Sep 2020 (Day 32), and she was treating them as seasonal allergies. On the same day (Day 32), the subject reported a sore throat, which she thought was strep throat. On 28 Sep 2020 (Day 34), the subject visited her primary care physician; she was not tested for strep or COVID-19 at that visit, but was treated with azithromycin (from 28 Sep 2020 to 02 Oct 2020) for sore throat. As per protocol, a potential COVID-19 illness visit was conducted and she did a self-swab test on 28 Sep 2020 (Day 34). The swab results were not available at the time of this report. The sore throat resolved on 02 Oct 2020 (Day 38). The subject reported that she fell ill again on 11 Oct 200 (Day 47), but she did not report this at her Visit 3 on 14 Oct 2020 (Day 50). She started taking guaifenesin for allergy symptoms and sore throat (from 14 Oct 2020 to 16 Oct 2020). The subject's condition worsened on 15 Oct 2020 (Day 51). She visited her primary care physician on 16 Oct 2020 (Day 52), where she was tested negative for COVID-19 and influenza. On the same day (Day 52), a chest x-ray showed right lower lobe pneumonia with pleural effusion. The subject was treated with doxycycline (from 16 Oct 2020 to 23 Oct 2020) and salbutamol (since 16 Oct 2020) for pneumonia. As per protocol, the subject performed a COVID-19 self-swab test on 19 Oct 2020 (Day 55) but there was no information available regarding the swab sample results. The subject continued to be ill and went to the emergency room on 23 Oct 2020 (Day 59). A chest x-ray showed large pleural effusion, and the subject was hospitalized. The subject was treated with intravenous ceftriaxone sodium and azithromycin. On 24 Oct 2020 (Day 60), she underwent a thoracentesis and 700 cc of bloody fluid was drained out. The primary infection site was right lower lobe. The subject was diagnosed with right lower lobe pneumonia and loculated empyema with an onset date of 11 Oct 2020 (Day 47). The subject had an episode of self-limited tachycardia, which she felt was a result of her nebulizer treatment. On 30 Oct 2020 (Day 66), a computerized tomogram was scheduled however the results are unknown. The culture of her thoracentesis fluid showed no growth. All 3 tests for COVID-19 since her admission were negative. The subject was discharged from the hospital on 02 Nov 2020 (Day 69). The right lower lobe pneumonia and loculated empyema were ongoing at the time of last available report. In the opinion of the investigator, there was no reasonable possibility that the right lower lobe pneumonia and loculated empyema were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	110.82 kg	35 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	12:15
2	Placebo	22SEP2020 (23)	12:18

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocardial infarction	Myocardial Infarction	21OCT2020 (52)		ONGOING		
2	METAB	Type 2 diabetes mellitus	New Onset Type II Diabetes Mellitus	21OCT2020 (52)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Yes	NOT RELATED/OTHER: Cardiac Event	2	30	Y
2	3	TC	Y	Yes	NOT RELATED/OTHER: Insulin Resistance	2	30	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1081 10811135, a 48-year-old black/African American male with no reported medical history, received Dose 1 on 31 Aug 2020 and Dose 2 on 22 Sep 2020 (Day 23). The subject was diagnosed with new onset of type 2 diabetes mellitus and myocardial infarction on 21 Oct 2020, 29 days after receiving Dose 2. On 21 Oct 2020 (Day 52), the subject reported no symptoms during his Visit 3, but he was found to have elevated blood pressure (blood pressure value was not reported). The coordinator advised the subject to seek care with his primary care physician for the treatment of new onset of hypertension. On 26 Oct 2020 (Day 57), the subject informed the site that he had shortness of breath and burning in his chest since 21 Oct 2020 (Day 52). He was advised to immediately go to the emergency room for evaluation. The subject reported that he was hospitalized with a diagnosis of myocardial infarction and new onset of type 2 diabetes mellitus on the same day (Day 52). He had 3 coronary stents placed and was discharged from the hospital on 28 Oct 2020 (Day 59). The new onset of type 2 diabetes mellitus and myocardial infarction were considered to be life-threatening by the investigator and were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the type 2 diabetes mellitus and myocardial infarction were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	87.3 kg	28.7 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diabetes mellitus type II	Type 2 diabetes mellitus	2004	Past
hyperopia	Hypermetropia	2005	Present
presbyopia	Presbyopia	2005	Present
gastric bypass surgery	Gastric bypass	2009	Past
benign prostate hyperplasia	Benign prostatic hyperplasia	2012	Past
prostatic surgery	Prostatic operation	2012	Past
spinal fusion	Spinal fusion surgery	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	12:28
2	BNT162b2	28AUG2020 (22)	11:08

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholelithiasis	cholelithiasis	13AUG2020 (7)		15AUG2020 (9)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (15AUG2020)	NOT RELATED/OTHER: concurrent illness	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1082 10821076, a 57-year-old white male with a pertinent medical history of type 2 diabetes mellitus (in 2004) and gastric bypass (in 2009), received Dose 1 on 07 Aug 2020 and Dose 2 on 28 Aug 2020 (Day 22). The subject was diagnosed with cholelithiasis on 13 Aug 2020, 6 days after receiving Dose 1. Concomitant medication reported within 2 weeks prior to the onset of the cholelithiasis included diphenhydramine hydrochloride (since 01 Aug 2019) as a sleep aid. On 13 Aug 2020 (Day 7), the subject experienced abdominal pain, dry heaving, and sweating, and went to the emergency room; he was hospitalized on the same day (Day 7) for cholelithiasis. The subject rated his pain as 20 on scale of "1 to 10". On 14 Aug 2020 (Day 8), the subject underwent cholecystectomy, and the cholelithiasis resolved on 15 Aug 2020 (Day 9); the subject was discharged from the hospital on the same day. In the opinion of the investigator, there was no reasonable possibility that the cholelithiasis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a concurrent illness. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181.5 cm	120 kg	36.4 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left ankle fracture	Ankle fracture	1988	Past
left ankle open reduction internal fixation	Open reduction of fracture	1988	Past
arthritis	Arthritis	2000	Present
arthritis, bilateral knee	Arthritis	2000	Past
idiopathic peripheral neuropathy	Neuropathy peripheral	2000	Present
allergy to amitriptyline	Drug hypersensitivity	2005	Past
left knee replacement	Knee arthroplasty	2013	Past
COPD	Chronic obstructive pulmonary disease	2015	Present
right knee replacement	Knee arthroplasty	2015	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	2016	Past
appendicitis	Appendicitis	2016	Past
cataracts, bilateral	Cataract	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	14:51
2	Placebo	01SEP2020 (22)	13:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	METAB	Diabetes mellitus	diabetes	05NOV2020 (87)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	Y	Yes	NOT RELATED/OTHER: etiology unknown	2	66	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1082 10821094, a 59-year-old white male with a pertinent medical history of peripheral neuropathy (since 2000) and cataract (bilateral, since 2019), received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject was diagnosed with diabetes mellitus on 05 Nov 2020, 65 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the diabetes mellitus included gabapentin (since 2018) for neuropathy. On 05 Nov 2020 (Day 87), the subject visited his primary care physician for a routine check-up, and his laboratory results showed a random blood glucose of 750 (units and normal range not reported). On the same day, the subject was hospitalized and was started on insulin glargine for diabetes mellitus. The subject was discharged on 08 Nov 2020 (Day 90). The diabetes mellitus was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the diabetes mellitus was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.15 cm	124.18 kg	36.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	1986	Present
Sleep Apnea	Sleep apnoea syndrome	2014	Present
Allergic Rhinitis-Seasonal	Seasonal allergy	2016	Present
Hypertension	Hypertension	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	12:40
2	Placebo	23SEP2020 (20)	14:51

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	New Onset Atrial Fibrillation with rapid ventricular response	26OCT2020 (53)	00:00	ONGOING		
2	GENRL	Chest pain	Chest Pain	26OCT2020 (53)	00:00	28OCT2020 (55)	00:00	3
3	CARD	Mitral valve incompetence	Trivial Mitral Regurgitation	26OCT2020 (53)	00:00	ONGOING		
4	CARD	Palpitations	Heart Palpitations	26OCT2020 (53)	00:20	28OCT2020 (55)	00:00	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: Arrhythmia	2	34	Y
2	2	TC	N	Resolved (28OCT2020)	NOT RELATED/OTHER: Arrhythmia	2	34	N
3	1	TC	N	Yes	NOT RELATED/OTHER: Heart Disease	2	34	N
4	2	TC	N	Resolved (28OCT2020)	NOT RELATED/OTHER: Arrhythmia	2	34	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1083 10831194, a 48-year-old white male with a pertinent medical history of obesity (since 1986), sleep apnea syndrome (since 2014; uses continuous positive airway pressure), and hypertension (since Jan 2020), received Dose 1 on 04 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 20). The subject was diagnosed with atrial fibrillation (new onset atrial fibrillation with rapid ventricular response) on 26 Oct 2020, 33 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the atrial fibrillation included azilsartan medoxomil/chlortalidone (from an unspecified date in 2020 to 28 Oct 2020) for hypertension. On 26 Oct 2020 (Day 53), the subject presented to the emergency room with chest pain and heart palpitations. An electrocardiogram showed atrial fibrillation without acute ST segment abnormalities, and a transthoracic echocardiography indicated atrial fibrillation and trivial mitral valve regurgitation (reported as nonserious adverse event). A chest x-ray was normal. The subject was treated with flecainide 15 mg twice a day, metoprolol succinate 12.5 mg once daily (QD), and acetylsalicylic acid 81 mg QD. On 27 Oct 2020 (Day 54) while hospitalized, the subject had a computerized tomogram angiography of the chest that showed no evidence for pulmonary embolic disease or acute cardiopulmonary abnormality. A transesophageal echocardiogram guided cardioversion was planned; however, the subject's heart rate had converted to sinus rhythm spontaneously prior to cardioversion. On 28 Oct 2020 (Study Day 55), the chest pain and heart palpitations resolved, and the subject was discharged on oral flecainide acetate 50 mg for atrial fibrillation, acetylsalicylic acid 81 mg as cardiac prophylaxis, and metoprolol succinate 25 mg for hypertension. A COVID-19 test was not performed during this hospitalization. Atrial fibrillation and mitral valve incompetence were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.7 cm	73.35 kg	27.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	1983	Present
Decreased visual acuity	Visual acuity reduced	2003	Present
spine tumor	Bone neoplasm	2004	Past
Tumor removal surgery, from spine	Spinal operation	2004	Past
Amoxicillin Allergy	Drug hypersensitivity	2005	Present
Post-Menopausal	Postmenopause	2005	Present
Seasonal Allergies	Seasonal allergy	2005	Present
Hemangioma on Liver	Haemangioma of liver	2009	Past
hemangioma removal surgery	Haemangioma removal	2009	Past

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Morphine Allergy	Drug hypersensitivity	2010	Present
benign mass from bottom of right foot removal surgery	Foot operation	2010	Past
benign mass from bottom of right foot	Limb mass	2010	Past
Tumor removal surgery, from mouth	Oral cavity neoplasm surgery	2010	Past
tumor in mouth	Oral neoplasm	2010	Past
Vertigo	Vertigo	2010	Present
Situational Depression	Adjustment disorder with depressed mood	01MAY2020	Present
Prolapsed Bladder	Bladder prolapse	01MAY2020	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	17AUG2020 (1)	16:53
2	BNT162b2	09SEP2020 (24)	13:47

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	REPRO	Ovarian cyst	Left ovarian cyst, benign tumor	24AUG2020 (8)		19SEP2020 (34)		27	2	TC/TCN	Y
2	REPRO	Uterine prolapse	Prolapsed uterus	24AUG2020 (8)		19SEP2020 (34)		27	2	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19SEP2020)	NOT RELATED/OTHER: medical condition	1	8	Y
2	Resolved (19SEP2020)	NOT RELATED/OTHER: per PI Unknown, this is second time this has happened.Documentation is in medhx	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1084 10841219, a 56-year-old white female with a pertinent medical history of bone neoplasm (spine tumor) and spinal operation (tumor removal surgery) (both in 2004); postmenopause (since 2005); hemangioma of liver and hemangioma removal (both in 2009); limb mass (benign mass from bottom of right foot), foot operation (benign mass from bottom of right foot removal surgery), oral neoplasm, and oral cavity neoplasm surgery (tumor removal surgery) (all in 2010); and bladder prolapse (since 01 May 2020), received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject was diagnosed with an ovarian cyst (left ovarian cyst, benign) and uterine prolapse on 24 Aug 2020, 7 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the ovarian cyst and uterine prolapse included naproxen sodium (since 2000) for headaches, cyclizine (since 2010) for vertigo, fish oil and vitamin D3 (both since 01 May 2020) as supplements, and bupropion (since 01 May 2020) for depression. The subject was hospitalized from 24 Aug 2020 to 25 Aug 2020 (Day 8 to Day 9) because of the ovarian cyst and uterine prolapse; both resolved on 19 Sep 2020 (Day 34). The ovarian cyst and uterine prolapse were considered to be important medical events by the investigator. In the opinion of the investigator, there was no reasonable possibility that the ovarian cyst and uterine prolapse were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.6 cm	94 kg	29.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1995	Present
hernia	Hernia	1998	Past
hernia repair	Hernia repair	1998	Past
inflammation	Inflammation	1998	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	13:47
2	BNT162b2	25SEP2020 (29)	09:24

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cellulitis	Cellulitis in Left leg	08SEP2020 (12)		16SEP2020 (20)		9	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1084 10841317, a 30-year-old white male with a pertinent medical history of drug hypersensitivity (penicillin allergy; since 1995), received Dose 1 on 28 Aug 2020 and Dose 2 on 25 Sep 2020 (Day 29). The subject was diagnosed with cellulitis in the left leg on 08 Sep 2020, 11 days after receiving Dose 1. Concomitant medication reported within 2 weeks prior to the onset of the cellulitis included a multivitamin (since 2010) as a supplement. On 08 Sep 2020 (Day 12), the subject had mild muscle aches possibly related to the study intervention and also experienced left leg swelling. On 14 Sep 2020 (Day 18), the swelling worsened and he visited the emergency room. He described the left leg swelling to be hot to the touch and inflamed with lack of sensation to the left hip. The subject worked in construction company and used knee pads at work. The subject likely sustained a cut to his knee unknowingly as he had been on his knees while working in sanitation when the incident occurred. The subject was hospitalized on the same day (Day 18) for cellulitis, which was considered to be medically significant by the investigator. He was treated with sulfamethoxazole/trimethoprim, ibuprofen, and intravenous antibiotics. No culture was performed. A computerized tomogram scan and an ultrasound test done were unremarkable. A COVID-19 nasopharyngeal swab test done on 14 Sep 2020 (Day 18) was negative. On 16 Sep 2020 (Day 20), the cellulitis resolved and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the cellulitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.5 cm	96.2 kg	33.5 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
AMOXIXILLIN ALLERGY	Drug hypersensitivity	1986	Present
BETADINE ALLERGY	Drug hypersensitivity	1986	Present
BILATERAL DECREASED VISUAL ACUITY	Visual acuity reduced	1987	Present
HEADACHES	Headache	1991	Present
GENERAL MUSCLE PAINS	Myalgia	1991	Present
SEASONAL ALLERGIES	Seasonal allergy	2000	Present
LEFT BICEP TENDON TEAR	Tendon rupture	MAR2006	Past
LEFT BICEP TENDON REPAIR	Tenoplasty	MAR2006	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ABDOMINAL HERNIA	Abdominal hernia	SEP2019	Past
ABDOMINAL HERNIA REPAIR	Abdominal hernia repair	SEP2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	12:42
2	Placebo	02NOV2020 (20)	10:16

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Acute coronary syndrome	Acute Coronary Syndrome	26OCT2020 (13)		26OCT2020 (13)		1	3	TC/TCN	N
2	CARD	Acute myocardial infarction	ST-segment elevated MYOCARDIAL INFARCTION	26OCT2020 (13)	07:30	26OCT2020 (13)	15:55	1	2	TC	Y
3	INV	Blood creatinine increased	Elevated Creatinine	26OCT2020 (13)		27OCT2020 (14)		2	1	N	N
4	METAB	Hyperglycaemia	Hyperglycemia	26OCT2020 (13)		27OCT2020 (14)		2	1	N	N
5	VASC	Hypertensive urgency	Hypertensive Urgency	26OCT2020 (13)		29OCT2020 (16)		4	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (26OCT2020)	NOT RELATED/OTHER: ST-Segment Elevated Myocardial Infarction	1	13	N
2	Resolved (26OCT2020)	NOT RELATED/OTHER: previously undiagnosed coronary artery disease	1	13	Y
3	Resolved (27OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N
4	Resolved (27OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N
5	Resolved (29OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1084 10841480, a 46-year-old white male with no pertinent medical history, received Dose 1 on 14 Oct 2020 and Dose 2 on 02 Nov 2020 (Day 20). The subject experienced an acute myocardial infarction (ST-segment elevation) on 26 Oct 2020, 12 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of an acute myocardial infarction included ibuprofen and paracetamol (both since 1991) for general muscle pain and headache, and loratadine (since 2000) for allergies. On 26 Oct 2020 (Day 13), the subject was hospitalized because of an acute myocardial infarction, which was considered to be medically significant by the investigator. On the same day (Day 13), the subject's laboratory tests revealed elevated levels of troponin I at 1.13 ng/mL and 1.25 ng/mL at 1226 hours and at 1356 hours, respectively (normal range [NR]: 0.00 - 0.04 ng/mL), creatinine at 1.4 mg/dL (NR: 0.7 - 1.3 mg/dL), and glucose at 120 mg/dL (NR: 70 - 99 mg/dL). The subject was diagnosed with acute coronary syndrome, increased blood creatinine, hyperglycemia, and hypertensive urgency (all reported as nonserious adverse events). A SARS-CoV-2 polymerase chain reaction test was negative. On 26 Oct 2020 (Day 13), the subject was treated with heparin sodium/sodium chloride, nitroglycerin/dextrose, lidocaine hydrochloride, metoprolol tartrate, nitroglycerin, sodium chloride, aluminum hydroxide/magnesium hydroxide/simethicone, atropine sulfate, and epinephrine. The subject had 2 stents placed in the left anterior descending artery. The acute coronary syndrome and acute myocardial infarction were considered resolved on 26 Oct 2020 (Day 13). The blood creatinine increased and hyperglycemia resolved on 27 Oct 2020 (Day 14) and hypertensive urgency resolved on 29 Oct 2020 (Day 16). On 29 Oct 2020 (Day 16), the subject's creatinine and glucose levels were normal at 1.3 mg/dL and 91 mg/dL, respectively. On the same day (Day 16), the subject was discharged from the hospital with prescriptions for clopidogrel 75 mg/day, acetylsalicylic acid 325 mg/day, metoprolol 25 mg twice a day, and atorvastatin 40 mg/day. In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	85.91 kg	29.6 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	1990	Present
vasectomy	Vasectomy	1996	Past
hypertension	Hypertension	2015	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	16:23
2	Placebo	23SEP2020 (24)	16:41

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Fall	Fall in hole	17OCT2020 (48)		17OCT2020 (48)		1	1
2	INJ&P	Lower limb fracture	Left leg fracture of tibia/fibula	17OCT2020 (48)		18OCT2020 (49)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (17OCT2020)	NOT RELATED/OTHER: Fall in hole	2	25	N
2	TC/TCN	Y	Resolved (18OCT2020)	NOT RELATED/OTHER: STEPPING IN HOLE	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1085 10851216, a 61-year-old white male with no pertinent medical history, received Dose 1 on 31 Aug 2020 and Dose 2 on 23 Sep 2020 (Day 24). The subject had a fall and was diagnosed with a lower limb fracture on 17 Oct 2020, 24 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of lower limb fracture included levothyroxine (since 1990) for hypothyroidism, hydrochlorothiazide/triamterene (since 2017) for hypertension, and tadalafil (since Jun 2020) for benign prostatic hyperplasia. On 17 Oct 2020 (Day 48), the subject broke his left leg after stepping in a hole while working in his yard and was subsequently hospitalized. The subject had tibia and fibula fractures, for which he underwent surgery with insertion of screws and plates on 18 Oct 2020 (Day 49). The lower limb fracture was considered resolved on the same day (Day 49). The subject was discharged from the hospital on 19 Oct 2020 (Day 50) with paracetamol. A SARS-CoV-2 test performed during the hospital stay (on 17 Oct 2020 [Day 48]) was negative, and other medical records are pending. In the opinion of the investigator, there was no reasonable possibility that the lower limb fracture was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	80	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	80.8 kg	31.6 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY TO CODEINE	Drug hypersensitivity	1970	Present
FOOD ALLERGY TO ALCOHOL	Food allergy	1980	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	1980	Present
MIGRAINE HEADACHES	Migraine	1980	Present
NAUSEA	Nausea	1980	Present
OBESITY	Obesity	1980	Present
HEARING PROBLEMS (BILATERAL EARS)	Auditory disorder	1990	Present
FOOD ALLERGY TO SHRIMP	Food allergy	1990	Present
GOUT	Gout	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERLIPIDEMIA	Hyperlipidaemia	1992	Present
HYPERTENSION	Hypertension	1992	Present
CONGESTIVE HEART FAILURE (CLASS 2)	Cardiac failure congestive	1995	Present
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	Chronic obstructive pulmonary disease	1995	Present
CORONARY ARTERY DISEASE	Coronary artery disease	1995	Present
SHORTNESS OF BREATH	Dyspnoea	1995	Present
MITRAL VALVE DISORDER	Mitral valve disease	1998	Present
ANEMIA	Anaemia	2000	Present
CHRONIC KIDNEY DISEASE (STAGE 3)	Chronic kidney disease	2000	Present
DEPRESSION	Depression	2000	Present
OSTEOARTHRITIS (BILATERAL FEET)	Osteoarthritis	2000	Present
OSTEOARTHRITIS (BILATERAL HANDS)	Osteoarthritis	2000	Present
OSTEOARTHRITIS (BILATERAL LEGS)	Osteoarthritis	2000	Present
OSTEOPOROSIS	Osteoporosis	2000	Present
POST MENOPAUSAL	Postmenopause	2000	Present
SEASONAL ALLERGIC RHINITIS	Seasonal allergy	2000	Present
SLEEP APNEA	Sleep apnoea syndrome	2005	Present
RECURRENT CONSTIPATION	Constipation	2010	Present
DIABETIC NEUROPATHY	Diabetic neuropathy	2010	Present
TYPE 2 DIABETES	Type 2 diabetes mellitus	2010	Present
TREMOR (BILATERAL ARMS)	Tremor	2016	Present
MEMORY LOSS	Amnesia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	17:04
2	BNT162b2	26AUG2020 (20)	14:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	Functional Abdominal Pain	28OCT2020 (83)		05NOV2020 (91)		9	2
2	GASTR	Diverticulum	Diverticulosis	28OCT2020 (83)		ONGOING			2
3	GENRL	Fatigue	Fatigue	31AUG2020 (25)		01SEP2020 (26)		2	1
4	HEPAT	Gallbladder disorder	Distended Gallbladder	28OCT2020 (83)		ONGOING			1
5	GASTR	Hiatus hernia	Small Hiatal Hernia	28OCT2020 (83)		ONGOING			1
6	NERV	Toxic encephalopathy	Acute Toxic Metabolic Encephalopathy	28OCT2020 (83)		05NOV2020 (91)		9	3
7	INFEC	Urinary tract infection	Urinary Tract Infection	28OCT2020 (83)		05NOV2020 (91)		9	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (05NOV2020)	NOT RELATED/OTHER: Diverticulosis	2	64	N
2	N	N	Yes	NOT RELATED/OTHER: Poor Diet	2	64	N
3	N	N	Resolved (01SEP2020)	Study Treatment	2	6	N
4	N	N	Yes	NOT RELATED/OTHER: Idiopathic	2	64	N
5	N	N	Yes	NOT RELATED/OTHER: Idiopathic	2	64	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
6	TC	Y	Resolved (05NOV2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	64	Y
7	N	N	Resolved (05NOV2020)	NOT RELATED/OTHER: Probable Bacterial Infection	2	64	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1087 10871029, an 80-year-old white female with a pertinent medical history of hypertension (since 1992); myocardial infarction (in 1995); chronic obstructive pulmonary disease, coronary artery disease, and congestive cardiac failure (all since 1995); chronic kidney disease (since 2000); type 2 diabetes mellitus and associated diabetic neuropathy (both since 2010); tremor (bilateral arms, since 2016); and amnesia (since 2018), received Dose 1 on 07 Aug 2020 and Dose 2 on 26 Aug 2020 (Day 20). The subject was diagnosed with acute toxic metabolic encephalopathy on 28 Oct 2020, 63 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of acute toxic metabolic encephalopathy included omeprazole (since 1980) for gastroesophageal reflux disease; paroxetine hydrochloride (since 2000) for depression; bisacodyl (since 2000) and macrogol 3350 (since 2010) for constipation; atorvastatin (since 2005) for hyperlipidemia; carvedilol (since 2010) and amlodipine (since 2015) for hypertension; ipratropium/albuterol, salbutamol sulfate, and fluticasone propionate/salmeterol/xinafoate (all since 2012) for chronic obstructive pulmonary disease; gabapentin (since 2016) and topiramate (from 17 Oct 2020 to 28 Oct 2020) for tremors; rivaroxaban (since 2016) as a cardiac prophylaxis; metformin (since 2018) for type 2 diabetes mellitus; magnesium (since 2019) for cramps; and donepezil (since May 2019) for memory loss. On 28 Oct 2020 (Day 83), the subject had abdominal pain, diarrhea, vomiting, confusion, and possible urinary tract infection (UTI) and went to the emergency room. The subject was hospitalized on the same day (Day 83) and was also diagnosed with deep vein thrombosis, diverticulum, gallbladder disorder, and hiatus hernia (reported as nonserious adverse events). The subject was treated with intravenous antibiotics for the UTI. The subject's laboratory results during this hospitalization showed low albumin of 3.2 g/L, total protein of 6.2 IU, total bilirubin of 0.3, alanine aminotransferase of 11, aspartate aminotransferase of 16, and alkaline phosphatase of 102 (units and normal ranges not provided) on 30 Oct 2020 (Day 85); on 01 Nov 2020 (Day 87), the subject's hemoglobin was 13.4 g, hematocrit was 41.8%, mean cell volume was 92.5 fL, platelet count was 303/mm3, sodium was 140 mEq/L, potassium was 4.4 mEq/L, chloride was high at 111 mEq/L, carbon dioxide was 22.2 ppm, and anion gap was 7 mEq/L; white blood cell count was 9.3, creatinine was 0.96, glomerular filtration rate was 56, blood urea nitrogen was 11, glucose was high at 148, and calcium was 9.8 (units and normal ranges not provided). A SARS-CoV-2 test performed while in the hospital was negative. On 05 Nov 2020 (Study Day 91), the acute toxic metabolic encephalopathy, UTI, and abdominal pain were considered resolved and the subject was discharged from the hospital on an unknown date. The diverticulum, gallbladder disorder, and hiatus hernia were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the acute toxic metabolic encephalopathy was related to the study intervention, or clinical trial procedures, but rather it was related to the concomitant medication-topiramate. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	78.8 kg	33.9 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	1985	Present
CHRONIC BACK PAIN	Back pain	1995	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	1995	Present
TRAUMATIC BRAIN INJURY	Craniocerebral injury	2000	Present
GLAUCOMA	Glaucoma	2005	Present
POST-MENOPAUSAL	Postmenopause	2005	Present
ALLERGY TO NUCYNTA	Drug hypersensitivity	2010	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	15:37
2	Placebo	01SEP2020 (22)	14:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute coronary syndrome	ACUTE CORONARY SYNDROME	08SEP2020 (29)		10SEP2020 (31)		3	3
2	CARD	Angina unstable	UNSTABLE ANGINA	08SEP2020 (29)		10SEP2020 (31)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (10SEP2020)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	8	Y
2	N	N	Resolved (10SEP2020)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	22SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1087 10871070, a 59-year-old white female with a pertinent medical history of hypertension (since 1985), hypercholesterolemia (since 1995), craniocerebral injury (since 2000), coronary artery disease (since 2012) with stent placement (in Aug 2012, Jan 2015, 06 Jan 2020, and to mid distal left circumflex artery in Jul 2020), and peripheral neuropathy and angina pectoris (both since 2012), received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject was diagnosed with an acute coronary syndrome on 08 Sep 2020, 7 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the acute coronary syndrome included clopidogrel bisulfate and aspirin (both since 2012) and ranolazine (since 11 Aug 2020) all for coronary artery disease, isosorbide mononitrate and glyceryl trinitrate (both since 2012) both for angina. Other medications included: latanoprost (since 1995) for glaucoma, atorvastatin (since 2000) for hypercholesterolemia, escitalopram oxalate and lamotrigine (both since 2000) for brain injury, diltiazem (since 2005) for hypertension, fentanyl and oxycodone (both since 2010) and lidocaine (since 2012) all for chronic back pain, salbutamol (since 2012) for asthma, amitriptyline (since 2012) for neuropathy, clonazepam (since 2012) for anxiety, diphenhydramine hydrochloride (since 2012) for seasonal allergic rhinitis, estradiol/norethisterone acetate (since 2012) for hot flashes, gabapentin (since 2012) for neuropathy, lansoprazole (since 2012) for gastroesophageal reflux disease, methyl naltrexone (since 2012) for constipation, terbinafine (since 2012) for athlete's feet, trazodone (since 2012) for depression, and valacyclovir hydrochloride (since 2012) for cold sores. On 08 Sep 2020 (Day 29), the subject experienced chest pain and shortness of breath, and presented to the emergency room. The subject was hospitalized on the same day and a left heart catheterization with coronary angiography revealed change in coronary artery disease as well as mild elevation in left ventricular end-diastolic pressure and left ventricular function. The acute coronary syndrome was considered resolved on 10 Sep 2020 (Day 31) and the subject was discharged on the same day. The subject was started on carvedilol 12.5 mg twice a day (BID) that was titrated up to 25 mg BID and furosemide 20 mg once daily (both since 11 Sep 2020). A COVID-19 test was not performed during the hospitalization. In the opinion of the investigator, there was no reasonable possibility that the acute coronary syndrome was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.9 cm	127.7 kg	38.2 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEEP VEIN THROMBOSIS	Deep vein thrombosis	1994	Present
ALLERGY TO CODEINE	Drug hypersensitivity	2010	Present
ALLERGY TO CORTISONE	Drug hypersensitivity	2010	Present
CHRONIC BACK PAIN	Back pain	2018	Present
HYPERTENSION	Hypertension	2018	Present
NEUROPATHY (BILATERAL LEGS)	Neuropathy peripheral	2018	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	11:14
2	BNT162b2	09SEP2020 (20)	16:59

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pharyngitis streptococcal	STREP THROAT	01SEP2020 (12)		05SEP2020 (16)		5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (05SEP2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1087 10871150, a 71-year-old black/African American male with a pertinent medical history of drug hypersensitivity (allergy to codeine and cortisone; both since 2010), received Dose 1 on 21 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 20). The subject was diagnosed with Streptococcal pharyngitis on 01 Sep 2020, 11 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of Streptococcal pharyngitis included warfarin (since 1994) for deep vein thrombosis, testosterone cipionate (since 2017) for low energy, gabapentin (since 2018) for neuropathy, lisinopril and metoprolol succinate (both since 2018) for hypertension, oxycodone hydrochloride/paracetamol (since 2018) for chronic back pain, atorvastatin (since 2019) for hypercholesterolemia, and fish oil (since Feb 2020) as a dietary supplement. On 09 Sep 2020 (Day 20), during Visit 2, the subject reported that he was hospitalized for strep throat on 01 Sep 2020 (Day 12). The subject reported that he was feeling better and his condition was stabilized after treatment with unspecified antibiotics. The streptococcal pharyngitis was reported to be resolved on 05 Sep 2020 (Day 16) and the subject was discharged from the hospital on the same day. The subject also stated he was tested for COVID-19 while in the hospital and the results were negative. In the opinion of the investigator, there was no reasonable possibility that the Streptococcal pharyngitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	76.4 kg	27.4 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headaches	Headache	2009	Present
allergic rhinitis	Rhinitis allergic	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	10:08
2	BNT162b2	09OCT2020 (22)	13:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Meningioma	right frontal meningioma	23SEP2020 (6)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	1	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1088 10881220, a 49-year-old white female with a pertinent medical history of headache (since 2009) and cognitive disorder (since Jun 2020), received Dose 1 on 18 Sep 2020 and Dose 2 on 09 Oct 2020 (Day 22). The subject was diagnosed with right-sided frontal meningioma on 23 Sep 2020, 5 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the right-sided frontal meningioma included ethinylestradiol/etonogestrel (since 1990) for contraception, montelukast sodium and fexofenadine hydrochloride (both since 2015) both for allergic rhinitis, topiramate (since 2017) for headaches, and atorvastatin (since 2018) for hyperlipidemia. The subject reported cognitive issues and was diagnosed with a right-sided frontal meningioma. The meningioma was considered medically significant by the investigator. Relevant tests performed were unknown. The right-sided frontal meningioma was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the right-sided frontal meningioma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	98.55 kg	27.8 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1953	Past
tonsillitis	Tonsillitis	1953	Past
left knee arthroscopy	Arthroscopy	1991	Past
osteoarthritis	Osteoarthritis	1991	Present
vasectomy	Vasectomy	1991	Past
gastroparesis	Impaired gastric emptying	1995	Present
dizziness	Dizziness	2000	Present
left knee arthroscopy	Arthroscopy	2001	Past
right knee arthroscopy	Arthroscopy	2001	Past

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
elevated cholesterol	Blood cholesterol increased	2010	Present
right knee arthroscopy	Arthroscopy	2015	Past
hypertension	Hypertension	2015	Present
stroke	Cerebrovascular accident	2017	Past
watchman installed	Atrial appendage closure	2018	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	19AUG2020 (1)	10:39
2	Placebo	09SEP2020 (22)	12:35

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Atrial fibrillation	Chronic atrial fibrillation with RVR'	04OCT2020 (47)		05OCT2020 (48)		2	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (05OCT2020)	NOT RELATED/OTHER: subject is 71 years old and susceptible to heart issues	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	01OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1089 10891150, a 71-year-old multiracial male with a pertinent medical history of impaired gastric emptying (since 1995); dizziness (since 2000); increased blood cholesterol (since 2010); hypertension (since 2015); atrial appendage closure (in 2018); and atrial flutter and cardioversion (since unknown dates), received Dose 1 on 19 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 22). The subject was diagnosed with atrial fibrillation on 04 Oct 2020, 25 days after receiving Dose 2. On 07 Oct 2020 (Day 50), the subject informed the site that he experienced atrial fibrillation with rapid ventricular response on 04 Oct 2020 (Day 47), was evaluated in emergency room and subsequently hospitalized. The subject was treated with intravenous diltiazem drip (from 04 Oct 2020 to 05 Oct 2020). His heart condition did not improve and his blood pressure was reported as “soft” (clarification of this description is unavailable). The subject was seen by a cardiologist and required cardioversion to achieve a normal sinus rhythm. The atrial fibrillation was considered resolved on 05 Oct 2020 (Day 48) and he was discharged from the hospital on the same day. He was scheduled to follow-up with electrophysiology for possible ablation. In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to age and underlying cardiac disease. Pfizer concurred with the investigator’s causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	68.27 kg	23.5 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
abdominal surgery	Abdominal operation		Past
arthritis	Arthritis		Present
asthma	Asthma		Present
Atrial Fibrillation	Atrial fibrillation		Present
Lymph node biopsy	Biopsy lymph gland		Past
stroke	Cerebrovascular accident		Past
undescended testicle right	Cryptorchism		Past
amoxicillin drug allergy	Drug hypersensitivity		Present
codeine drug allergy	Drug hypersensitivity		Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
erythromycin drug allergy	Drug hypersensitivity		Present
penicillin drug allergy	Drug hypersensitivity		Present
beans food allergy	Food allergy		Present
hernia repair	Hernia repair		Past
hypertension	Hypertension		Present
funnel chest	Pectus excavatum		Present
PTSD	Post-traumatic stress disorder		Present
Seizure disorder	Seizure		Present
testicle exploration right	Testes exploration		Past
borderline personality disorder	Borderline personality disorder	2014	Present
COPD	Chronic obstructive pulmonary disease	17DEC2014	Present
schizophrenia	Schizophrenia	03NOV2017	Present
Polysubstance Abuse	Substance abuse	17AUG2018	Present
skin rash	Rash	27JUL2020	Present
left hand fracture	Hand fracture	12AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	14:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Chronic obstructive pulmonary disease	worsening of COPD	26AUG2020 (2)		27AUG2020 (3)		2	2
2	INJ&P	Fall	Fall	09SEP2020 (16)	03:00	09SEP2020 (16)	03:00	1	2
3	INJ&P	Hip fracture	Left Hip Closed Fracture	09SEP2020 (16)	03:00	25SEP2020 (32)		17	3
4	GASTR	Nausea	nausea	27SEP2020 (34)		28SEP2020 (35)		2	2
5	PSYCH	Psychotic disorder	Psychosis	27SEP2020 (34)		ONGOING			3
6	PSYCH	Substance abuse	worsening of polysubstance abuse	27SEP2020 (34)		28SEP2020 (35)		2	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (27AUG2020)	NOT RELATED/OTHER: Med HX of COPD	1	2	N
2	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: fall from dumpster	1	16	N
3	TC	Y	Resolved (25SEP2020)	NOT RELATED/OTHER: Fall	1	16	Y
4	N	N	Resolved (28SEP2020)	NOT RELATED/OTHER: subject detoxing from substance use	1	34	N
5	TC/TCN	Y	Yes	NOT RELATED/OTHER: Hx of mental disorders	1	34	Y
6	N	N	Resolved (28SEP2020)	NOT RELATED/OTHER: medical history of polysubstance abuse	1	34	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1089 10891182, a 47-year-old white male with a pertinent medical history of stroke, post-traumatic stress disorder, and seizures (since unknown dates), borderline personality disorder (since 2014), schizophrenia (since 03 Nov 2017), substance abuse (since 17 Aug 2018), and hand fracture (on 12 Aug 2020), received Dose 1 on 25 Aug 2020. The subject was diagnosed with a hip fracture on 09 Sep 2020, 15 days after receiving Dose 1 and a psychotic disorder (psychosis) on 27 Sep 2020, 33 days after receiving Dose 1. On 09 Sep 2020 (Day 16), the subject had a fall that caused a left hip closed fracture requiring hospitalization. No relevant tests were reported. On 25 Sep 2020 (Day 32), the hip fracture was considered resolved and the subject was discharged from the hospital on the same day. On 27 Sep 2020 (Day 34), the subject reported nausea and substance abuse (reported as nonserious adverse events) and was hospitalized because of psychosis. The subject was treated with lorazepam 2 mg intravenously once, followed by 1 mg orally on 28 Sep 2020 (Day 35). On the same day (Day 35), the nausea and substance abuse were considered resolved and the subject was transferred to a psychiatric facility on 28 Sep 2020 (Day 35) for additional care. The psychosis was ongoing at the time of the last available report. A SARS-CoV-2 test was negative during the hospitalization. In the opinion of the investigator, there was no reasonable possibility that the hip fracture and psychotic disorder were related to the study intervention, concomitant medications, or clinical trial procedures; the hip fracture was related to a fall and the psychotic disorder was likely related to the subject's underlying psychiatric history. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	102 kg	33.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Prostate Cancer	Prostate cancer	1988	Past
Sleep Apnea	Sleep apnoea syndrome	1990	Present
Chronic Myeloid Leukemia	Chronic myeloid leukaemia	1991	Present
Hypertension	Hypertension	2000	Present
Elevated Lipids	Lipids increased	2019	Present
chronic kidney disease, mild	Chronic kidney disease	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	13:30
2	Placebo	21SEP2020 (20)	10:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	IMMUN	Anaphylactic shock	anaphylactic shock	09OCT2020 (38)		09OCT2020 (38)		1	4
2	INJ&P	Arthropod bite	ant bite, left ankle	09SEP2020 (8)	15:00	10SEP2020 (9)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: anaphylactic shock to ant bite	2	19	Y
2	N	N	Resolved (10SEP2020)	NOT RELATED/OTHER: NA	1	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901300, a 68-year-old white male with a pertinent medical history of sleep apnea syndrome (since 1990), chronic myeloid leukemia (since 1991), hypertension (since 2000), and chronic kidney disease (since Aug 2019), received Dose 1 on 02 Sep 2020 and Dose 2 on 21 Sep 2020 (Day 20). The subject was diagnosed with anaphylactic shock on 09 Oct 2020, 18 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the anaphylactic shock included lisinopril, hydrochlorothiazide, and amlodipine (all since 2010) all for hypertension; citalopram (since 2010) for depression; imatinib (since 2015) as a prophylaxis for chronic myeloid leukemia; and atorvastatin (since Aug 2019) for elevated lipids. On 09 Oct 2020 (Day 38), the subject went to an emergency room because of tongue and throat swelling in response to an ant bite on his left ankle. The subject also reported a small red spot associated with itching for a short time. The subject was treated with epinephrine, intravenous prednisone, and diphenhydramine. The symptoms resolved 90 minutes after treatment; however, the subject was kept overnight for observation and monitored for 20 hours. The anaphylactic shock was considered resolved on 09 Oct 2020 (Day 38), and he was discharged from the hospital on 10 Oct 2020 (Day 39). The subject continued to receive prednisone until 15 Oct 2020 (Day 44). The anaphylactic shock was considered medically significant and life-threatening by the investigator. In the opinion of the investigator, there was no reasonable possibility that the anaphylactic shock was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the ant bite. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	84.6 kg	25.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1976	Present
chest pain	Chest pain	2008	Past
cyst in esophagus	Oesophageal cyst	2008	Past
removal of esophageal cyst	Oesophageal lesion excision	2008	Past
DVT	Deep vein thrombosis	2017	Past
restless leg syndrome	Restless legs syndrome	2017	Present
depression	Depression	OCT2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	11:43
2	Placebo	17SEP2020 (21)	10:02

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Diarrhoea	Diarrhea	17SEP2020 (21)		03OCT2020 (37)		17	1
2	RESP	Hypoxia	hypoxia	26SEP2020 (30)		27SEP2020 (31)		2	3
3	RESP	Nasal congestion	nasal congestion	10OCT2020 (44)		17OCT2020 (51)	10:00	8	1
4	RESP	Pneumonia aspiration	Aspiration Pneumonia	26SEP2020 (30)		06OCT2020 (40)		11	3
5	INJ&P	Toxicity to various agents	poisoning by cocaine	26SEP2020 (30)		27SEP2020 (31)		2	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (03OCT2020)	Study Treatment	2	1	N
2	TC/TCN	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: opioid overdose	2	10	Y
3	N	N	Resolved (17OCT2020)	NOT RELATED/OTHER: environmental irritant	2	24	N
4	TC	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: poisoning by cocaine	2	10	Y
5	TC/TCN	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: substance abuse	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1091 10911197, a 54-year-old black/African American male with a pertinent medical history of seasonal allergy (since 1976) and chest pain (in 2008), received Dose 1 on 28 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 21). The subject was diagnosed with hypoxia, aspiration pneumonia, and toxicity to various agents (poisoning by cocaine) on 26 Sep 2020, 9 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of hypoxia, aspiration pneumonia, and toxicity to various agents included multivitamins (since Aug 2019) as supplements, gabapentin (from 2019 to 06 Oct 2020) for restless leg syndrome, and escitalopram oxalate and aripiprazole (since Oct 2019) both for depression. The subject informed the site via a phone call that on 26 Sep 2020 (Day 30), he had chills and vomiting and was found unresponsive and pulseless. Emergency medical services performed cardiopulmonary resuscitation, intubated him and administered naloxone hydrochloride 4 mg. He regained consciousness and transported to the emergency room. Once he regained consciousness, the subject was admitted to using cocaine and inhaling fentanyl; but denied daily use of opioids. He also denied having chest pain, dyspnea, fever, cough, sputum, abdominal pain, vomiting, or diarrhea prior to the overdose. A drug screening in the ER was positive for cocaine and tetrahydrocannabinol. The subject received multiple additional doses of naloxone hydrochloride in the ER and a chest x-ray showed fluid around his lungs suggestive of pneumonia. The subject was hospitalized on the same day (Day 30). Relevant laboratory tests included procalcitonin of <0.05 ng/mL (normal range [NR]: <0.50 ng/mL), high alcohol levels of 0.16 g/dL (NR: 0-0 g/dL); SARS-CoV-2 test was negative. On 27 Sep 2020 (Day 31), a computed tomography angiography of chest showed multifocal patchy nonspecific ground glass densities in both the lungs suggestive of aspiration pneumonia. A repeat chest x-ray on 27 Sep 2020 (Day 31) showed no findings of active cardiopulmonary disease. An electrocardiogram on the same day (Day 31) showed normal sinus rhythm and his troponin I level was <0.03 ng/mL (NR: <0.06 ng/mL). During the hospitalization, the subject was treated with atropine 1 mg/mL as needed (PRN), ipratropium bromide/salbutamol sulfate 3 mL inhalation (INH) every 4 hours, nicotine patch 14 mg/24 hour once a day (QD), glyceryl trinitrate 0.4 mg sublingual PRN, oxygen INH QD, sodium chloride 0.9% IV 1000 mL, paracetamol 650 mg 2 tabs PO PRN, paracetamol 650 mg one suppository rectal PRN, and ondansetron 4 mg PRN. On 27 Sep 2020 (Day 31), the hypoxia and toxicity to various agents (poisoning by cocaine) were considered resolved and the subject was discharged from the hospital. Discharge medications included aripiprazole 2 mg QD, amoxicillin-clavulanate 875/125 mg 1 tablet every 12 hours, escitalopram 20 mg QD, fluticasone 0.05 mg/INH, and gabapentin 600 mg TID. On 06 Oct 2020 (Day 40), the aspiration pneumonia was considered resolved. In the opinion of the investigator, there was no reasonable possibility that the hypoxia, toxicity to various agents, and aspiration pneumonia were related to the study intervention, concomitant medications, or clinical trial procedure, but rather to the opioid overdose and other substance abuse. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.3 cm	87.5 kg	33.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
broken jaw repair surgery	Fracture treatment	1992	Past
Broken jaw	Jaw fracture	1992	Past
occasional migraines	Migraine	1995	Present
allergic rhinitis	Rhinitis allergic	2000	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2005	Past
Bilateral carpal tunnel release	Carpal tunnel decompression	2011	Past
menorrhagia	Menorrhagia	2015	Past
Reduction Mammoplasty (breast reduction)	Mammoplasty	DEC2018	Past
endometrial ablation	Endometrial ablation	DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	10:48
2	BNT162b2	06OCT2020 (22)	09:32

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Appendicitis	Appendicitis	22OCT2020 (38)		23OCT2020 (39)	05:00	2	4	TCN
2	GENRL	Chills	Chills	06OCT2020 (22)	21:30	07OCT2020 (23)	08:00	2	1	N
3	GENRL	Injection site pain	Injection Site Pain	06OCT2020 (22)	13:00	07OCT2020 (23)		2	1	N
4	GENRL	Injection site pain	soreness at injection site	16SEP2020 (2)		17SEP2020 (3)		2	1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (23OCT2020)	NOT RELATED/OTHER: Inflammation of Appendix, Unknown Cause	2	17	Y
2	N	Resolved (07OCT2020)	Study Treatment	2	1	N
3	N	Resolved (07OCT2020)	Study Treatment	2	1	N
4	N	Resolved (17SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	27OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1091 10911300, a 46-year-old white female with no pertinent medical history, received Dose 1 on 15 Sep 2020 and Dose 2 on 06 Oct 2020 (Day 22). The subject was diagnosed with appendicitis on 22 Oct 2020, 16 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the appendicitis included cetirizine (since 2000) for allergic rhinitis. On 22 Oct 2020 (Day 38), the subject experienced a rapid onset of right-sided lower abdominal pain and went to the emergency room. A computerized tomogram of the abdomen and pelvis showed acute appendicitis without evidence of collection or perforation and scattered colonic diverticula without inflammatory changes. Laboratory tests showed a white blood cell count of 1.50 × 103/mm3 (normal range [NR]: 4.0-10.5 × 103/mm3), absolute neutrophils of 10.3 × 103/mm3 (NR: 2.0-7.3 × 103/mm3), and alanine aminotransferase of 58 U/µL (NR: 7 - 52 U/µL). She was not hospitalized as all the hospital beds were full at the facility. The subject underwent a laparoscopic appendectomy without any complications and was released from the operating room with prescriptions of docusate and oxycodone/acetaminophen, the next day (Day 39). On 23 Oct 2020 (Day 39), the appendicitis resolved. The appendicitis was considered medically significant by the investigator. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.96 cm	85.82 kg	29 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
environmental allergies	Hypersensitivity	1952	Present
seasonal allergies	Seasonal allergy	1952	Present
umbilical hernia	Umbilical hernia	1955	Past
Myopia	Myopia	JUN1962	Present
tonsillitis	Tonsillitis	JUN1962	Past
appendicitis	Appendicitis	JUN1968	Past
dyslipidemia	Dyslipidaemia	JUN1988	Present
hypertension	Hypertension	JUN1988	Present
inguinal hernia	Inguinal hernia	2011	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
basal cell carcinoma right shoulder	Basal cell carcinoma	2012	Past
actinic keratosis	Actinic keratosis	JUN2013	Present
plantar fasciitis in the right foot	Plantar fasciitis	JUN2017	Past
basal cell carcinoma on nose	Basal cell carcinoma	AUG2018	Past
gastro esophageal reflux disease	Gastrooesophageal reflux disease	JUN2019	Present
basal cell carcinoma on nose	Basal cell carcinoma	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	15:54
2	BNT162b2	06OCT2020 (49)	14:30

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Atrial fibrillation	Arrhythmia atrial fibrillation	26AUG2020 (8)		27AUG2020 (9)		2	2	TC	Y
2	INV	Troponin increased	Elevated troponin	26AUG2020 (8)		26AUG2020 (8)		1	1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (27AUG2020)	NOT RELATED/OTHER: medical records being reviewed not able to answer at this time.	1	8	Y
2	Resolved (26AUG2020)	NOT RELATED/OTHER: Unknown	1	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1092 10921015, a 68-year-old white male with a pertinent medical history of hypertension and dyslipidemia (since Jun 1988), received Dose 1 on 19 Aug 2020 and Dose 2 on 06 Oct 2020 (Day 49). The subject was diagnosed with atrial fibrillation on 26 Aug 2020, 7 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the atrial fibrillation included multivitamins (since 1995), ubidecarenone and fish oil (both, since 2000), ascorbic acid/chondroitin sulfate sodium/collagen/glucosamine sulfate/manganese (since Mar 2020) and ergocalciferol (since Jun 2020) all as supplements; atorvastatin (since 1998) for dyslipidemia; azelastine and mometasone furoate (both since 2000) for allergies; omeprazole (since Jun 2019) for gastroesophageal reflux disease; and valsartan (since 25 Jul 2019) for hypertension. On 26 Aug 2020 (Day 8), the subject presented to the emergency department with dizziness, tachycardia, and a rapid heartbeat with the highest rate of 167 beats per minute (bpm) recorded at 0900 hours. The subject reported that he had not experienced such symptoms in the past. At the bedside, he had palpitations and experienced light headedness while standing; however, he denied chest pain, shortness of breath, fever, chills, nausea, vomiting, or any exacerbating or mitigating factors. The subject was hospitalized for 1 day (Day 8), and pertinent laboratory tests and imaging studies were reviewed. An electrocardiogram showed atrial fibrillation with a heart rate of 171 bpm with no acute changes. The atrial fibrillation with rapid ventricular response persisted for about 8 hours on telemetry. The subject was treated with diltiazem 10 mg intravenously and 125 mg in sodium chloride 0.9% 125 mL infusion bag. He did not undergo conversion. His initial troponin value was elevated at 92, which was later noted to be 88 (unit and normal range not provided) and troponin I value was elevated at 343 ng/L (normal range [NR]: <20 ng/L). On the same day (Day 8), the elevated troponin resolved. On 27 Aug 2020 (Day 9), his laboratory test results showed blood glucose of 102 mg/dL (high; NR: 70-99 mg/dL), low hemoglobin of 13.1 g/dL (NR: 13.5-16.5 g/dL), low hematocrit of 37.5% (NR: 40%-50%), low red blood cells of 4.19×106/mm3 (NR: 4.40-5.80 ×106/mm3), and low mean platelet volume of 6.5 fL (NR: 7.4-11.5 fL). The subject was treated with heparin and aspirin. Additional treatment included apixaban 5 mg twice a day and flecainide acetate 50 mg as needed. The atrial fibrillation was considered resolved on 27 Aug 2020 (Day 9) and the subject was discharged from the hospital on that same day in stable condition and in normal sinus rhythm. Upon follow-up on 09 Sep 2020 (Day 22), it was reported that there was no recurrence of atrial fibrillation. Dose 2 was delayed because of pending clearance from his cardiologist. In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	91 kg	33.8 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
postmenopausal	Postmenopause	2003	Present
Gastric Bypass	Gastric bypass	2007	Present
dyslipidemia	Dyslipidaemia	2010	Present
hypertension	Hypertension	2010	Present
type 2 diabetes	Type 2 diabetes mellitus	2010	Present
Lap Band procedure	Gastric banding	2012	Present
gastro esophageal reflux disease	Gastrooesophageal reflux disease	2015	Present
anxiety	Anxiety	2018	Present
Hernia repair	Hernia repair	26JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	10:03
2	Placebo	19OCT2020 (49)	09:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	Epigastric Pain	07OCT2020 (37)	21:30	08OCT2020 (38)	17:30	2	3
2	GASTR	Chronic gastritis	Chronic Focally Active Gastritis	07OCT2020 (37)		ONGOING			2
3	EYE	Eye swelling	Swelling of eyes	17SEP2020 (17)		18SEP2020 (18)		2	2
4	GASTR	Lip swelling	Swelling of lip	17SEP2020 (17)		18SEP2020 (18)		2	2
5	SKIN	Urticaria	Hives (Urticaria)	17SEP2020 (17)		18SEP2020 (18)		2	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: Gastric Pouch distention	1	37	Y
2	N	N	Yes	NOT RELATED/OTHER: Unknown	1	37	N
3	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N
4	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N
5	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1092 10921123, a 67-year-old white female with a pertinent medical history of postmenopause (since 2003); gastric bypass (since 2007); type 2 diabetes mellitus, hypertension, and dyslipidemia (all since 2010); gastric banding (since 2012); and gastroesophageal reflux disease (GERD, since 2015); anxiety (since 2018); hernia and hernia repair (both on 26 Jun 2020); and obesity (since 01 Sep 2020), received Dose 1 on 01 Sep 2020 and Dose 2 on 19 Oct 2020 (Day 49). The subject reported upper abdominal pain on 07 Oct 2020, 36 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the upper abdominal pain included multivitamin (since 1995), calcium (since 2010), magnesium oxide and colecalciferol (both since 2015) all as supplements; clonidine, benazepril hydrochloride/hydrochlorothiazide (since Aug 2005), acetylsalicylic acid (from Aug 2010 to 02 Oct 2020) and amlodipine besilate (since Aug 2015) all for hypertension; metformin hydrochloride (since Aug 2007), pioglitazine hydrochloride and glimepiride (both since 2010) for type 2 diabetes mellitus; pravastatin sodium (since 2010) for dyslipidemia; omeprazole (since Aug 2015) for GERD, venlafaxine hydrochloride (since 2018) for anxiety; and hydroxyzine hydrochloride and famotidine (both since 02 Oct 2020) for hives. On 07 Oct 2020 (Day 37), the subject experienced upper abdominal pain and was taken to the emergency room on 08 Oct 2020 (Day 38). On the same day (Day 38), a SARS-CoV-2 nucleic acid amplification test was negative, a computerized tomogram (CT) of the abdomen showed no adhesions or obstruction, and a definitive cause of the pain was not found. An abdominal and pelvic CT with contrast showed left renal cysts, diverticulosis, internal distension of gastric pouch, simple left ovarian cyst, elongated fluid collection, and obstruction at the level of the gastro-jejunostomy was noted. The subject underwent upper endoscopy. Based on the esophagogastroduodenoscopy and CT scan findings, a stricture was ruled out. A gastric pouch biopsy later confirmed chronic gastritis and was negative for Helicobacter pylori. During her hospitalization she was treated with hydromorphone intravenous (IV) drip, enalapril IV for blood pressure control, enoxaparin sodium for deep vein thrombosis prophylaxis, and metoclopramide IV to promote gastrointestinal motility. On 08 Oct 2020 (Day 38), the upper abdominal pain resolved and the subject was discharged from the hospital on 09 Oct 2020 (Day 39) and advised to discontinue hydromorphone. The chronic gastritis was ongoing at the time of the last available report. The investigator considered there was a reasonable possibility that the upper abdominal pain was related to concomitant medication-metformin, but unrelated to study intervention or clinical trial procedure. The cause of the epigastric pain was the gastric pouch distention. Pfizer did not concur with the investigator's causality of concomitant medication, but instead considered the upper abdominal pain as most likely coincidental and associated with the underlying clinical conditions (past surgery).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	134.64 kg	40.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
type 2 diabetes	Type 2 diabetes mellitus	2003	Present
asthma Controlled	Asthma	2004	Present
seasonal allergies	Seasonal allergy	2005	Present
obesity	Obesity	2010	Present
dyslipidemia	Dyslipidaemia	MAY2010	Present
hypertension	Hypertension	SEP2010	Present
transient ischemic attack	Transient ischaemic attack	06DEC2013	Past
insomnia	Insomnia	2017	Present
coronary artery bypass graft	Coronary artery bypass	10JAN2020	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
coronary artery disease	Coronary artery disease	10JAN2020	Present
atrial fibrillation	Atrial fibrillation	06JUL2020	Present
insertion of intra-cardiac defibrillator	Implantable defibrillator insertion	06JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	11:06
2	BNT162b2	06OCT2020 (22)	10:49

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Cardiac failure congestive	Congestive heart failure	01OCT2020 (17)	01:00	03OCT2020 (19)		3	2	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (03OCT2020)	NOT RELATED/OTHER: Progression of cardiovascular disease	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	03NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1092 10921187, a 72-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 2003), asthma (since 2004), obesity (since 2010), dyslipidemia (since May 2010), hypertension (since Sep 2010), transient ischemic attack (since 06 Dec 2013), coronary artery disease (since 10 Jan 2020), status post coronary artery bypass (on 10 Jan 2020), atrial fibrillation (since 06 Jul 2020), and implantable defibrillator insertion (on 06 Jul 2020), received Dose 1 on 15 Sep 2020 and Dose 2 on 06 Oct 2020 (Day 22). The subject was diagnosed with congestive cardiac failure on 01 Oct 2020, 16 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the congestive cardiac failure included acetylsalicylic acid (since 2019) and furosemide sodium (since Jan 2020) for coronary artery disease; salbutamol sulfate (since 2004) for asthma; metformin (since 2007) and human insulin (since Jun 2018) for type 2 diabetes mellitus; atorvastatin (since 2010) for dyslipidemia; amitriptyline hydrochloride (since 2017) for insomnia; and potassium chloride (since Jan 2020) as a supplement;. On 01 Oct 2020 (Day 17), the subject woke up with severe shortness of breath and was taken to the emergency department via ambulance. He reported progressive shortness of breath over the prior 2 days, pain while taking a deep breath, but denied chest pain, fever, chills, abdominal pain, nausea, vomiting, or diarrhea. The subject was diagnosed with congestive heart failure (CHF) and the shortness of breath was attributed to the CHF. The subject was hospitalized in the coronavirus disease (COVID-19) unit and a SARS-CoV-2 test was negative on 02 Oct 2020 (Day 18). The subject was placed on oxygen therapy and furosemide sodium dose was increased to 40 mg once daily. On 03 Oct 2020 (Day 19), the congestive cardiac failure was considered to be resolved, and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the congestive cardiac failure was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the progression of cardiovascular disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	26	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.8 cm	90.9 kg	27.2 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1995	Present
Eczema	Eczema	1995	Present
Seasonal allergies	Seasonal allergy	1995	Present
Inguinal hernia	Inguinal hernia	1998	Past
Inguinal hernia repair	Inguinal hernia repair	1998	Past
Diabetes Type II	Type 2 diabetes mellitus	2011	Present
wisdom teeth removal	Wisdom teeth removal	2013	Past
Anxiety	Anxiety	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	11:21
2	Placebo	10NOV2020 (47)	11:21

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Colon injury	colon injury	16OCT2020 (22)		23OCT2020 (29)		8	3
2	INJ&P	Road traffic accident	motor vehicle accident	16OCT2020 (22)		16OCT2020 (22)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (23OCT2020)	NOT RELATED/OTHER: Motor vehicle accident	1	22	Y
2	N	N	Resolved (16OCT2020)	NOT RELATED/OTHER: driving accident	1	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1094 10941155, a 26-year-old white male with a pertinent medical history of inguinal hernia and status post inguinal hernia repair (in 1998) and type 2 diabetes mellitus (since 2011), received Dose 1 on 25 Sep 2020 and Dose 2 on 10 Nov 2020 (Day 47). The subject reported a colon injury on 16 Oct 2020, 21 days after receiving Dose 1. On 16 Oct 2020 (Day 22), the subject was involved in a motor vehicle accident while driving to the clinic for Visit 2. The subject was hospitalized and found to have a colon injury due to the trauma he sustained during the accident, which required colostomy. On 23 Oct 2020 (Day 29), the colon injury resolved with a new longstanding colostomy, and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the colon injury was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the motor vehicle accident. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	99.3 kg	33 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
congenital jaw misalignment	Congenital jaw malformation	(b) (6) 1954	Past
tonsillectomy	Tonsillectomy	1965	Past
tonsillitis	Tonsillitis	1965	Past
hepatitis B	Hepatitis B	1981	Past
migraines	Migraine	1985	Present
jaw surgery- fix misalignment	Jaw operation	2000	Past
mitral valve prolapse	Mitral valve prolapse	2005	Present
postmenopausal symptoms	Menopausal symptoms	2009	Present
seasonal allergies	Seasonal allergy	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cartilage deterioration (both knees)	Cartilage injury	2011	Past
partial knee replacement (left)	Knee arthroplasty	2011	Past
partial knee replacement (right)	Knee arthroplasty	2013	Past
ankel surgery (right ankle)	Ankle operation	2017	Past
torn right ankle tendon	Tendon rupture	2017	Past
cataracts (bilateral)	Cataract	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	15:10
2	BNT162b2	28AUG2020 (22)	09:53

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Pulmonary embolism	Pulmonary Embolism	30OCT2020 (85)		07NOV2020 (93)		9	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (07NOV2020)	NOT RELATED/OTHER: HRT and prolonged immobilization	2	64	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	28SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1095 10951101, a 65-year-old postmenopausal white female with a pertinent medical history of mitral valve prolapse (since 2005), partial left knee replacement (in 2011), partial right knee replacement (in 2013), and ankle operation and tendon rupture (both in 2017), received Dose 1 on 07 Aug 2020 and Dose 2 on 28 Aug 2020 (Day 22). The subject was diagnosed with pulmonary embolism on 30 Oct 2020, 63 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the pulmonary embolism included sumatriptan succinate (since 2005) for migraines and estrogen patch 0.0375 mg and oral progesterone 100 mg (since 2010) for postmenopausal symptoms. The subject presented to the emergency room after experiencing shortness of breath and cough on 30 Oct 2020 (Day 85), while she was traveling to an another state. A chest x-ray performed on 03 Nov 2020 (Day 89) was normal. A SARS-CoV-2 test was negative on the same day (Day 89). The subject continued to feel unwell and went back to the hospital at which time she was admitted on 05 Nov 2020 (Day 91). A repeat SARS-CoV-2 test on 05 Nov 2020 (Day 91) was also negative. On the same day (Day 91), a computerized tomography angiogram showed a pulmonary embolism. The subject was treated with an anticoagulant for the pulmonary embolism and hormone replacement therapy (HRT) with estrogen and progesterone was permanently discontinued. On 07 Nov 2020 (Day 93), the subject recovered from the pulmonary embolism and was discharged from the hospital on the same day. In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the study intervention or clinical trial procedures, but rather it was related to the HRT and prolonged immobilization. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	82	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	103.8 kg	32 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hepatitis A	Hepatitis A	1965	Past
Coronary stents Insertion (3)	Coronary arterial stent insertion	1995	Present
Post Traumatic Stress Disorder	Post-traumatic stress disorder	1995	Present
Diabetes mellitus Type 2	Type 2 diabetes mellitus	1995	Present
Hypercholesterolemia	Hypercholesterolaemia	1998	Present
Hypertension	Hypertension	2000	Present
hyperthyroidism	Hyperthyroidism	2009	Past
Hypothyroidism	Hypothyroidism	2009	Present
Thyroidectomy	Thyroidectomy	2009	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Eastern Equine Encephalitis	Encephalitis eastern equine	2010	Present
Coronary artery disease	Coronary artery disease	2013	Present
Sleep apnea	Sleep apnoea syndrome	2016	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2018	Present
Pacemaker Implant	Cardiac pacemaker insertion	23DEC2019	Past
Mild cellulitis (right arm)	Cellulitis	MAR2020	Present
insomnia	Insomnia	15JUL2020	Present
Pacemaker Explant	Cardiac pacemaker removal	24JUL2020	Past
Muscle strain (left arm)	Muscle strain	31JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	17:55
2	Placebo	27AUG2020 (21)	15:11

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Dizziness	Dizziness, secondary to Clonidine reaction	31AUG2020 (25)	16:00	02SEP2020 (27)		3	2	N	Y

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
2	METAB	Hypoglycaemia	Hypoglycemia	12AUG2020 (6)	12:00	12AUG2020 (6)	13:00	1	1	TCN	N
3	CARD	Tachyarrhythmia	Suspected tachy-arrythmia	08SEP2020 (33)		22SEP2020 (47)		15	3	TC	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (02SEP2020)	NOT RELATED/OTHER: unknown	2	5	Y
2	Resolved (12AUG2020)	NOT RELATED/OTHER: Hypoglycemia, on insulin, is type II diabetic	1	6	N
3	Resolved (22SEP2020)	NOT RELATED/OTHER: underlying cardiac condition likely requiring pacemaker	2	13	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	28SEP2020	
Withdrawn	FOLLOW-UP	28SEP2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1095 10951107, an 82-year-old white male with a pertinent medical history of coronary arterial stent insertion and type 2 diabetes mellitus (DM) (both since 1995); hypercholesterolemia (since 1998); hypertension (since 2000); hypothyroidism (since 2009); coronary artery disease (since 2013); cardiac pacemaker insertion (on 23 Dec 2019); and cardiac pacemaker removal (on 24 Jul 2020), received Dose 1 on 07 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 21). The subject experienced dizziness on 31 Aug 2020 and tachyarrhythmia on 08 Sep 2020, 4 and 12 days after receiving Dose 2; respectively. Concomitant medications reported within 2 weeks prior to the onset of dizziness and tachyarrhythmia included metformin (since 2008), insulin lispro (since 2015), insulin glargine (since 2016), and dulaglutide (since 2018) all for type 2 DM; atorvastatin (since 2008) for hypercholesterolemia; levothyroxine sodium (since 2009) for hypothyroidism; valsartan (since 2013) for hypertension; ranolazine extended release (since 2015) for coronary artery disease; acetylsalicylic acid (since 15 Jul 2020) as a cardiac prophylaxis; and hydrazaline (since 15 Jul 2020) and clonidine orally 0.2 mg once daily (from 06 Aug 2020 to an unknown date) for an unspecified indication. On 31 Aug 2020 (Day 25), the subject experienced severe dizziness and was hospitalized. On admission, an echocardiogram and a SARS-CoV-2 tests were performed; however, the results were unknown. According to the subject, the dizziness was a reaction to the concomitant medication clonidine that had been recently started. He was treated with intravenous fluids during the hospitalization and treatment with clonidine was discontinued. On 02 Sep 2020 (Day 27), the subject recovered from the dizziness and was discharged from the hospital. The subject's spouse reported that the subject experienced substernal chest pain on 08 Sep 2020 (Day 33) and was hospitalized on the same day for suspected tachyarrhythmia. A cardiac evaluation was performed; however, the results were unknown. No other details were provided. The subject was hospitalized for approximately 14 days. On 22 Sep 2020 (Day 47), the subject recovered from the tachyarrhythmia. The subject requested withdrawal from the study on 28 Sep 2020. In the opinion of the investigator, there was no reasonable possibility that the dizziness and tachyarrhythmia were related to the study intervention or clinical trial procedures and tachyarrhythmia to concomitant medications; the dizziness was considered related to the concomitant medication-clonidine. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	84.6 kg	28.1 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	1986	Past
Osteoarthritis (left knee)	Osteoarthritis	2000	Past
Knee replacement (left)	Knee arthroplasty	2001	Past
Osteoarthritis (right knee)	Osteoarthritis	2018	Present
Atrial Septal Defect	Atrial septal defect	05NOV2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	12:08
2	BNT162b2	22SEP2020 (23)	14:26

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Dizziness	Dizziness	05NOV2020 (67)		06NOV2020 (68)		2	1
2	MUSC	Myalgia	post vaccination myalgia	31AUG2020 (1)	18:00	31AUG2020 (1)	23:00	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: Atrial Septal Defect	2	45	Y
2	N	N	Resolved (31AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine 1 dose IM once for influenza prophylaxis	INFLUENZA VACCINE	13OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1095 10951180, a 66-year-old white male with no pertinent medical history, received Dose 1 on 31 Aug 2020 and Dose 2 on 22 Sep 2020 (Day 23). The subject experienced dizziness on 05 Nov 2020, 44 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the dizziness included acetaminophen (since 2018) for knee osteoarthritis. On 05 Nov 2020 (Day 67), the subject woke up feeling “not right and very dizzy” and was taken to the hospital. The dizziness was initially thought to be due to a transient ischemic attack that was later ruled out. On the same day (Day 67), a SARS-CoV-2 (nasal swab) test was negative; a magnetic resonance imaging and an echocardiogram were performed, however results are unknown, but according to the subject the work-up revealed an atrial septal defect. The dizziness resolved on 06 Nov 2020 (Day 68). On an unknown date, the subject was discharged from the hospital. The atrial septal defect was ongoing at the time of last available report. In the opinion of the investigator, there was no reasonable possibility that the dizziness was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the atrial septal defect. Pfizer concurred with the investigator’s causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	77.5 kg	25.7 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1954	Past
Tonsillitis	Tonsillitis	1954	Past
Inguinal Hernia Repair	Inguinal hernia repair	1986	Past
Hypertension	Hypertension	2009	Present
Benign prostatic Hyperplasia	Benign prostatic hyperplasia	2010	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Angina	Angina pectoris	SEP2010	Present
Coronary Stent placement	Coronary arterial stent insertion	SEP2010	Present
Coronary Artery disease	Coronary artery disease	SEP2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myocardial infarction	Myocardial infarction	SEP2010	Past
Erectile Dysfunction	Erectile dysfunction	2011	Present
Osteoarthritis	Osteoarthritis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	11:46
2	BNT162b2	21SEP2020 (20)	09:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Bladder cancer	Bladder Cancer	02NOV2020 (62)		ONGOING		
2	GENRL	Injection site pain	Injection site pain right arm	21SEP2020 (20)	18:00	22SEP2020 (21)	08:00	2
3	GENRL	Injection site pain	injection site pain right arm	02SEP2020 (1)	16:00	03SEP2020 (2)	12:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Yes	NOT RELATED/OTHER: cancer	2	43	Y

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	1	N	N	Resolved (22SEP2020)	Study Treatment	2	1	N
3	1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1095 10951204, a 68-year-old white male with a pertinent medical history of inguinal hernia repair (in 1986), benign prostatic hyperplasia and hypercholesterolemia (both since 2010), and erectile dysfunction (since 2011), received Dose 1 on 02 Sep 2020 and Dose 2 on 21 Sep 2020 (Day 20). The subject was diagnosed with bladder cancer on 02 Nov 2020, 42 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the bladder cancer included glyceryl trinitrate (since 2010) for angina, acetylsalicylic acid (since Sep 2010) for cardiac prophylaxis, sildenafil citrate (since 2011) for erectile dysfunction, metoprolol tartrate (since Apr 2015) for hypertension, niacin (since 2016) and ezetimibe (since Dec 2019) for hypercholesterolemia, and equate prostate (since 14 Sep 2020) for benign prostatic hyperplasia. On 02 Nov 2020 (Day 62), the subject was evaluated by his physician and was diagnosed with bladder cancer. Surgery was scheduled for 04 Nov 2020 (Day 64). The bladder cancer was considered to be medically significant by the investigator and was reported to be ongoing at the time of the last available report. No additional information is available at this time. In the opinion of the investigator, there was no reasonable possibility that the bladder cancer was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and considered the bladder cancer to be most likely coincidental and associated with the underlying clinical conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	115.2 kg	33.3 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Lichen Planus	Lichen planus	01JAN2009	Present
Hypertension	Hypertension	01FEB2014	Present
Erectile dysfunction	Erectile dysfunction	01JAN2015	Present
Eczema	Eczema	01OCT2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	16:16
2	BNT162b2	24SEP2020 (21)	09:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1			shortness of breath	13NOV2020 (71)		ONGOING			2
2	GENRL	Fatigue	Fatigue	24SEP2020 (21)	16:00	25SEP2020 (22)	14:00	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: possible viral illness	2	51	Y
2	N	N	Resolved (25SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1095 10951228, a 64-year-old black/African American male with a pertinent medical history of hypertension (since 01 Feb 2014), received Dose 1 on 04 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 21). The subject reported shortness of breath on 13 Nov 2020, 50 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of shortness of breath included acetylsalicylic acid (since Oct 2014) as a cardiac prophylaxis, sildenafil (since Jan 2015) for erectile dysfunction, amlodipine and losartan (both since Oct 2016) for hypertension, and cortisone acetate and aloe vera (both since Oct 2018) for eczema. On 15 Nov 2020 (Day 73), the subject presented to the emergency department with fever, cough, shortness of breath, and muscle aches. He was admitted for work-up for pneumonia and tuberculosis, which included a chest x-ray, computed tomography of the chest, and tuberculin test; however, results of these tests are unknown. A SARS-CoV-2 test was negative. He did not require oxygen though the shortness of breath was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the shortness of breath was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a possible viral illness. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.96 cm	96.36 kg	32.5 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DIABETES MELLITUS TYPE 2	Type 2 diabetes mellitus	1990	Present
ANXIETY	Anxiety	2017	Present
CHRONIC KIDNEY DISEASE	Chronic kidney disease	2017	Present
DEPRESSION	Depression	2017	Present
DIABETIC NEUROPATHY	Diabetic neuropathy	2017	Present
DRUG ABUSE COCAINE	Drug abuse	2017	Past
HYPERLIPIDEMIA	Hyperlipidaemia	2017	Present
HYPERTENSION	Hypertension	2017	Present
INSOMIA	Insomnia	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SLEEP APNEA	Sleep apnoea syndrome	2017	Present
CONGESTIVE HEART FAILURE	Cardiac failure congestive	04JUL2017	Present
CORONATY ARTERY DISEASE	Coronary artery disease	04JUL2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	12:32
2	Placebo	10SEP2020 (24)	11:10

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INV	Hepatic enzyme increased	Elevated Liver Enzymes	21SEP2020 (35)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1096 10961044, a 58-year-old white male with a body mass index of 32.5 kg/m2 and a pertinent medical history of type 2 diabetes mellitus (since 1990); drug abuse (cocaine, in 2017); chronic kidney disease, hypertension, and hyperlipidemia (all since 2017); coronary artery disease and congestive cardiac failure (both since 04 Jul 2017); received Dose 1 on 18 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 24). The subject was diagnosed with increased hepatic enzymes on 21 Sep 2020, 11 days after receiving Dose 2. On 21 Sep 2020 (Day 35), the subject visited his physician, where he was diagnosed with increased hepatic enzymes. The physician had been working up the elevated hepatic enzymes, but on 05 Oct 2020 (Day 49), the subject presented to the emergency room and was subsequently hospitalized. The laboratory tests performed on an unspecified date showed aspartate aminotransferase of 465, alanine aminotransferase of 711, alkaline phosphatase of 124, and total bilirubin of 1.1 (units and normal ranges were not reported). The subject's hepatitis panel, acetaminophen, and salicylate levels were all normal. The subject had an ultrasound performed, but results are pending and evaluation of the increased hepatic enzymes was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the increased hepatic enzymes was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	100.18 kg	29.9 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	2002	Present
TONSILLECTOMY	Tonsillectomy	2002	Past
UMBILICAL HERNIA	Umbilical hernia	2002	Past
HYPERLIPIDEMIA	Hyperlipidaemia	2014	Present
HYPERTENSION	Hypertension	2014	Present
ANXIETY	Anxiety	2015	Present
TESTOSTERONE DEFICIENCY	Androgen deficiency	2017	Present
Insomnia	Insomnia	2017	Present
Intermittent lower back pain	Back pain	AUG2019	Present

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Car accident	Road traffic accident	AUG2019	Past
HERNIATED C5-C7 DISC	Intervertebral disc protrusion	FEB2020	Past
C5-C7 FUSION	Spinal fusion surgery	FEB2020	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	19AUG2020 (1)	13:14
2	Placebo	09SEP2020 (22)	13:26

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	NERV	Diplegia	Bilateral Lower extremity paralysis	04OCT2020 (47)	09:00	05OCT2020 (48)		2	3	N	Y
2	VASC	Hypertension	worsening of hypertension	14SEP2020 (27)		ONGOING			1	TC	N
3	METAB	Hypokalaemia	HYPOKALEMIA	SEP2020 ()		SEP2020 ()			3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (05OCT2020)	NOT RELATED/OTHER: unknown	2	26	Y
2	Yes	NOT RELATED/OTHER: past medical history	2	6	N
3	Resolved (SEP2020)	NOT RELATED/OTHER: PERSONAL ILLNESS, possibly related to con med amlodipine			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1096 10961062, a 47-year-old white male with a pertinent medical history of hyperlipidemia and hypertension (both since 2014), androgen deficiency (since 2017), and intervertebral disc protrusion and spinal fusion surgery (both in Feb 2020), received Dose 1 on 19 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 22). The subject reported hypokalemia on an unspecified date in Sep 2020 and diplegia (bilateral lower extremity paralysis) on 04 Oct 2020, 25 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the hypokalemia and diplegia included amlodipine besilate (since 2019) for hypertension. The subject was hospitalized for 4 days because of hypokalemia. Amlodipine besilate was permanently discontinued with resolution of the hypokalemia. On 04 Oct 2020 (Day 47), the subject presented to the emergency room with bilateral lower extremity paralysis and was hospitalized for observation and discharged on 05 Oct 2020 (Day 48). The subject had a follow-up with a neurologist on an unspecified date and the neurological evaluation showed no abnormal findings. In the opinion of the investigator, there was no reasonable possibility that the hypokalemia nor the diplegia were related to the study intervention or clinical trial procedures. The hypokalemia was thought to be related to personal illness and a concomitant medication (amlodipine besilate). The etiology for diplegia was unknown. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	78	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	99.09 kg	31.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Atrial Fibrillation	Atrial fibrillation	09APR2018	Present
BPH	Benign prostatic hyperplasia	09APR2018	Present
Gout	Gout	09APR2018	Present
Hyperlipidemia	Hyperlipidaemia	09APR2018	Present
Hypertension	Hypertension	09APR2018	Present
Diabetes Mellitus Type II	Type 2 diabetes mellitus	09APR2018	Present
Transient Cerebral ischemia	Transient ischaemic attack	09JUL2019	Past
depressive Disorders	Depression	20NOV2019	Present
Obstructive Sleep Apnea	Sleep apnoea syndrome	20NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:50
2	BNT162b2	09SEP2020 (21)	09:05

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Pneumonia	Pneumonia	20SEP2020 (32)		05OCT2020 (47)	11:00	16	3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (05OCT2020)	NOT RELATED/OTHER: Pt contracted pneumonia from somewhere	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1097 10971011, a 78-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 09 Apr 2018), received Dose 1 on 20 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 21). The subject was diagnosed with pneumonia on 20 Sep 2020, 11 days after receiving Dose 2. On 20 Sep 2020 (Day 32), the subject presented to the emergency room (ER) with fever, chills, nonproductive cough and body aches, since the prior night. The subject also experienced generalized weakness and mild epigastric pain but denied nausea, vomiting, diarrhea, or constipation. A SARS-CoV-2 test was negative. A chest x-ray performed on that same day (Day 32) revealed left upper lobe pneumonia. The subject was subsequently hospitalized and treated with ceftriaxone 1 g intravenously (IV) once on 20 Sep 2020 and 2 g IV once daily (QD) from 20 Sep 2020 to 22 Sep 2020; azithromycin 500 mg once on 20 Sep 2020 and 250 mg from 21 Sep 2020 to 25 Sep 2020; and doxycycline 100 mg QD from 22 Sep 2020 to 26 Sep 2020. The pneumonia resolved on 05 Oct 2020 (Day 47) and the subject was discharged from the hospital on an unspecified date. A repeat chest x-ray on an unspecified date showed no evidence of pneumonia. In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	74.55 kg	22.9 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Impotence	Erectile dysfunction	03APR2000	Present
Essential Hypertension	Essential hypertension	03APR2018	Present
Mechanical Heart valve Replacement	Heart valve replacement	03APR2018	Past
Hyperlipidemia	Hyperlipidaemia	03APR2018	Present
Chronic Back Pain1	Back pain	01OCT2018	Present
Neuropathy	Neuropathy peripheral	01OCT2018	Present
Lumbar Radiculopathy	Lumbar radiculopathy	04FEB2019	Present
Gout	Gout	15APR2019	Present
Osteoarthritis	Osteoarthritis	29JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	11:48
2	Placebo	15SEP2020 (25)	13:37

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Encephalopathy	Acute encephalopathy	18OCT2020 (58)	21:40	ONGOING			3
2	SURG	Hospitalisation	Hospitalization not otherwise specified.	13NOV2020 (84)		ONGOING			3
3	INFEC	Urinary tract infection	urinary tract infection	19SEP2020 (29)		01NOV2020 (72)		44	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: COVID 19 and UTI and OPiod use	2	34	Y
2	N	Y	Yes	NOT RELATED/OTHER: unknown at this time	2	60	Y
3	TC	N	Resolved (01NOV2020)	NOT RELATED/OTHER: unknown	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1097 10971017, a 76-year-old white male with a pertinent medical history of heart valve replacement (on 03 Apr 2018), hyperlipidemia and essential hypertension (both since 03 Apr 2018), back pain and peripheral neuropathy (both since 01 Oct 2018), lumbar radiculopathy (since 04 Feb 2019), gout (since 15 Apr 2019), benign prostatic hyperplasia (since 26 Jun 2020), osteoarthritis (since 29 Jun 2020), and knee arthroplasty (left knee, on 07 Jul 2020), received Dose 1 on 22 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 25). The subject was diagnosed with acute encephalopathy on 18 Oct 2020, 33 days after receiving Dose 2 and on 13 Nov 2020, 59 days after receiving Dose 2 was subsequently hospitalized for retroperitoneal hemorrhage. Concomitant medications reported within 2 weeks prior to the onset of encephalopathy and hospitalized for retroperitoneal hemorrhage included acetylsalicylic acid (since 03 Apr 2018) for cardiac prophylaxis, atorvastatin (since 04 May 2020) for hyperlipidemia, oxycodone (from 08 Jun 2020 to 19 Oct 2020) for chronic back pain/left knee pain, promethazine (since 08 Jun 2020) for nausea, celecoxib (since 08 Jun 2020) for osteoarthritis, allopurinol (since 09 Jun 2020) for gout, lisinopril (since 09 Jun 2020) and amlodipine (since 20 Jun 2020) both for hypertension, tamsulosin (since 26 Jun 2020) for benign prostatic hyperplasia, warfarin (since 13 Jul 2020) as blood thinner-mechanical heart valve, and gabapentin (since 17 Jul 2020) for neuropathy. On 18 Oct 2020 (Day 58), the subject felt stomach discomfort and reported left rib cage pain and decreased appetite. On 19 Oct 2020 (Day 59), the subject took his morning dose of oxycodone after which he became very quiet and confused, and had polyuria and was taken to the emergency room (ER). A SARS-CoV-2 NAAT was positive. A computerized tomogram of the brain/head showed no acute intracranial findings, chest x-ray showed patchy ground glass infiltrate left lower lobe, right lung was clear; venous duplex Doppler ultrasound showed no evidence of deep vein thrombosis. The subject was diagnosed with COVID-19 pneumonia and a urinary tract infection (UTI; a nonserious event) and treated with ceftriaxone sodium 2 g intravenously (IV) every 24 hours, azithromycin 500 mg once daily (QD), dexamethasone 6 mg QD, sodium chloride 0.9% 1000 mL IV. The subject had acute encephalopathy, which was thought likely secondary to COVID-19 pneumonia, UTI, and opioid use. Therapy with oxycodone was permanently discontinued. The urinary tract infection resolved on 01 Nov 2020 (Day 72). The encephalopathy was ongoing at the time of the last available report. On 13 Nov 2020 (Day 84), the subject was again hospitalized for a retroperitoneal hemorrhage. The hospitalization was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the encephalopathy was related to the study intervention or clinical trial procedures, but rather it was related to a concomitant medication: oxycodone, COVID-19, UTI, and opioid use. Pfizer concurred with the investigator's causality assessment. In the opinion of the investigator, there was no reasonable possibility that the hospitalization for retroperitoneal hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	89.09 kg	28.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Coronary arteriosclerosis	Arteriosclerosis coronary artery	12JUN2018	Present
Essential Hypertension	Essential hypertension	12JUN2018	Present
Hyperlipidemia	Hyperlipidaemia	12JUN2018	Present
Type II Diabetes	Type 2 diabetes mellitus	12JUN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	12:48
2	BNT162b2	14SEP2020 (22)	11:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	Non-STEMI	15SEP2020 (23)	12:33	15SEP2020 (23)	12:33	1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: Three vessel Disease	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1097 10971025, a 73-year-old white male with a pertinent medical history of coronary artery arteriosclerosis, essential hypertension, hyperlipidemia, and type 2 diabetes mellitus (all since 12 Jun 2018), received Dose 1 on 24 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 22). The subject was diagnosed with an acute myocardial infarction (non ST segment elevation) on 15 Sep 2020, 1 day after receiving Dose 2. On 15 Sep 2020 (Day 23), the subject was hospitalized with a non-ST segment elevation myocardial infarction. The subject had no chest pain, shortness of breath, or any neurologic symptoms. The next day, on 16 Sep 2020 (Day 24), the subject experienced a sudden onset of light-headedness and dizziness. On the same day (Day 24), an echocardiogram showed akinesia of the basal inferior region. The subject was started on a heparin drip and underwent a heart catheterization that revealed three-vessel disease. The findings on the catheterization were similar to a prior catheterization and an outpatient stress test was recommended. The subject also reported a shuffling gait that resolved subsequently after hospitalization. In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	61.36 kg	22.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pulmonary Fibrosis	Pulmonary fibrosis	DEC2015	Present
ADHD	Attention deficit hyperactivity disorder	23MAR2018	Present
COPD	Chronic obstructive pulmonary disease	23MAR2018	Present
Fibromyalgia	Fibromyalgia	23MAR2018	Present
Hyperlipidemia	Hyperlipidaemia	23MAR2018	Present
Hypertension	Hypertension	23MAR2018	Present
Degenerative Lumbar disc	Intervertebral disc degeneration	23MAR2018	Present
Vit D deficiency	Vitamin D deficiency	23MAR2018	Present
Chronic depression	Depression	22APR2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peripheral Vascular Disease	Peripheral vascular disorder	18FEB2020	Present
Anxiety	Anxiety	23MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	13:35
2	BNT162b2	17SEP2020 (21)	14:03

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Acute kidney injury	Acute kidney injury	22OCT2020 (56)	23:57	25OCT2020 (59)	11:48	4	3
2	NERV	Uraemic encephalopathy	Uremic encephalopathy	22OCT2020 (56)	23:58	25OCT2020 (59)	11:48	4	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (25OCT2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	36	Y
2	TC	Y	Resolved (25OCT2020)	NOT RELATED/OTHER: uremic encaphalopathy due to AKI.	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1097 10971061, a 67-year-old white female with a pertinent medical history of hyperlipidemia and hypertension (both since 23 Mar 2018) and peripheral vascular disorder (since 18 Feb 2020), received Dose 1 on 28 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 21). The subject experienced acute kidney injury and uremic encephalopathy on 22 Oct 2020, 35 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the acute kidney injury and uremic encephalopathy included ibuprofen (from 2018 to 25 Oct 2020) for pain, duloxetine (since 30 Oct 2018) for depression, amphetamine aspartate/amfetamine sulfate/dexamfetamine saccharate/dexamfetamine sulfate (from 01 Nov 2018 to 25 Oct 2020) for attention deficit hyperactivity disorder, amlodipine (since 01 Nov 2018) for hypertension, fentanyl and oxycodone hydrochloride (both since 01 Nov 2018) for pain, alprazolam (since 01 Nov 2018) for anxiety, vitamin D3 (since 01 Nov 2018) as a supplement, hydrochlorothiazide/lisinopril (since 17 Dec 2019) for hypertension, and alendronate sodium (since 14 Apr 2020) for osteoporosis. On 22 Oct 2020 (Day 56), the subject was incoherent and was sent to the emergency room by her primary care physician. Laboratory tests and procedures revealed hyponatremia of 125, blood urea nitrogen of 127, creatinine of 5.74 (normal ranges and units not reported), blood in the urine (7 red blood cells noted on urinalysis), and a urine drug screen which was positive for amphetamines, benzodiazepines and oxycodone. A computerized tomogram (CT) of the chest without contrast showed biapical pulmonary fibrosis, and coronary artery atherosclerotic calcification. A CT of the abdomen and pelvis revealed no bowel distention or wall thickening surrounding inflammatory changes. A COVID-19 test was not done. The subject was diagnosed with and hospitalized for acute kidney injury and uremic encephalopathy because of a history of increased ibuprofen use. She was diagnosed with acute kidney injury secondary by an excessive use of nonsteroidal anti-inflammatory drugs. On 23 Oct 2020 (Day 57), a renal ultrasound showed mildly increased renal cortical echo texture consistent with medical renal disease. The medications amfetamine aspartate/amphetamine sulfate/dexamfetamine saccharate/dexamfetamine sulfate and ibuprofen were discontinued and the dose of oxycodone hydrochloride was reduced. The acute kidney injury and uremic encephalopathy resolved and the subject was discharged on 25 Oct 2020 (Day 59). In the opinion of the investigator, there was no reasonable possibility that the acute kidney injury and uremic encephalopathy were related to the study intervention or clinical trial procedures, but rather they were related to the concomitant medication: ibuprofen. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	101.36 kg	36 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Angioplasty	Angioplasty	01OCT2003	Past
Right Knee Replacement	Knee arthroplasty	31MAY2005	Past
Right Rotator Cuff Repair	Rotator cuff repair	30NOV2006	Past
Cardiac Stent Insertion	Coronary arterial stent insertion	01MAY2008	Past
Obstructive Sleep Apnea	Sleep apnoea syndrome	15DEC2008	Present
Bladder stone removal	Bladder calculus removal	21APR2011	Past
Kidney stone removal	Renal stone removal	06JUN2011	Past
Appendectomy	Appendicectomy	19AUG2011	Past
Left Rotator Cuff repair	Rotator cuff repair	05OCT2011	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bladder Cancer	Bladder cancer	01MAY2012	Past
HEART CATHETERIZATION	Catheterisation cardiac	06FEB2013	Past
Cataract removal	Cataract operation	2014	Past
Neuropathy	Neuropathy peripheral	2015	Present
Hyperlipidemia	Hyperlipidaemia	13JUL2015	Present
Hypertension	Hypertension	15DEC2015	Present
Diabetes Mellitus Type II	Type 2 diabetes mellitus	15DEC2015	Present
Left Knee Replacement	Knee arthroplasty	26OCT2016	Past
Depression	Depression	26JUN2018	Present
Hypothyroidism	Hypothyroidism	29JAN2019	Present
GERD	Gastrooesophageal reflux disease	25MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	16:15
2	BNT162b2	23SEP2020 (23)	10:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pneumonia	Pneumonia	07OCT2020 (37)		ONGOING			3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: Pt contracted pneumonia from unknown source	2	15	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1097 10971084, an 84-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 15 Dec 2015), received Dose 1 on 01 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 23). The subject was diagnosed with pneumonia on 07 Oct 2020, 14 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the pneumonia included glyceryl trinitrate (since 18 Sep 2003) for angina pectoris, atorvastatin (since 13 Jul 2015) for hyperlipidemia, metformin hydrochloride (since 15 Dec 2015) for type 2 diabetes, duloxetine (since 26 Jun 2018) and fluoxetine hydrochloride (since Feb 2020) for depression, levothyroxine (since 29 Jan 2019) for hypothyroidism, sotalol hydrochloride (since 15 Mar 2019) for atrial fibrillation, lisinopril (since 23 Oct 2019) for hypertension, and donepezil (since Dec 2019) for memory loss. The subject required hospitalization for 6 days because of the pneumonia. No further details were reported and relevant tests were unknown. The pneumonia was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.69 cm	86.82 kg	29.7 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1980	Present
Myocardial Infarction	Myocardial infarction	1996	Past
A-Fib	Atrial fibrillation	2016	Present
COPD	Chronic obstructive pulmonary disease	2016	Present
Cronary Artery Disease	Coronary artery disease	2016	Present
Depression	Depression	2016	Present
Hyperlipidemia	Hyperlipidaemia	2016	Present
Hypertension	Hypertension	FEB2016	Present
Type 2 Diabetes	Type 2 diabetes mellitus	2017	Present
CHF	Cardiac failure congestive	2018	Present
GERD	Gastrooesophageal reflux disease	03AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	10:41
2	Placebo	24SEP2020 (35)	09:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Angina unstable	Unstable Angina Pectoris Moderate	04OCT2020 (45)		05OCT2020 (46)		2	1
2	CARD	Cardiac failure congestive	Diastolic Congestive Heart Failure with acute exacerbation	07OCT2020 (48)		09OCT2020 (50)		3	1
3	GENRL	Chest pain	ChestPain	07OCT2020 (48)	19:30	09OCT2020 (50)	12:00	3	1
4	RESP	Chronic obstructive pulmonary disease	COPD with acute exacerbation	07OCT2020 (48)		09OCT2020 (50)		3	1
5	NERV	Dizziness	Dizziness	07OCT2020 (48)		07OCT2020 (48)		1	1
6	RESP	Dyspnoea	Shortness of Breath	01OCT2020 (42)		07OCT2020 (48)		7	1
7	INJ&P	Fall	fall	07OCT2020 (48)		07OCT2020 (48)		1	1
8	INFEC	Pneumonia	Community Acquired Pneumonia	07OCT2020 (48)		09OCT2020 (50)		3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: unknown	2	11	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	N	N	Resolved (09OCT2020)	NOT RELATED/OTHER: unknown	2	14	N
3	TC/TCN	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	Y
4	TC	N	Resolved (09OCT2020)	NOT RELATED/OTHER: COPD	2	14	N
5	TC	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	N
6	N	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Pneomonia	2	8	N
7	TC	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	N
8	N	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: uknown	2	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	09SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1098 10981024, a 68-year-old white male with a pertinent medical history of myocardial infarction (in 1996); atrial fibrillation, chronic obstructive pulmonary disease (COPD), coronary artery disease, and hyperlipidemia (all since 2016); hypertension (since Feb 2016); congestive cardiac failure (since 2018); and gastroesophageal reflux disease (since 03 Aug 2020), received Dose 1 on 21 Aug 2020 and Dose 2 on 24 Sep 2020 (Day 35). The subject experienced chest pain and pneumonia on 07 Oct 2020, 13 days after receiving Dose 2.

Concomitant medications reported within 2 weeks prior to the onset of the chest pain and pneumonia included montelukast (since 1980) for seasonal allergies; rivaroxaban (since 2016) and digoxin (since 02 Feb 2016) for atrial fibrillation; citalopram (since 2016) for depression; clopidogrel and isosorbide mononitrate (both since 2016) for coronary artery disease; budesonide/formoterol fumarate (since 2016) for COPD; atorvastatin (since 02 Feb 2016) for hyperlipidemia; lisinopril (since 02 Feb 2016), metoprolol succinate (since 02 Feb 2016), and amlodipine (since 01 Mar 2016) for hypertension; and metformin (since 01 Mar 2016) for type 2 diabetes mellitus.

On 01 Oct 2020 (Day 42), the subject reported dyspnea and three days later on 04 Oct 2020 (Day 45) also reported unstable angina that resolved the following day. An electrocardiogram (ECG) was performed (results not included) on 04 Oct 2020 (Day 45); and on 05 Oct 2020 (Day 46), the subject reported fever (temperature not recorded), cough, and chills.

Two days later, on 07 Oct 2020 (Day 48), the subject presented to the emergency room and was subsequently hospitalized for chest pain. A chest x-ray showed bilateral infiltrates and a SARS-CoV-2 molecular detection test was negative. The viral respiratory pathogen panel was negative and troponin I was normal. An ECG showed narrative atrial fibrillation and transthoracic echocardiogram without contrast performed on 08 Oct 2020 (Day 49) was normal; influenza screen was negative. The subject was admitted for community acquired pneumonia. During the hospitalization, the subject was treated with ceftriaxone, azithromycin, and paracetamol, as well as hydralazine hydrochloride, naloxone hydrochloride, ondansetron, furosemide, arformoterol tartrate, and famotidine. The pneumonia and chest pain resolved on 09 Oct 2020 (Day 50); and the subject was discharged from the hospital. The vitals measurements at the time of discharge included: blood pressure of 132/75 mmHg, pulse rate of 79 beats per minute, respiratory rate of 18 breaths per minute, temperature of 36.7°C, and oxygen saturation of 96%.

In the opinion of the investigator, there was no reasonable possibility that the chest pain and pneumonia were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	109.36 kg	37.1 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TUBAL LIGATION	Female sterilisation	2000	Past
HYSTERECTOMY	Hysterectomy	2000	Past
MENORRHAGIA	Menorrhagia	2000	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2015	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present
INSOMNIA	Insomnia	2019	Present
DEPRESSION	Depression	JAN2020	Present
CHRONIC RIGHT UPPER QUADRANT PAIN	Abdominal pain upper	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	11:28
2	BNT162b2	26AUG2020 (22)	14:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholelithiasis	CHOLELITHIASIS	11SEP2020 (38)		15SEP2020 (42)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: UNKNOWN	2	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1107 11071044, a 61-year-old white female with a body mass index of 37.1 kg/m2 and a pertinent medical history of upper abdominal pain (in Mar 2020), received Dose 1 on 05 Aug 2020 and Dose 2 on 26 Aug 2020 (Day 22). The subject was diagnosed with cholelithiasis on 11 Sep 2020, 16 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the cholelithiasis included fluoxetine hydrochloride (since Jan 2020) for depression. On 11 Sep 2020 (Day 38), the subject presented to the emergency room with worsening of right upper quadrant abdominal pain. On the same day (Day 38), a SARS-CoV-2 polymerase chain reaction test was negative and a chest x-ray showed no acute findings; however, an ultrasound of the abdomen showed cholelithiasis and the subject was subsequently hospitalized. On 12 Sep 2020 (Day 39), the subject underwent cholecystectomy and was discharged from the hospital. The subject was treated with naproxen sodium (as needed for 3 days after the surgery) and the cholelithiasis resolved on 15 Sep 2020 (Day 42). In the opinion of the investigator, there was no reasonable possibility that the cholelithiasis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	133.82 kg	46.1 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OVERWEIGHT	Overweight	2010	Present
TRAUMATIC RIGHT ANKLE FRACTURE	Ankle fracture	2017	Past
RIGHT ANKLE REPAIR	Ankle operation	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	15:01
2	Placebo	27AUG2020 (22)	07:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Anaemia	ANEMIA	09NOV2020 (96)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	75	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1107 11071065, a 43-year-old black/African American female with a body mass index of 46.1 kg/m2 and a family history of sickle cell anemia (mother), received Dose 1 on 06 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 22). The subject was diagnosed with anemia on 09 Nov 2020, 74 days after receiving Dose 2. On 09 Nov 2020 (Day 96), the subject was hospitalized for anemia. Laboratory tests done on the same day (Day 96) showed hemoglobin of 5.6 g/dL (normal range [NR]: 11.5 - 15.0 g/dL), hematocrit of 21.9% (NR: 34.5% - 45.0%), red blood cell (RBC) count of 3.57 × 106/µL (NR: 4.00 - 5.40 × 106/µL) and a SARS CoV-2 test was negative. On 10 Nov 2020 (Day 97), a blood smear showed microcytic anemia with abnormal RBC morphology including sickle cells; absolute reticulocyte count of 39.9 × 103/µL (NR: 50.0 - 100.0 × 103/µL), serum ferritin of 3.4 ng/mL (NR: 4.6 - 204.0 ng/mL), iron: 215 µg/dL (normal range: 50 - 170 µg/dL). A urine toxicology test was positive for benzodiazepines, cocaine, and opiates. On 11 Nov 2020 (Day 98), the hemoglobin was 7.2 g/dL and hematocrit was 25.8%. Splenomegaly was noted and was considered as not clinically significant. The subject was treated with 2 units of RBCs as a treatment for anemia. The subject was discharged from the hospital on 11 Nov 2020 (Day 98). The anemia was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the anemia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	83.64 kg	33.7 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Appendectomy	Appendicectomy	JAN1962	Past
Appendicitis	Appendicitis	JAN1962	Past
Tubal Ligation	Female sterilisation	JAN1988	Past
Depression	Depression	JAN1995	Present
Carpel Tunnel Syndrome, Bi-lateral	Carpal tunnel syndrome	JAN1997	Past
Diverticulosis	Diverticulum	JAN1998	Present
Hemorrhoids	Haemorrhoids	JAN1998	Present
Hypertension	Hypertension	JAN2000	Present
Obesity	Obesity	JAN2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis, Hip, Hands	Osteoarthritis	JAN2000	Present
Hand Surgery, Bi-lateral Thumb	Limb operation	JAN2002	Past
Hand Surgery, Bi-lateral Thumb	Limb operation	JAN2006	Past
Hypercholesterolemia	Hypercholesterolaemia	JAN2010	Present
HYPERTRIGLYCERIDEMIA	Hypertriglyceridaemia	JAN2010	Present
Deep Vein Thrombosis	Deep vein thrombosis	JAN2014	Present
Hot Flashes	Hot flush	JAN2017	Present
PTSD	Post-traumatic stress disorder	JUN2018	Present
Anxiety	Anxiety	01JUN2018	Present
Seasonal Allergies	Seasonal allergy	01AUG2019	Present
Cataract Surgery	Cataract operation	OCT2019	Past
Cystocele	Cystocele	OCT2019	Present
Rectocele	Rectocele	OCT2019	Present
Colonoscopy	Colonoscopy	JAN2020	Present
Polyp removal	Polypectomy	JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03AUG2020 (1)	11:00
2	BNT162b2	23AUG2020 (21)	10:18

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	RESP	Cough	COUGH	20AUG2020 (18)	08:00	04SEP2020 (33)		16	1	N
2	INFEC	Diverticulitis	Diverticulitis flair-up	08NOV2020 (98)	18:00	13NOV2020 (103)		6	4	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (04SEP2020)	NOT RELATED/OTHER: POST NASAL DRIP	1	18	N
2	Y	Resolved (13NOV2020)	NOT RELATED/OTHER: Previous medical history of diverticulosis	2	78	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091111, a 67-year-old white female with a pertinent medical history of appendectomy (in Jan 1962), diverticulosis and hemorrhoids (both since Jan 1998), obesity (since Jan 2000), rectocele (since Oct 2019), and polypectomy (in Jan 2020), received Dose 1 on 03 Aug 2020 and Dose 2 on 23 Aug 2020 (Day 21). The subject reported diverticulitis on 08 Nov 2020, 77 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the diverticulitis included benazepril (since 01 Jan 1990) for hypertension, atorvastatin (since 01 Aug 2018) for hypercholesterolemia, venlafaxine (since 06 Aug 2018) for anxiety, amlodipine (since 07 Aug 2018) for hypertension, and vitamin D (since 17 Jul 2019) for vitamin D deficiency. On 08 Nov 2020 (Day 98), the subject was hospitalized for complaints of vomiting, diarrhea, sweating, chills, and dehydration. The subject was treated with antibiotics (names not provided). SARS-CoV-2 test on admission was negative. On 12 Nov 2020 (Day 102), the subject was discharged from the hospital; and the acute diverticulitis resolved on 13 Nov 2020 (Day 103). In the opinion of the investigator, there was no reasonable possibility that the diverticulitis was related to the study intervention, concomitant medications, or a clinical trial procedure, but rather it was related to the subject's medical history of diverticulosis. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	111.82 kg	46.5 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OSTEOARTHRITIS BILATERAL KNEES	Osteoarthritis	2000	Present
Anxiety	Anxiety	JAN2010	Present
Obesity	Obesity	2015	Present
Postmenopausal	Postmenopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	15:51
2	Placebo	24AUG2020 (21)	11:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Deep vein thrombosis	Deep Vein Thrombosis	07SEP2020 (35)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Right Total Knee Replacement on 31 Aug 2020	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	21SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091164, a 58-year-old white female with a pertinent medical history of bilateral knee osteoarthritis (since 2000) and obesity (since 2015), received Dose 1 on 04 Aug 2020 and Dose 2 on 24 Aug 2020 (Day 21). The subject was diagnosed with deep vein thrombosis on 07 Sep 2020, 14 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the deep vein thrombosis included trazodone (since 01 Jan 2019) for insomnia and sertraline (since 20 May 2020) for anxiety. On 31 Aug 2020 (Day 28), the subject had a total right knee replacement. On 07 Sep 2020 (Day 35), she developed deep vein thrombosis due to physical inactivity and was hospitalized. The subject was treated with rivaroxaban 20 mg twice a day from 07 Sep 2020 (Day 35) for deep vein thrombosis. The subject was discharged from the hospital on an unspecified date on outpatient rivaroxaban. The deep vein thrombosis was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the deep vein thrombosis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the total right knee replacement. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	27	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	90.91 kg	27.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RECONSTRUCTIVE RIGHT EAR SURGERY	Otoplasty	01JAN2013	Past
SEASONAL ALLERGIES	Seasonal allergy	2015	Present
BILATERAL LASIK SURGERY	Keratomileusis	01JAN2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	13:15
2	BNT162b2	04SEP2020 (25)	14:18

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Appendicitis	ACUTE APPENDICITIS	17AUG2020 (7)		02SEP2020 (23)		17	4	TC	Y
2	INFEC	Peritoneal abscess	Peritoneal Abscess	17AUG2020 (7)		02SEP2020 (23)		17	4	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (02SEP2020)	NOT RELATED/OTHER: ACUTE APPENDICITIS WITH PERITONEAL ABSCESS	1	7	Y
2	Resolved (02SEP2020)	NOT RELATED/OTHER: Acute appendicitis with peritoneal abscess	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091204, a 27-year-old white male with no pertinent medical history, received Dose 1 on 11 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 25). The subject was diagnosed with appendicitis and peritoneal abscess on 17 Aug 2020, 6 days after receiving Dose 1. No significant concomitant medications were reported within 2 weeks prior to the onset of the appendicitis and peritoneal abscess. On 17 Aug 2020 (Day 7), the subject was hospitalized for abdominal pain and diagnosed with appendicitis and peritoneal abscess. He was treated with piperacillin/tazobactam 2.25 g intravenously every 6 hours (from 17 Aug 2020 to 22 Aug 2020), and acetaminophen/oxycodone 325/5 mg (from 21 Aug 2020 to 22 Aug 2020) for pain. No appendectomy was performed. No SARS-CoV-2 test was performed in the hospital. The subject was discharged from the hospital on 21 Aug 2020 (Day 11) on ciprofloxacin and metronidazole (from 22 Aug 2020 to 25 Aug 2020); and amoxicillin 500 mg orally twice a day (from 26 Aug 2020 to 02 Sep 2020). The acute appendicitis with peritoneal abscess resolved on 02 Sep 2020 (Day 23). The subject was instructed to delay the second dose of study vaccination until completion of antibiotic treatment. In the opinion of the investigator, there was no reasonable possibility that the appendicitis and peritoneal abscess were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	59.91 kg	20 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MIGRAINE HEADACHES	Migraine	01JAN1989	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	01JAN2005	Present
BREAST CANCER	Breast cancer	01JAN2012	Past
ANXIETY	Anxiety	01JAN2015	Present
DEPRESSION	Depression	01JAN2015	Present
HYSTERECTOMY	Hysterectomy	01JAN2019	Past
POSTMENOPAUSAL	Postmenopause	01JAN2019	Present
OSTEOPOROSIS	Osteoporosis	01JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	09:35
2	Placebo	09SEP2020 (20)	13:11

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Complicated appendicitis	Acute appendicitis with necrosis	30SEP2020 (41)	23:00	02OCT2020 (43)	11:00	3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (02OCT2020)	NOT RELATED/OTHER: Infection of appendix	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091276, a 62-year-old white female with no pertinent medical history, received Dose 1 on 21 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 20). The subject was diagnosed with complicated appendicitis (acute appendicitis with necrosis) on 30 Sep 2020, 21 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the complicated appendicitis included atorvastatin (since 2010) for high cholesterol; levothyroxine sodium and liothyronine (both since 2015) for hypothyroidism; desvenlafaxine succinate and clonazepam (both since 2018) for anxiety; topiramate (since 2018) and zolmitriptan (since 08 Jan 2020), both for migraine; and ibandronate sodium (since Jan 2020) for osteoporosis. On 30 Sep 2020 (Day 41), the subject was hospitalized for appendicitis. She was treated with intravenous medications and had an appendectomy. Pathology findings revealed acute appendicitis with necrosis. On 01 Oct 2020 (Day 42), a SARS-CoV-2 nasopharyngeal swab test was negative. On 02 Oct 2020 (Day 43), the complicated appendicitis resolved, and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the complicated appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	82.27 kg	30.1 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VASECTOMY	Vasectomy	1997	Past
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
HYPOTHYROIDISM	Hypothyroidism	2010	Present
OSTEOARTHRITIS-RIGHT KNEE	Osteoarthritis	2014	Present
SLEEP APNEA	Sleep apnoea syndrome	2015	Present
ROSACEA	Rosacea	2017	Present
ENLARGED PROSTATE	Prostatomegaly	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	13:21
2	BNT162b2	22SEP2020 (22)	14:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Deep vein thrombosis	Deep Vein Thrombosis (Right Leg)	20OCT2020 (50)		ONGOING			3
2	MUSC	Osteoarthritis	Worsening osteoarthritis of the right knee	14OCT2020 (44)	09:00	15OCT2020 (45)		2	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: Knee surgery (right)	2	29	N
2	TC/TCN	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: Previous medical history	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	23OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091387, a 58-year-old white male with a pertinent medical history of hypothyroidism (since 2010) and osteoarthritis (right knee, since 2014), received Dose 1 on 01 Sep 2020 and Dose 2 on 22 Sep 2020 (Day 22). The subject reported a worsening of osteoarthritis of the right knee on 14 Oct 2020, 22 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the worsening of the osteoarthritis of the right knee included rosuvastatin (since 2010) for hypercholesterolemia, alfuzosin (since 2018) for enlarged prostate, and levothyroxine (since 2018) for hypothyroidism. On 14 Oct 2020 (Day 44), the subject was hospitalized and underwent knee replacement surgery. He was observed overnight and was discharged from the hospital the next day, 15 Oct 2020 (Day 45). The worsening of osteoarthritis of the right knee was considered to be resolved on the same day (Day 45). No SARS-CoV-2 test was performed during the hospitalization. In the opinion of the investigator, there was no reasonable possibility that the worsening of osteoarthritis of the right knee was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the subject's pre-existing medical history of osteoarthritis. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	82.73 kg	29.4 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FIBROMYALGIA	Fibromyalgia	1990	Present
ALLERGY TO AUGMENTIN	Drug hypersensitivity	1995	Present
ALLERGY TO KEFLEX	Drug hypersensitivity	1995	Present
ALLERGY TO BIAXIN	Drug hypersensitivity	2005	Present
ALLERGY TO LATEX	Rubber sensitivity	2005	Present
HYSTERECTOMY	Hysterectomy	2006	Past
POSTMENOPAUSAL	Postmenopause	2006	Present
ALLERGY TO SEPTRA	Drug hypersensitivity	2008	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	2010	Present
Hemiplegic Migraine	Hemiplegic migraine	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	15:07
2	Placebo	28SEP2020 (21)	08:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Hemiplegic migraine	Hemiplegic Migraine	20OCT2020 (43)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Related to subjects history of headaches	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091448, a 46-year-old postmenopausal white female with a pertinent medical history of hemiplegic migraine (since 2010), received Dose 1 on 08 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 21). The subject experienced hemiplegic migraine on 20 Oct 2020, 22 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the hemiplegic migraine included cyclobenzaprine (since 1995) and oxycodone hydrochloride/paracetamol (since 2016), both for fibromyalgia. On 20 Oct 2020 (Day 43), the subject visited the emergency room and was hospitalized due to an exacerbation of hemiplegic migraine. A SARS-CoV-2 test was positive on 21 Oct 2020 (Day 44). During the hospitalization, a magnetic resonance imaging of the head, a non-contrast computerized tomogram (CT) scan of the brain, CT angiography of the head/neck, and a CT perfusion scan were all normal. A complete blood count and coagulation tests were unremarkable; a metabolic panel showed potassium of 3.1 and troponin of <0.02 (units and normal ranges not provided). The subject was discharged from the hospital on 22 Oct 2020 (Day 45). The hemiplegic migraine was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the hemiplegic migraine was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the subject's prior history of migraines. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	111.36 kg	40.8 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEPATITIS C	Hepatitis C	2005	Past
DEPRESION	Depression	2010	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
HYPERTENSION	Hypertension	2010	Present
ALLERGIES SEASONAL	Seasonal allergy	2010	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	05OCT2020 (1)	15:51
2	BNT162b2	24OCT2020 (20)	14:44

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	RESP	Dyspnoea	Shortness of breath	06NOV2020 (33)		ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		4	TC	Y	Yes	NOT RELATED/OTHER: Inflammation	2	14	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091558, a 63-year-old white male with a pertinent medical history of hypertension and hypercholesterolemia (both since 2010), received Dose 1 on 05 Oct 2020 and Dose 2 on 24 Oct 2020 (Day 20). The subject experienced dyspnea on 06 Nov 2020, 13 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the dyspnea included montelukast for allergies, nifedipine for hypertension, trazodone for depression, and rosuvastatin for hypercholesterolemia (all since 2010), and acetylsalicylic acid (since 2018) as prophylaxis. The subject reported that on 06 Nov 2020 (Day 33), he was hospitalized because of difficulty breathing and cough. A SARS-CoV-2 test was negative on the day of admission (Day 33). The subject was treated for infection and inflammation in the hospital. On 09 Nov 2020 (Day 36), the subject was discharged from the hospital. The dyspnea was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the dyspnea was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	95.25 kg	33.3 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	2000	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2005	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
NEPHROLITHIASIS	Nephrolithiasis	JAN2019	Present
SLEEP DISTURBANCE	Sleep disorder	JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	12:37
2	Placebo	25AUG2020 (22)	10:51

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Type 2 diabetes mellitus	Diabetes Type 2	12NOV2020 (101)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: diabetes mellitus type 2 uncontrolled	2	80	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1110 11101031, a 66-year-old white male with a pertinent medical history of coronary artery disease (unknown duration), hypertension (since 2000), hypercholesterolemia (since 2015), and nephrolithiasis and sleep disorder (both since Jan 2019), received Dose 1 on 04 Aug 2020 and Dose 2 on 25 Aug 2020 (Day 22). The subject was diagnosed with type 2 diabetes mellitus on 12 Nov 2020, 79 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the type 2 diabetes mellitus included lisinopril and atenolol (both since 2000) for hypertension; acetylsalicylic acid (since 2000) as a cardiac prophylaxis; rosuvastatin (since 2015) for hypercholesterolemia; omeprazole (since 2015) for gastroesophageal reflux disease; allopurinol (since Jan 2019) for nephrolithiasis; and eszopiclone (since Jan 2019) for insomnia. On 12 Nov 2020 (Day 101), the subject had a syncopal event during a spinning class, and was subsequently taken to the emergency room. The subject reported that he was prediabetic for a few years, with a glucose level of approximately equal to 200 mg/dL (normal range not reported). That same day (Day 101), laboratory test results showed glucose of 600 mg/dL, troponin was normal (value not reported), and calcium level of 450 mg/dL (normal range not reported); an electrocardiogram showed peaked T wave. The subject was hospitalized for uncontrolled diabetes mellitus (DM) and was treated with insulin. The syncope was attributed to the DM. On 13 Nov 2020 (Day 102), while admitted, the subject underwent cardiac catheterization which showed no changes, and he was discharged from the hospital on the same day. His DM was controlled with insulin glargine and insulin aspart. The type 2 diabetes mellitus was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the type 2 diabetes mellitus was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	57.55 kg	21.7 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to codeine	Drug hypersensitivity	1972	Present
Postmenopausal	Postmenopause	1987	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Farsighted	Hypermetropia	2010	Present
Hypertension	Hypertension	2010	Present
Hypothyroidism	Hypothyroidism	2010	Present
Melanoma (left forearm)	Malignant melanoma	2010	Past
Mohs surgery	Micrographic skin surgery	2010	Past
Muscle spasms	Muscle spasms	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	13:31
2	BNT162b2	01SEP2020 (22)	12:34

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	PSYCH	Mental disorder	Undiagnosed Mental Disorder (not otherwise specified)	25SEP2020 (46)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: mental instability	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1111 11111095, a 73-year-old white female with a pertinent medical history hypertension and hypothyroidism (both since 2010), received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject reported a mental disorder on 25 Sep 2020, 24 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the mental disorder included lisinopril (since 2010) for hypertension, levothyroxine (since 2010) for hyperthyroidism, magnesium (since 2017) for muscle spasms, and acetylsalicylic acid (since Jul 2020) as prophylaxis. On 25 Sep 2020 (Day 46), the subject was hospitalized for 3 days because of an unspecified mental disorder. The COVID-19 testing status was unknown. The mental disorder was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the mental disorder was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	75.91 kg	26.2 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Overweight	Overweight	1970	Present
Hypertension	Hypertension	1997	Present
Kidney stones	Nephrolithiasis	1997	Past
Tubal ligation	Female sterilisation	1998	Past
Diverticulosis	Diverticulum	2010	Present
Cholecystectomy	Cholecystectomy	2012	Past
Gallstones	Cholelithiasis	2012	Past
Disseminated porokeratosis	Porokeratosis	2013	Present
Sleep apnea	Sleep apnoea syndrome	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Carpal tunnel syndrome (right)	Carpal tunnel syndrome	2014	Past
Farsighted	Hypermetropia	2015	Present
Uterine ablation	Endometrial ablation	2016	Past
Post-menopause	Postmenopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	13:26
2	BNT162b2	04SEP2020 (22)	16:56

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pyelonephritis	Pyelonephritis	28SEP2020 (46)		02OCT2020 (50)		5	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (02OCT2020)	NOT RELATED/OTHER: kidney stones/nephrolithiasis	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1111 11111109, a 56-year-old white female with a pertinent medical history of being overweight (since 1970), nephrolithiasis (in 1997), hypertension (since 1997), and diverticulum (since 2010), received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). The subject was diagnosed with pyelonephritis on 28 Sep 2020, 24 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the pyelonephritis included lisinopril (since 1997) for hypertension and diphenhydramine (since an unknown date) as a sleep aid. On 28 Sep 2020 (Day 46), the subject was hospitalized for pyelonephritis associated with kidney stones, and a kidney stent was placed. She was treated with pyridium, ciprofloxacin, and oxybutynin. On 01 Oct 2020 (Day 49), the subject was discharged from the hospital and the pyelonephritis resolved on 02 Oct 2020 (Day 50). While in the hospital, a SARS-CoV-2 swab test was negative. In the opinion of the investigator, there was no reasonable possibility that the pyelonephritis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to kidney stones/nephrolithiasis. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	American Indian or Alaska	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	66.73 kg	25.6 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	1987	Present
Back Pain	Back pain	2000	Present
Vitamin D deficiency	Vitamin D deficiency	2010	Present
Farsighted	Hypermetropia	2012	Present
Low libido	Libido decreased	2012	Present
Seasonal allergies	Seasonal allergy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	15:18
2	BNT162b2	24SEP2020 (38)	11:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Subarachnoid haemorrhage	Subarachnoid hemorrhage	26AUG2020 (9)		03SEP2020 (17)		9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (03SEP2020)	NOT RELATED/OTHER: unknown	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1111 11111130, a 48-year-old American Indian/Alaska native female with a pertinent medical history of vitamin D deficiency (since 2010), received Dose 1 on 18 Aug 2020 and Dose 2 on 24 Sep 2020 (Day 38). The subject was diagnosed with a subarachnoid hemorrhage on 26 Aug 2020, 8 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the subarachnoid hemorrhage included cholecalciferol (since 2010) for vitamin D deficiency and loratadine (since 2017) for seasonal allergies. On 26 Aug 2020 (Day 9), the subject presented to the hospital with a complaint of gradually worsening headache; computerized tomography (CT) of the head without contrast showed acute subarachnoid hemorrhage and she was hospitalized. A CT angiogram of the head and neck with and without contrast showed patent vessels, no significant stenosis, no evidence of vasospasm, aneurysm, malformation, or no dissection. Electrocardiogram, hematology, and chemistry panel results were unremarkable. On 27 Aug 2020 (Day 10), an angiogram showed cerebrovascular hemorrhage. The subject was transferred to the neurology intensive care unit, and treated with bupropion and amlodipine. On 03 Sep 2020 (Day 17), an angiogram showed cerebrovascular hemorrhage; however, a repeat angiogram confirmed no source of bleed. On the same day (Day 17), the subject was discharged from the hospital as the subarachnoid hemorrhage was considered resolved. In the opinion of the investigator, there was no reasonable possibility that the subarachnoid hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	77	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	70.55 kg	22.6 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Alcohol use	Alcohol use		Present
High cholesterol	Blood cholesterol increased	2010	Present
Indigestion (acid)	Dyspepsia	2010	Present
Hypertension	Hypertension	2010	Present
Type II Diabetes Mellitus	Type 2 diabetes mellitus	2010	Present
Transient ischemic attack	Transient ischaemic attack	2016	Past
Transient ischemic attack	Transient ischaemic attack	2017	Past
Low libido	Libido decreased	2018	Present
Constipation	Constipation	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	09:58
2	Placebo	05NOV2020 (22)	09:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Pancreatitis acute	Acute Pancreatitis	19OCT2020 (5)		21OCT2020 (7)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (21OCT2020)	NOT RELATED/OTHER: Alcohol use	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1111 11111193, a 77-year-old white male with a pertinent medical history of blood cholesterol increased, dyspepsia, hypertension, and type 2 diabetes mellitus (all since 2010); and alcohol use (since an unknown date), received Dose 1 on 15 Oct 2020 and Dose 2 on 05 Nov 2020 (Day 22). The subject was diagnosed with acute pancreatitis on 19 Oct 2020, 4 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the acute pancreatitis included metformin for type 2 diabetes mellitus; valacyclovir for an unspecified condition; simvastatin for high cholesterol; losartan, doxazosin, and amlodipine for hypertension; omeprazole for dyspepsia; and clopidogrel (all since 2010). On 19 Oct 2020 (Day 5), the subject visited the emergency room with a complaint of severe abdominal pain and was hospitalized with a diagnosis of acute pancreatitis. The subject was treated with intravenous fluids and pain medication. On 21 Oct 2020 (Day 7), the acute pancreatitis resolved and the subject was discharged from the hospital on the same day. It was reported that a COVID-19 test was not done during the hospitalization. In the opinion of the investigator, there was no reasonable possibility that the acute pancreatitis was related to the study intervention, concomitant medications, or clinical trial procedures but rather it was related to alcohol use. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.5 cm	127.7 kg	37.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Neuropathy	Neuropathy peripheral	JAN1986	Present
Type 2 Diabetes Mellitus	Type 2 diabetes mellitus	01JAN1986	Present
Trama Right Leg	Limb injury	01JAN2005	Past
Trauma Left Leg	Limb injury	01JAN2005	Past
Anxiety	Anxiety	01JAN2010	Present
Amputed Right Leg	Leg amputation	01NOV2012	Past
Depression	Depression	01JAN2013	Present
Asthma	Asthma	OCT2015	Present
Recurrent Methicillin-resistant Staphylococcus aureus Infections	Staphylococcal infection	JAN2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	03NOV2017	Present
Amputed Left Leg	Leg amputation	01JAN2018	Past
Hyperlipidemia	Hyperlipidaemia	14NOV2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	15:03
2	BNT162b2	30SEP2020 (38)	09:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Acute kidney injury	acute kidney injury	12SEP2020 (20)		ONGOING		
2	CARD	Atrial fibrillation	Atrial fibrillation	14SEP2020 (22)	10:00	ONGOING		
3	GENRL	Chest pain	chest pain	14SEP2020 (22)	10:00	14SEP2020 (22)	11:00	1
4	CARD	Left ventricular hypertrophy	Left Ventricular Hypertrophy	14SEP2020 (22)	10:00	ONGOING		
5	CARD	Mitral valve incompetence	mitral valve regurgitation	14SEP2020 (22)	10:00	ONGOING		
6	MUSC	Pain in extremity	bilateral hand pain	12SEP2020 (20)		13SEP2020 (21)		2
7	RESP	Pulmonary hypertension	Pulmonary Hypertension	14SEP2020 (22)	10:00	ONGOING		
8	INJ&P	Skin injury	skin avulsion, left finger	12SEP2020 (20)		12SEP2020 (20)		1

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
9	INFEC	Staphylococcal infection	MRSA infection Right Stump	12SEP2020 (20)	08:00	08OCT2020 (46)		27
10	CARD	Tricuspid valve incompetence	Tricuspid regurgitation	14SEP2020 (22)	10:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Yes	NOT RELATED/OTHER: Hypertension	1	20	N
2	2	N	N	Yes	NOT RELATED/OTHER: Hypertension	1	22	N
3	2	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: Hypertension	1	22	N
4	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
5	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
6	1	N	N	Resolved (13SEP2020)	NOT RELATED/OTHER: Musculoskeletal	1	20	N
7	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
8	2	N	N	Resolved (12SEP2020)	NOT RELATED/OTHER: Musculoskeletal	1	20	N
9	2	TC	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: Infection	1	20	Y
10	1	N	N	Yes	NOT RELATED/OTHER: Hypertension	1	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Pneumonia vaccine	PNEUMOCOCCAL VACCINE	26AUG2020
Influenza Vaccine	INFLUENZA VACCINE	23SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1114 11141080, a 61-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 01 Jan 1986), limb injury (both legs, on 01 Jan 2005), leg amputation (right leg, on 01 Nov 2012), recurrent methicillin-resistant Staphylococcus aureus infection (since Jan 2017), hypertension (since 03 Nov 2017), leg amputation (left leg, on 01 Jan 2018), and thrombocytopenia (since unknown date), received Dose 1 on 24 Aug 2020 and Dose 2 on 30 Sep 2020 (Day 38). The subject was diagnosed with a staphylococcal infection on 12 Sep 2020, 19 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the staphylococcal infection included insulin glargine and insulin lispro (both since Jan 2000) and semaglutide (since Mar 2016) all for type 2 diabetes; and sertraline (since 01 Jan 2013) for anxiety. On 12 Sep 2020 (Day 20), the subject was hospitalized for a methicillin-resistant Staphylococcus aureus infection of the right stump. (He has been seen the day prior in the emergency room and sent home with a prescription for oral doxycycline 100 mg twice a day.) In the hospital, he was treated with intravenous (IV) vancomycin, linezolid 600 mg orally every 12 hours, and ceftriaxone sodium 1 g intravenously once. The subject was also noted to have a left finger skin avulsion, which resolved on the same day (Day 20). On 14 Sep 2020 (Day 22), the electrocardiogram showed possible atrial flutter at 95 and premature ventricular contractions and echography showed trace mitral and tricuspid regurgitation; and pulmonary artery pressure of 58 mmHg. On 24 Sep 2020 (Day 32), the subject was discharged from the hospital and the blood culture results were pending at the time of discharge. The staphylococcal infection resolved on 08 Oct 2020 (Day 46). A SARS-CoV-2 test was not performed during the hospitalization. In the opinion of the investigator, there was no reasonable possibility that the staphylococcal infection was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	82.36 kg	26.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Shoulder Pain	Arthralgia	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	12:48
2	Placebo	18SEP2020 (22)	11:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Thrombocytopenia	Thrombocytopenia	27OCT2020 (61)		11NOV2020 (76)		16	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (11NOV2020)	NOT RELATED/OTHER: Unknown at this time	2	40	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1116 11161045, a 66-year-old black/African American male with no pertinent medical history, received Dose 1 on 28 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 22). The subject was diagnosed with thrombocytopenia on 27 Oct 2020, 39 days after receiving Dose 2.

On 27 Oct 2020 (Day 61), the subject visited the emergency room for shortness of breath, chest pain and a history of 4 months of rectal bleeding and was hospitalized. Key laboratory assessments on the day of admission included a red blood cell (RBC) count of 2.53 × 106/µL (normal range [NR]: 4.5 - 5.8 × 106/µL), hemoglobin (Hgb) of 4.7 g/dL (NR: 14.0 - 17.4 g/dL), hematocrit (Hct) of 17.1% (NR: 42.0% - 52.0%), mean cell volume (MCV) of 67.6 fL (NR: 80.0 - 100.0 fL), mean cell hemoglobin (MCH) of 18.6 pg (NR: 28.0 - 34.0 pg), mean cell hemoglobin concentration (MCHC) of 27.5 g/dL (NR: 32.0 - 36.0 g/dL), platelet count of 20 × 103/µL (NR: 150 - 400 × 103/µL), red blood cell distribution width-standard deviation (RDW-SD) of 44.1 fL (NR: 39.3 - 46.1 fL), red blood cell distribution width (RDW-CV) of 18.1% (NR: 12.0%-14.6%), nucleated red blood cells (NRBC) of 0.6% (NR: 0.0% - 0.2%), NRBC count of 0.03 × 103/µL (NR: 0.00 - 0.01 × 103/µL), monocytes percentage of 10.9% (NR: 2.0% - 10.0%), international normalized ratio (INR) of 1.11 (NR: 0.90 - 1.10), prothrombin time (PT) of 14.3 seconds (NR: 12.1 - 14.9 seconds). His white blood cell (WBC) count was normal (4.94 × 103/µL [NR: 4.5 - 11.0 × 103/µL]).

Also, on the day of admission, urinalysis, chest x-ray, and abdominal ultrasound results were unremarkable and a SARS-CoV-2 test was negative. The subject was transfused with packed red blood cells and platelets.

During the hospitalization, the subject also underwent a colonoscopy which did not show any clinically significant findings. An esophagogastroduodenoscopy showed candida esophagitis, for which he was treated with fluconazole at 200 mg orally daily for 2 weeks. A bone marrow biopsy was normal.

The subject was reported to have sinus bradycardia on electrocardiogram however was noted to be asymptomatic during the hospitalization.

On 10 Nov 2020 (Day 75), the subject's laboratory results showed RBC of 4.05 × 106/µL, WBC of 8.72 × 103/µL, Hgb of 9.9 g/dL, Hct of 32.5%, MCV of 80.2 fL, MCH of 24.4 pg, MCHC of 30.5 g/dL, platelet count of 367 × 103/µL, RDW-SD of 69.2 fL, RDW-CV of 24.5%, neutrophil percentage of 89.0% (NR: 40.0%-75.0%), lymphocytes percentage of 6.3% (NR: 20.0%-51.0%), and mean platelet volume of 8.9 fL (NR: 9.4-12.4 fL). On the same day (Day 75), the subject was discharged from the hospital in a stable condition. The thrombocytopenia was noted as resolved on 11 Nov 2020 (Day 76).

In the opinion of the investigator, there was no reasonable possibility that the thrombocytopenia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	20	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151.13 cm	91.73 kg	40.1 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2019	Present
Abdominal Pain undiagonised origin	Abdominal pain	AUG2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	11:54
2	BNT162b2	22SEP2020 (23)	14:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Bile duct stone	Choledocholithiasis	13SEP2020 (14)	19:00	19SEP2020 (20)	01:01	7	3	TC/TCN	Y
2	GASTR	Obstructive pancreatitis	Gall Stone Pancreatitis	13SEP2020 (14)		18SEP2020 (19)		6	3	TC/TCN	Y
3	CARD	Sinus arrhythmia	Sinus Arythima	14SEP2020 (15)	00:00	ONGOING			1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19SEP2020)	NOT RELATED/OTHER: Patient had underlying, undiagnosed condition	1	14	Y
2	Resolved (18SEP2020)	NOT RELATED/OTHER: Undiagnosed preexisiting condition	1	14	Y
3	Yes	NOT RELATED/OTHER: This was likely there before and just undiagnosed	1	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1116 11161059, a 20-year-old black/African American female with a pertinent medical history of obesity (since 2019) and abdominal pain (in Aug 2019), received Dose 1 on 31 Aug 2020 and Dose 2 on 22 Sep 2020 (Day 23). The subject was diagnosed with a bile duct stone and obstructive pancreatitis on 13 Sep 2020, 13 days after receiving Dose 1. On 13 Sep 2020 (Day 14), the subject presented to the emergency room (ER) with severe stomach pain. An ultrasound scan performed in the ER showed a stone in the distal common bile duct and she was hospitalized. A computerized tomogram revealed inflammation in the liver and pancreas and gallstones. Admission laboratory tests showed elevated alanine aminotransferase (ALT) of 238 IU/L (normal range [NR]: 30-65 IU/L), aspartate aminotransferase (AST) of 340 IU/L (NR: <35 IU/L), and lipase of 9005 IU/L (NR: 73-393 IU/L). During her hospitalization, an abdominal ultrasound on 14 Sep 2020 (Day 15) revealed choledocholithiasis/dilated common bile duct. An endoscopic retrograde cholangiopancreatography showed a gallbladder full of stones and repeat laboratory tests showed ALT of 136 IU/L, AST of 59 IU/L, bilirubin of 0.6 mg/dL (NR: <1.1 mg/dL), and lipase of 50 IU/L. Tests for hepatitis B and hepatitis C, methicillin-resistant Staphylococcus aureus and SARS-CoV-2 were all negative. On 16 Sep 2020 (Day 17), the gallbladder was removed. On the same day (Day 17), the laboratory test results showed ALT of 88 IU/L, AST of 23 IU/L, bilirubin of 0.4 mg/dL, and ALP of 157 IU/L. On 18 Sep 2020 (Day 19), the obstructive pancreatitis resolved and the subject was discharged from the hospital. On 19 Sep 2020 (Day 20), the bile duct stone resolved. On 22 Sep 2020 (Day 23), the subject visited the clinic for Visit 2 and reported that she had recovered completely and was no longer taking any medication. Furthermore, she reported that she had no pain or residual issues from the surgery. In the opinion of the investigator, there was no reasonable possibility that the bile duct stone and obstructive pancreatitis were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
194.56 cm	122.36 kg	32.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FISH ALLERGY	Food allergy	1979	Present
ALCOHOLISM	Alcoholism	2005	Past
BIPOLAR DISORDER	Bipolar disorder	2016	Present
DEPRESSION	Depression	2016	Present
HYPERTENSION	Hypertension	2016	Present
SCHIZOPHRENIA	Schizophrenia	2016	Present
ANXIETY	Anxiety	2017	Present
INSOMNIA	Insomnia	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CONSTIPATION	Constipation	2018	Present
DIABETES MELLITUS TYPE II	Type 2 diabetes mellitus	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	16:02
2	Placebo	10SEP2020 (22)	13:12

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RENAL	Acute kidney injury	ACUTE KIDNEY INJURY	26AUG2020 (7)		30AUG2020 (11)		5	1	TC	N
2	MUSC	Musculoskeletal stiffness	NECK STIFFNESS	21SEP2020 (33)	08:00	ONGOING			1	N	N
3	MUSC	Pain in extremity	ARM SORENESS, LEFT	22SEP2020 (34)	08:00	02OCT2020 (44)		11	2	N	N
4	MUSC	Rhabdomyolysis	RHABDOMYOLYSIS	26AUG2020 (7)		30AUG2020 (11)		5	1	TC	N

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
5	PSYCH	Suicidal ideation	Suicidal ideation	27AUG2020 (8)		30AUG2020 (11)		4	4	TC	Y
6	NERV	Syncope	Syncopal Episode	26AUG2020 (7)		30AUG2020 (11)		5	4	N	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (30AUG2020)	NOT RELATED/OTHER: HEAT RELATED EVENT	1	7	N
2	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN PER INVESTIGATOR	2	12	N
3	Resolved (02OCT2020)	NOT RELATED/OTHER: ETIOLOGY NOT KNOWN PER INVESTIGATOR	2	13	N
4	Resolved (30AUG2020)	NOT RELATED/OTHER: HEAT RELATED EVENT	1	7	N
5	Resolved (30AUG2020)	NOT RELATED/OTHER: Per participant: "due to being in the hospital"	1	8	Y
6	Resolved (30AUG2020)	NOT RELATED/OTHER: Due to heat, acute kidney injury, rhabdomyolysis	1	7	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	14SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1117 11171036, a 45-year-old white male with a pertinent medical history of alcoholism (from 2005 to 2017); hypertension, depression, schizophrenia, and bipolar disorder (all since 2016); insomnia and anxiety (both since 2017); and type 2 diabetes mellitus (since 2019), received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject reported syncope on 26 Aug 2020, 6 days after receiving Dose 1 and suicidal ideation on 27 Aug 2020, 7 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of syncope and suicidal ideation included gabapentin (since 2016) for schizophrenia and alcoholism, hydroxyzine hydrochloride (since 2017) for anxiety, trazodone hydrochloride (since 2017) for insomnia, aripiprazole (since 2018) for bipolar disorder/schizophrenia, and acamprosate calcium (since 2018) for alcoholism. On 26 Aug 2020 (Day 7), the subject reported that he walked a few miles to the grocery store and back to his house and then did some yardwork outside his house and had a fall due to syncope. He reported that he was fine post vaccination and those the fall was because of heat exhaustion. He was taken to the emergency room (ER) by an ambulance and was hospitalized overnight for observation. The subject denied undergoing any invasive procedures other than a blood draw. On the same day (Day 7), laboratory results showed creatine phosphokinase of 644 U/L (normal range [NR]: 2 - 200 U/L), blood urea nitrogen of 20 mg/dL (NR: 6 - 20 mg/dL), creatinine of 2.16 mg/dL (NR: 0.67 – 1.17 mg/dL), estimated glomerular filtration rate (eGFR) of 33 mL/minute/1.73m2 (NR: >60 mL/minute/1.73m2), β-hydroxybutyrate of 1.1 mmol/L (NR: <0.5 mmol/L), and urine ketones of 2+ (NR: negative). On the same day (Day 7), the subject was diagnosed with acute kidney injury and rhabdomyolysis (both were reported as nonserious adverse events). The next day on 27 Aug 2020 (Day 8), he stated that he might do something to himself if they sent him back to his house. According to the subject, being in the hospital overnight triggered his suicidal ideations. During the hospitalization, the subject was treated with trazodone 100 mg once daily (QD) (from 27 Aug 2020 to 29 Aug 2020); docusate sodium 100 mg twice a day (BID), lactated Ringers solution, and enoxaparin sodium 40 mg QD (all from 27 Aug 2020 to 30 Aug 2020); mirtazapine 15 mg QD (from 28 Aug 2020 to 29 Aug 2020); and hydrocodone bitartrate/paracetamol as needed (one tablet given each day) (from 29 Aug 2020 to 30 Aug 2020). On 30 Aug 2020 (Day 11), the acute kidney injury, rhabdomyolysis, syncope, and suicidal ideation resolved. The subject was discharged from the hospital on 30 Aug 2020 (Day 11) with a discharge diagnosis of heat related illness with syncope, metabolic abnormalities, acute kidney injury secondary to dehydration, rhabdomyolysis secondary to heat, type 2 diabetes mellitus, bipolar disorder, and schizophrenia. In the opinion of the investigator, there was no reasonable possibility that the syncope and suicidal ideation were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	91.3 kg	35.7 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PSORIASIS	Psoriasis	1957	Present
ALLERGY TO IODINE	Iodine allergy	1976	Present
BRONCHIAL ASTHMA	Asthma	1990	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	1990	Present
HYPERTENSION	Hypertension	1990	Present
OSTEOARTHRITIS BILATERAL KNEE, HIP	Osteoarthritis	1990	Present
OSTEOARTHRITIS SPINE	Spinal osteoarthritis	1990	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2010	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	14:15
2	Placebo	08SEP2020 (23)	14:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1			bilateral pulmonary embolism	11NOV2020 (87)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: pulmonary embolism	2	65	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1118 11181044, a 73-year-old white female with a pertinent medical history of psoriasis (since 1957), asthma and hypertension (both since 1990), hyperlipidemia (since 2010), and coronary artery disease (since 2011), received Dose 1 on 17 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 23). The subject was diagnosed with a bilateral pulmonary embolism on 11 Nov 2020, 64 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the bilateral pulmonary embolism included glucosamine, vitamin B complex, vitamin D, and tocopherol, calcium, and zinc (all since 1985) as dietary supplements, losartan potassium (since 1990) for hypertension, loratadine (since 2000) for environmental allergies, atorvastatin (since 2000) for hyperlipidemia, acetylsalicylic acid (since 2011) for cardiac prophylaxis, and metoprolol tartrate (since 2012) for hypertension, bacitracin/neomycin sulfate/polymyxin B sulfate (since 10 Oct 2020) for psoriasis, and pantoprazole (since 03 Nov 2020) for gastroesophageal reflux disease. On 11 Nov 2020 (Day 87), the subject presented to the emergency room with shortness of breath and low oxygen saturation levels and was hospitalized. On the same day (Day 87), laboratory results showed high D-dimer of 14480 ng/mL (NR: ≤499 ng/mL), high blood urea nitrogen of 23 mg/dL (NR: 10 – 20 mg/dL), low glomerular filtration rate of 56 mL/minute/1.73m2 (NR: >60 mL/minute/1.73m2), and normal glucose of 110 mg/dL (NR: 72 – 140 mg/dL). Ventilation/perfusion scan revealed multiple segments of ventilation/perfusion mismatch defect involving bilateral lungs, which was suggestive of pulmonary embolism. A chest x-ray was notable only for revealed thoracic aortic vascular calcifications. A venous ultrasound of bilateral lower extremities was normal. An electrocardiogram showed normal sinus rhythm. A SARS-CoV-2 NAAT performed during the hospitalization was negative. The subject was treated with acetaminophen 650 mg per oral (PO) every 4 hours (Q4H) as needed (PRN), fluticasone propionate/salmeterol xinafoate inhalation 250 µg (50 µg /inhalation) 1 puff twice a day (BID), albuterol nebulizer 2.5 mg Q4H PRN, acetylsalicylic acid 81 mg PO once daily (QD), atorvastatin 80 mg PO QD before bed, clarithromycin 5 mg PO QD, metoprolol tartrate 25 mg PO BID, magnesium hydroxide 30 mL PO QD-PRN, glyceryl trinitrate 0.4 mg sublingual every 5 minutes PRN, intravenous ondansetron 4 mg Q4H QD, calcium carbonate/cholecalciferol 500 mg PO QD, minerals/vitamins 1 tablet PO QD, valsartan 160 mg PO QD, vitamin E 400 IU PO QD, and vitamin D3 2000 IU PO QD. The subject was discharged from the hospital on 14 Nov 2020 (Day 90). The subject was treated with apixaban 5 mg 4 times a day from 14 Nov 2020 to 21 Nov 2020 and 5 mg BID since 22 Nov 2020. The bilateral pulmonary embolism was considered ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the bilateral pulmonary embolism was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.3 cm	52.9 kg	20.1 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
migraines	Migraine	1977	Present
dermatitis	Dermatitis	1990	Present
metamucil allergy	Drug hypersensitivity	1990	Present
hypertension	Hypertension	2009	Present
hypothyroidism	Hypothyroidism	2009	Present
post menopausal	Postmenopause	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	15:32
2	BNT162b2	10SEP2020 (24)	12:18

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Diverticulitis	Sigmoid diverticulitis	04SEP2020 (18)		18SEP2020 (32)	00:00	15	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: Sigmoid diverticulosis	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1118 11181057, a 63-year-old white female with no pertinent medical history, received Dose 1 on 18 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 24). The subject was diagnosed with diverticulitis on 04 Sep 2020, 17 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the diverticulitis included sumatriptan (since 1979) for migraines, levothyroxine sodium (since 2009) for hypothyroidism, and losartan potassium (since 2018) for hypertension. On 04 Sep 2020 (Day 18), the subject presented to the emergency room with abdominal pain and was hospitalized. Laboratory results showed a white blood cell count of 13.7 K/µL (normal range [NR]: 4.0 – 10.5 K/µL), C-reactive protein of 5.7 mg/dL (NR: <0.9 mg/dL), urinalysis revealed ketones of 10 mg/dL (NR: negative), and a SARS-CoV-2 test was negative. A computerized tomogram of the abdomen showed sigmoid diverticulitis. Treatment included intravenous (IV) morphine (1 mg), metronidazole 500 mg/sodium chloride at 100 mL/hour (from 04 Sep 2020 to 06 Sep 2020), IV sodium chloride 0.9% (1000 mL bag) at 80 mL/hour and IV ceftriaxone 1 g/D5W 50 mL at 100 mL/hour (from 05 Sep 2020 to 06 Sep 2020). Culture was not performed. The subject was discharged from the hospital on metronidazole tablet 500 mg per oral (PO) twice a day (BID) and cefdinir capsule 300 mg PO BID (both to be taken until 16 Sep 2020). On 18 Sep 2020 (Day 32), the diverticulitis resolved. In the opinion of the investigator, there was no reasonable possibility that the diverticulitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	80.5 kg	30.4 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	1990	Present
sarcoidosis	Sarcoidosis	2010	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2014	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present
RHINITIS	Rhinitis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	13:26
2	Placebo	11SEP2020 (23)	11:37

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Gout	GOUT RIGHT FOOT	06OCT2020 (48)	00:00	ONGOING			1
2	MUSC	Musculoskeletal chest pain	chest wall pain	14SEP2020 (26)	10:30	03NOV2020 (76)		51	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	26	N
2	TC	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown at this time	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1118 11181074, a 73-year-old white female with a pertinent medical history of sarcoidosis (since 2010), received Dose 1 on 20 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 23). The subject experienced musculoskeletal chest pain (chest wall pain) on 14 Sep 2020, 3 days after receiving Dose 2.

Concomitant medications reported within 2 weeks prior to the onset of the musculoskeletal chest pain included salbutamol (since 2010) for sarcoidosis, atorvastatin (since 2014) for hyperlipidemia, citalopram (since 2014) for depression, levocetirizine (since 2018) for seasonal allergies, buspirone (since 2018) for depression, fluticasone propionate (since 2019) for rhinitis, and ascorbic acid (since Feb 2020) as a dietary supplement.

On 14 Sep 2020 (Day 26), the subject presented to the emergency room complaining of chest pressure (chest wall pain) and was hospitalized. On the same day (Day 26), a SARS-CoV-2 test was negative. The subject was discharged from the hospital on 15 Sep 2020 (Day 27) on a 5-day course of prednisone 2 × 20 mg per oral (PO) once daily (QD) and zolpidem 5 mg PO QD at bedtime for 28 days. The investigator reported that the subject continued to have musculoskeletal chest pain and on 03 Nov 2020 (Day 76) she underwent a procedure to receive a pacemaker as a result of the chest wall pain. The musculoskeletal chest pain was considered resolved on the same day (Day 76).

In the opinion of the investigator, there was no reasonable possibility that the musculoskeletal chest pain was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	86.36 kg	26.5 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High Cholesterol	Blood cholesterol increased	2001	Present
Vasectomy	Vasectomy	2001	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2004	Present
Lower back pain	Back pain	2009	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:53
2	BNT162b2	16SEP2020 (22)	08:58

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	ST elevation myocardial infarction	27SEP2020 (33)		13OCT2020 (49)		17	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (13OCT2020)	NOT RELATED/OTHER: related to cardiovascular risk	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1124 11241106, a 48-year-old white male with a pertinent medical history of blood cholesterol increased (since 2001) and family history of coronary artery disease, received Dose 1 on 26 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 22). The subject was diagnosed with an acute myocardial infarction on 27 Sep 2020, 11 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the acute myocardial infarction included atorvastatin (since 2001) for hypercholesterolemia. On 27 Sep 2020 (Day 33), the subject fell off a bike and became unresponsive. Cardiopulmonary resuscitation was performed and he was hospitalized due to sudden cardiac arrest (reported as "heart attack"). An electrocardiogram revealed ventricular fibrillation and large anterior wall ST elevation suggestive of myocardial infarction. Laboratory results showed high prothrombin time of 12.6 seconds and high troponin I of 0.149 ng/mL (normal ranges were not reported). A SARS-CoV-2 test was negative. A cardiac catheterization (interventional) showed 100% stenosis/occlusion of the left anterior descending artery, and a drug eluding stent was placed. An echocardiogram showed anterior hypokinesia with ejection fraction of 40%-45%. A computerized tomogram of the head performed given her fall from the bike was unremarkable. The subject was discharged from the hospital on 30 Sep 2020 (Day 36) on acetaminophen 650 mg every 4 hours as needed for pain, acetylsalicylic acid 81 mg per oral daily for anticoagulation, clopidogrel 75 mg daily for clot prevention, lisinopril 5 mg daily and metoprolol extended release 50 mg daily for blood pressure management, and nitroglycerin 0.4 mg sublingually as needed for chest pain. The subject was also instructed to follow a cardiac diet and eliminate processed foods. On 13 Oct 2020 (Day 49), the subject completely recovered from the acute myocardial infarction and returned to his daily activities. In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to cardiovascular risk. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	70	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	77.1 kg	31.3 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
urinary Tract Infection - Recurrent	Urinary tract infection	1951	Present
Bronchitis - Recurrent	Bronchitis	1960	Present
Seasonal Allergies	Seasonal allergy	1960	Present
Myopia	Myopia	1962	Present
Migraines	Migraine	1980	Present
Allergy to Non-Steroidal Anti-Inflammatory drugs	Drug hypersensitivity	1990	Present
hypothyroidism	Hypothyroidism	1992	Present
Hypertension	Hypertension	1993	Present
Asthma	Asthma	1995	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	1995	Present
Hyperlipidemia	Hyperlipidaemia	1998	Present
postmenopausal	Postmenopause	2000	Present
Uterine polyps	Uterine polyp	2002	Past
Hysterectomy	Hysterectomy	2005	Past
osteoarthritis - Bilateral Hips	Osteoarthritis	2008	Present
osteoarthritis - Generalized	Osteoarthritis	2008	Present
Osteoarthritis - Left Shoulder	Osteoarthritis	2018	Present
Hearing Loss Bilateral	Deafness bilateral	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	17:52
2	BNT162b2	18AUG2020 (20)	10:39

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Asthma	worsening of asthma	01OCT2020 (64)		ONGOING	
2	NEOPL	Invasive ductal breast carcinoma	Malignant invasive ductal carcinoma left breast	05NOV2020 (99)	11:55	ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		1	TC	N	Yes	NOT RELATED/OTHER: allergy	2	45	N
2		3	N	Y	Yes	NOT RELATED/OTHER: malignancy	2	80	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Influenza vaccination	INFLUENZA VACCINE	08SEP2020

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	15SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1127 11271023, a 70-year-old white female with a pertinent medical history of hypothyroidism (since 1992), hypertension (since 1993), hyperlipidemia (since 1998), uterine polyp (in 2002), and hysterectomy (in 2005), received Dose 1 on 30 Jul 2020 and Dose 2 on 18 Aug 2020 (Day 20). The subject was diagnosed with invasive ductal breast carcinoma on 05 Nov 2020, 79 days after receiving Dose 2. The subject informed the site that she had an ultrasound scan on 05 Nov 2020 (Day 99), which showed invasive ductal carcinoma of the left breast. It was considered as a medically significant event by the investigator. The subject visited a physician and was scheduled to meet a surgeon for the invasive ductal breast carcinoma. The invasive ductal breast carcinoma was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the invasive ductal breast carcinoma was related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	90.64 kg	29 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1953	Past
Tonsillitis	Tonsillitis	1953	Past
Appendectomy	Appendicectomy	1956	Past
Appendicitis	Appendicitis	1956	Past
Vasectomy	Vasectomy	1974	Past
Anxiety	Anxiety	1995	Present
Diabetes Type 2	Type 2 diabetes mellitus	2005	Present
Prostate Cancer, malignant	Prostate cancer	2008	Past
Prostectomy	Prostatectomy	2008	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
elevated cholesterol	Blood cholesterol increased	2010	Present
Glaucoma	Glaucoma	2010	Present
Acid Reflux	Gastrooesophageal reflux disease	2012	Present
Low Vitamin D	Vitamin D decreased	2015	Present
Arthritis	Arthritis	DEC2017	Present
Muscle Fatigue	Muscle fatigue	2019	Present
Hypotension	Hypotension	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	17:51
2	Placebo	27AUG2020 (28)	12:59

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Fall	Fall	28AUG2020 (29)	09:30	28AUG2020 (29)	09:30	1
2	INJ&P	Skin laceration	Facial Lacerations	28AUG2020 (29)	09:30	20SEP2020 (52)		24

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (28AUG2020)	NOT RELATED/OTHER: Hypotension	2	2	N
2	2	TCN	Y	Resolved (20SEP2020)	NOT RELATED/OTHER: Fall	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	24SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1128 11281014, a 79-year-white male with a pertinent medical history of type 2 diabetes mellitus (since 2005), vitamin D decreased (since 2015), muscle fatigue (since 2019), and hypotension (since Aug 2019), received Dose 1 on 31 Jul 2020 and Dose 2 on 27 Aug 2020 (Day 28). The subject reported a skin laceration (facial lacerations) on 28 Aug 2020, 1 day after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the skin laceration included sertraline hydrochloride (since 1995) for anxiety; famotidine (since 2000) for acid reflux; pioglitazone hydrochloride (since 2005) and insulin aspart and insulin degludec (both since 2015) for type 2 diabetes; ezetimibe/simvastatin (since 2010) for elevated cholesterol; latanoprost, dorzolamide hydrochloride/timolol maleate, brimonidine, xantofyl, and acetazolamide (all since 2010) all for glaucoma; acetylsalicylic acid (since 2015) for heart health; vitamin B complex (since 2015) for muscle weakness; vitamin D3 (since 2015) for low vitamin D; Hypericum perforatum (since 2015) for anxiety; chondroitin/glucosamine (since 2015) for arthritis; and midodrine (since 2017) for hypotension. On 28 Aug 2020 (Day 29), the subject presented to the emergency room with facial lacerations resulting from a fall. On the same day (Day 29), he was hospitalized and had stitches on his face. No broken bones or neurological trauma were reported. It was determined that the fall that caused the facial lacerations was due to an episode of hypotension. On 02 Sep 2020 (Day 34), the subject was discharged from the acute care hospital and sent to the rehabilitation center to convalesce. On 20 Sep 2020 (Day 52), the skin laceration resolved. In the opinion of the investigator, there was no reasonable possibility that the skin laceration was related to the study intervention, concomitant medications, or clinical trial procedures; but rather it was related to a fall. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	54.64 kg	22 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
low back pain	Back pain	1987	Present
migraines	Migraine	1987	Present
restless leg syndrome	Restless legs syndrome	1988	Present
total hysterectomy	Hysterectomy	2002	Past
polycystic ovarian disorder	Polycystic ovaries	2002	Past
seizure disorder	Seizure	2003	Present
muscle spasms	Muscle spasms	2008	Present
anxiety	Anxiety	2010	Present
depression	Depression	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteopenia	Osteopenia	2015	Present
seasonal allergies	Seasonal allergy	2015	Present
bipolar disorder	Bipolar disorder	2018	Present
shortness of breath	Dyspnoea	2018	Present
hyperlipidemia	Hyperlipidaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	14:33
2	BNT162b2	01SEP2020 (21)	13:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INV	Blood potassium decreased	Low potassium	03OCT2020 (53)		22OCT2020 (72)		20	2
2	INFEC	Escherichia urinary tract infection	Escherichia coli urinary tract infection	03OCT2020 (53)		22OCT2020 (72)		20	2
3	RENAL	Nephrolithiasis	Kidney Stones	03OCT2020 (53)		22OCT2020 (72)		20	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: HYPOKALEMIA	2	33	Y
2	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	2	33	Y
3	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: RENAL CALCULUS	2	33	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1128 11281103, a 48-year-old white female with a pertinent medical history of back pain (since 1987), restless legs syndrome (since 1988), polycystic ovaries (in 2002), muscle spasms (since 2008), and hyperlipidemia (since 2019), received Dose 1 on 12 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 21). The subject was diagnosed with blood potassium decreased, Escherichia coli urinary tract infection, and nephrolithiasis on 03 Oct 2020, 32 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the blood potassium decreased, Escherichia coli urinary tract infection, and nephrolithiasis included levetiracetam (since 2003) for seizure disorder, quetiapine fumarate (since 2010) for bipolar disorder, paroxetine hydrochloride (since 2010) for anxiety, butalbital/caffeine/paracetamol (since 2010) and topiramate (since 2013) for migraines, gabapentin (since 2013) and oxycodone hydrochloride/paracetamol (since 2016) for low back pain, buspirone hydrochloride (since 2014) for depression, baclofen (since 2018) for muscle spasms, ropinirole hydrochloride (since 2018) for restless leg syndrome, fish oil and vitamin D2 (since 2019) as vitamin supplements, atorvastatin (since 2019) for hyperlipidemia, cetirizine hydrochloride (since 2019) for seasonal allergies, and albuterol inhaler (since 2020) for shortness of breath. On 03 Oct 2020 (Day 53), the subject experienced shortness of breath, sore throat, vomiting, and fever (99℉ to 100℉). On 07 Oct 2020 (Day 57), a SARS-CoV-2 test was negative. On 14 Oct 2020 (Day 64), her potassium was low at 2.3 mmol/L (normal range: 3.5 - 5.1 mmol/L), and a urinalysis showed 1+ leukocytes esterase (normal low: negative). A chest x-ray was normal, and the computerized tomogram of the abdomen/pelvis with contrast showed no evidence of diverticulitis. On 14 Oct 2020 (Day 64), the subject went to the emergency room as she could not get a follow-up appointment with her primary care physician. She was hospitalized for nephrolithiasis, blood potassium decreased, and Escherichia coli urinary tract infection. While hospitalized, the subject was also reported to have been treated with doxycycline for diarrhea and ondansetron hydrochloride for nausea (both from 20 Oct 2020 to 22 Oct 2020). On 22 Oct 2020 (Day 72), the blood potassium decreased, Escherichia coli urinary tract infection, and nephrolithiasis resolved. In the opinion of the investigator, there was no reasonable possibility that the blood potassium decreased, Escherichia coli urinary tract infection, and nephrolithiasis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1936	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	83.91 kg	23.7 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	(b) (6) 1936	Present
hypercholesterolemia	Hypercholesterolaemia	1950	Present
drug allergy: penicillin	Drug hypersensitivity	1958	Present
tobacco smoker	Tobacco user	1960	Past
hypertriglyceridemia	Hypertriglyceridaemia	2000	Present
cataracts-bilateral	Cataract	2010	Past
Left hip replacement surgery	Hip arthroplasty	2010	Past
Intraocular Lens Replacement-Bilateral	Intraocular lens implant	2010	Past
left leg weakness	Muscular weakness	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis left hip	Osteoarthritis	2010	Present
allergic rhinitis-seasonal	Seasonal allergy	2010	Present
mitral valve replacement	Mitral valve replacement	2012	Past
coronary artery disease	Coronary artery disease	2013	Past
mitral valve disease	Mitral valve disease	2013	Past
basal cell skin cancer	Basal cell carcinoma	2015	Past
vertigo	Vertigo	2015	Present
mild memory loss	Amnesia	2018	Present
atrial fibrillation	Atrial fibrillation	2018	Past
cholecystectomy	Cholecystectomy	2018	Past
Cholelithiasis	Cholelithiasis	2018	Past
clostridium difficile infection	Clostridium difficile infection	2018	Past
hemicolectomy	Colectomy	2018	Past
diverticulosis	Diverticulum	2018	Past
seborrhea-face/scalp	Seborrhoea	2018	Present
vena cava thrombosis	Vena cava thrombosis	2018	Past
deep vein thrombosis	Deep vein thrombosis	JUN2018	Past
ivc filter insertion	Vena cava filter insertion	JUN2018	Past
erectile dysfunction	Erectile dysfunction	2019	Present
abnormal gait	Gait disturbance	14JAN2020	Present
bilateral foot edema	Oedema peripheral	14JAN2020	Past
cough variant asthma	Cough variant asthma	MAY2020	Present
short bowel syndrome	Short-bowel syndrome	18MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10AUG2020 (1)	11:44
2	BNT162b2	31AUG2020 (22)	10:11

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	EYE	Diplopia	double vision	21AUG2020 (12)		22AUG2020 (13)		2	3	N
2	EAR	Vertigo	Worsened Vertigo	21AUG2020 (12)		24AUG2020 (15)		4	3	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (22AUG2020)	NOT RELATED/OTHER: related to vertigo	1	12	Y
2	Y	Resolved (24AUG2020)	NOT RELATED/OTHER: subject history of vertigo exacerbation	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	28SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1129 11291074, an 84-year-old white male with a pertinent medical history of myopia (since 17 Jun 1936), tobacco user (in 1960), bilateral cataract and bilateral intraocular lens implant (both in 2010), vertigo (since 2015), and gait disturbance (since 14 Jan 2020), received Dose 1 on 10 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 22). The subject reported diplopia and worsened vertigo on 21 Aug 2020, 11 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the diplopia and worsened vertigo included multivitamins (since 2010) as a supplement, acetaminophen (since 2018) for osteoarthritis, loratadine (since 2018) for allergic rhinitis, and salbutamol sulfate (since 10 Aug 2020) for cough variant asthma. On 21 Aug 2020 (Day 12), the subject experienced worsening of vertigo along with diplopia and went to the emergency room. He was hospitalized and underwent an electrocardiogram which showed discernible P-waves, variable PR interval without a pattern, and a varying rhythm rate indicative of possible sick sinus syndrome. No ST-elevation was observed. On the same day (Day 12), a chest x-ray showed no acute cardiopulmonary disease. Computerized tomogram of the brain showed no evidence of acute intracranial abnormality; a generalized brain atrophy with mild periventricular white matter hypodensity possibly representing chronic microvascular ischemic changes and chronic appearing left superior cerebellar hemisphere lacunar infarct were observed. On 21 Aug 2020 (Day 12), a SARS-CoV-2 nasal swab test was negative. On 22 Aug 2020 (Day 13), the diplopia (double vision) resolved and the vertigo symptoms improved. On 23 Aug 2020 (Day 14), a magnetic resonance imaging of the brain showed posterior right temporal lobe single focus of diffusion-weighted images hyperintensity without corresponding apparent diffusion coefficient (ADC) hypointensity, which could represent a sub-acute lacunar infarct with normalized ADC map. Mild periventricular white matter chronic microvascular ischemic changes with no acute intracranial hemorrhage was observed. The subject was not started on any medications. The subject was given a walker at the hospital and was subsequently discharged on 23 Aug 2020 (Day 14). On 24 Aug 2020 (Day 15), the worsened vertigo resolved but he was still having issues with balance. In the opinion of the investigator, there was no reasonable possibility that the diplopia and worsened vertigo were related to the study intervention, concomitant medications or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	83.27 kg	27.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Strawberry allergy	Food allergy	1953	Present
Penicillin allergy	Drug hypersensitivity	1958	Present
asthma	Asthma	1961	Past
right wrist fracture	Wrist fracture	1965	Past
Kenalog allergy	Drug hypersensitivity	1973	Present
Prednisone allergy	Drug hypersensitivity	1973	Present
Nut allergy	Food allergy	1975	Present
jawbone cyst removal	Bone cyst excision	1979	Past
arthroscopy right knee	Arthroscopy	1985	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arthroscopy left knee	Arthroscopy	1993	Past
hypercholesterolemia	Hypercholesterolaemia	1995	Present
left anterior cruciate ligament reconstruction	Ligament operation	JUL1996	Past
left knee osteoarthritis	Osteoarthritis	1998	Present
iliotibial band friction syndrome	Iliotibial band syndrome	2000	Present
left knee repair	Knee operation	2000	Past
removal of bottom screw left knee	Knee operation	2000	Past
antiphospholipid syndrome	Antiphospholipid syndrome	2002	Present
anxiety	Anxiety	2002	Present
depression	Depression	2002	Present
encephalitis	Encephalitis	2002	Past
right sided hemiplegia	Hemiplegia	2002	Present
hypertension	Hypertension	2002	Present
viral meningitis	Meningitis viral	2002	Past
seasonal allergies	Seasonal allergy	2003	Present
Fatty liver disease	Hepatic steatosis	11FEB2003	Present
spasmodic dysphonia	Spasmodic dysphonia	04AUG2003	Present
sleep apnea	Sleep apnoea syndrome	2004	Present
temporomandibular joint dysfunction	Temporomandibular joint syndrome	26JUL2004	Present
gout	Gout	2005	Present
arthroscopy left knee	Arthroscopy	21NOV2005	Past
right radial styloid tenosynovitis surgical release	Tenotomy	05APR2006	Past
type 2 diabetes	Type 2 diabetes mellitus	2009	Present
left radial styloid tenosynovitis release	Tenotomy	20JUL2009	Past
diabetic neuropathy bilateral feet	Diabetic neuropathy	27OCT2009	Present
diabetic neuropathy bilateral hands	Diabetic neuropathy	27OCT2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left total knee repair	Knee operation	13MAY2010	Past
right iritis	Iritis	22NOV2010	Past
acute lymes disease	Lyme disease	08AUG2011	Past
partial detached retina left eye	Retinal detachment	12APR2012	Past
revision left total knee replacement	Knee arthroplasty	15AUG2013	Past
revision left total knee replacement	Knee arthroplasty	10OCT2014	Past
laser surgery left eye	Eye laser surgery	19NOV2014	Past
Upper respiratory infection	Upper respiratory tract infection	27JAN2015	Past
iliotibial band release	Fascia release	07JUL2015	Past
left knee pyogenic granuloma removal	Skin neoplasm excision	13NOV2015	Past
right inner thigh fungal infection	Fungal skin infection	28SEP2016	Past
allergy induced edema	Allergic oedema	2017	Present
Norvasc allergy	Drug hypersensitivity	2017	Present
patella femur realignment surgery	Bone operation	14JUN2017	Past
unstable medial collateral ligament left knee	Ligament disorder	26JUL2017	Present
left sided cataracts	Cataract	2018	Past
cataract removal left eye	Cataract operation	2018	Past
Ocular ischemic syndrome	Ocular ischaemic syndrome	2018	Present
Open angle glaucoma	Open angle glaucoma	2018	Present
rosacea	Rosacea	2018	Present
lumbar fusion	Spinal fusion surgery	2018	Past
lumbar laminectomy	Spinal laminectomy	2018	Past
steroid responder	Therapy responder	29OCT2018	Present
lesion removal right elbow	Elbow operation	30JAN2019	Past
Tropical ulcer right elbow	Tropical ulcer	15JUL2019	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
revision left total knee replacement	Knee arthroplasty	20AUG2019	Past
injection left iliotibial band	Injection	17APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	11:45
2	Placebo	15SEP2020 (22)	12:02

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Osteomyelitis	osteomyelitis distal phalanx right 3rd toe	31AUG2020 (7)		26SEP2020 (33)		27	3
2	EYE	Retinal detachment	detached left retina	26OCT2020 (63)		28OCT2020 (65)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (26SEP2020)	NOT RELATED/OTHER: related to bacterial infection	1	7	Y
2	TC/TCN	N	Resolved (28OCT2020)	NOT RELATED/OTHER: worsening of past medical history	2	42	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1129 11291138, a 67-year-old white male with a pertinent medical history of osteoarthritis (left knee, since 1998), type 2 diabetes mellitus (since 2009), diabetic neuropathy (bilateral feet and bilateral hands since 27 Oct 2009), knee arthroplasty (revision total left knee replacement on 15 Aug 2013, on 10 Oct 2014, and on 20 Aug 2019), skin neoplasm excision (left knee pyogenic granuloma removal on 13 Nov 2015), fungal skin infection (on 28 Sep 2016), ligament disorder (since 26 Jul 2017), spinal fusion surgery and spinal laminectomy (both in 2018), and injection (left iliotibial band on 17 Apr 2020), received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). The subject experienced osteomyelitis (distal phalanx of the right third toe) on 31 Aug 2020, 6 days after receiving Dose 1. On 31 Aug 2020 (Day 7), the subject presented to the emergency room with a right third toe infection that was positive for Streptococcus, Staphylococcus, and Pseudomonas, and negative for methicillin-resistant Staphylococcus aureus. He was treated as an outpatient with sulfamethoxazole/trimethoprim 500 mg twice a day (from 31 Aug 2020 to 13 Sep 2020) and a probiotic 1 capsule once daily (QD) (on 31 Aug 2020). During the follow-up appointment, the infection was ongoing and the subject was started on levofloxacin 500 mg QD (on 14 Sep 2020). The SARS-CoV-2 test was negative on 16 Sep 2020 (Day 23). The subject was hospitalized on 26 Sep 2020 (Day 33) for the worsened right third toe infection. On 26 Sep 2020 (Day 33), a right foot x-ray showed osteomyelitis of the distal phalanx right third toe and C-reactive protein quantitative was <2.9 mg/L (normal range [NR]: 0.0 - 3.0 mg/L). While in the hospital, the subject was treated with metronidazole 500 mg intravenously (IV) and aztreonam 1000 mg IV (both on 26 Sep 2020), vancomycin 1750 mg IV (from 26 Sep 2020 to 29 Sep 2020), oxycodone 10 mg orally (PO) as needed (from 26 Sep 2020 to 30 Sep 2020), ertapenem IV, and calcium/vitamin D NOS PO supplement. On 27 Sep 2020 (Day 34), a magnetic resonance imaging of the foot showed bony destructive process consistent with osteomyelitis and his erythrocyte sedimentation rate was 3 mm/hour (NR: 0 - 30 mm/hour). The nuclear medicine gallium limited test on 28 Sep 2020 (Day 35) also showed osteomyelitis of distal phalanx right third toe and he had a surgical removal of part of his right third toe. On 29 Sep 2020 (Day 36), a gallium scan and vascular blood flow study were performed; however, the results were not provided. On 30 Sep 2020 (Day 37), the blood culture showed no growth within 72 hours, and had no anaerobes isolated. The subject was discharged from the hospital on 30 Sep 2020 (Day 37) with a prescription for ertapenem 1 g QD (from 30 Sep 2020 to 07 Oct 2020). On 01 Oct 2020 (Day 38), the blood culture Set 1 showed a gram-positive bacillus, and blood culture Set 2 had no growth within 5 days. The osteomyelitis was considered resolved on 07 Oct 2020 (Day 44). In the opinion of the investigator, there was no reasonable possibility that the osteomyelitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186.2 cm	92 kg	26.5 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eye glass wearer	Corrective lens user	1949	Present
benign prostatic hyperplasia	Benign prostatic hyperplasia	1990	Past
eczema, bilaterally in arms and legs	Eczema	1990	Present
transurethral resection of prostate	Transurethral prostatectomy	1990	Past
elevated cholesterol, specific level unknown	Blood cholesterol increased	2010	Present
diabetes type II without any history of ketoacidosis	Type 2 diabetes mellitus	2010	Present
diabetic neuropathy of feet, bilaterally	Diabetic neuropathy	2011	Present
insomnia	Insomnia	2011	Present
atrial fibrillation	Atrial fibrillation	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
coronary artery disease	Coronary artery disease	2012	Present
high blood pressure	Hypertension	2012	Present
full denture wearer	Denture wearer	2015	Present
edema in ankles	Oedema peripheral	2016	Present
edema in both legs	Oedema peripheral	2016	Present
osteoporosis	Osteoporosis	2016	Present
bilateral cataracts	Cataract	2018	Past
heart failure with reserved ejection fraction	Cardiac failure	2019	Present
decreased hearing in both ears	Hypoacusis	2019	Present
chronic obstructive pulmonary disease, severe	Chronic obstructive pulmonary disease	JAN2019	Present
peripheral neuropathy of feet, bilaterally	Neuropathy peripheral	APR2019	Present
urinary incontinence, urge	Urge incontinence	AUG2019	Present
chronic kidney disease, stage 3	Chronic kidney disease	OCT2019	Present
dizziness	Dizziness	JAN2020	Past
cataract surgery in both eyes	Cataract operation	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	13:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Asthenia	generalized weakness, intermittent	SEP2020 ()		ONGOING			2
2	CARD	Atrial fibrillation	Atrial fibrillation with rapid ventricular response	08OCT2020 (31)		13OCT2020 (36)		6	2
3	INJ&P	Fall	Frequent falls	SEP2020 ()		ONGOING			2
4	METAB	Hypovolaemia	hypovolemia	08OCT2020 (31)		13OCT2020 (36)		6	2
5	METAB	Hypovolaemia	hypovolemia	18OCT2020 (41)		25OCT2020 (48)		8	2
6	VASC	Orthostatic hypotension	Hypotension, orthostatic	18OCT2020 (41)		25OCT2020 (48)		8	3
7	NERV	Paraesthesia	tingling of bilateral limbs, intermittent	SEP2020 ()		ONGOING			1
8	INJ&P	Skin abrasion	abrasion of right forearm	SEP2020 ()		ONGOING			1
9	NERV	Syncope	Syncope	08OCT2020 (31)		13OCT2020 (36)		6	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
2	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: Hypovolemia	1	31	N
3	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
4	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: due to poor intake	1	31	N
5	N	N	Resolved (25OCT2020)	NOT RELATED/OTHER: Inadequate intake	1	41	N
6	TC	Y	Resolved (25OCT2020)	NOT RELATED/OTHER: Hypovolemia due to poor oral intake	1	41	Y
7	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
8	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
9	TC	Y	Resolved (13OCT2020)	NOT RELATED/OTHER: Hypovolemia	1	31	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1131 11311145, a 75-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 2010); diabetic neuropathy and insomnia (both since 2011); atrial fibrillation, coronary artery disease, and hypertension (all since 2012); cardiac failure (since 2019); chronic obstructive pulmonary disease (since Jan 2019); peripheral neuropathy (since Apr 2019); dizziness (in Jan 2020); and vertigo (since Jan 2020), received Dose 1 on 08 Sep 2020. The subject experienced syncope on 08 Oct 2020, 30 days after receiving Dose 1 and orthostatic hypotension on 18 Oct 2020, 40 days after receiving Dose 1.

Narrative Comment
Concomitant medications reported within 2 weeks prior to the onset of the syncope and orthostatic hypotension included metformin hydrochloride/sitagliptin (since 2011) and metformin (since 14 Sep 2020) both for type 2 diabetes mellitus, metoprolol tartrate (since 2012) for hypertension, atorvastatin calcium (since 2012) for hyperlipidemia, lisinopril (since 2013) for hypertension, acetylsalicylic acid (since 2015) for paroxysmal atrial fibrillation, calcium carbonate/colecalciferol (since 2017) for osteoporosis, fluticasone furoate/umeclidinium bromide/vilanterol trifenatate (since 05 Mar 2019) for chronic obstructive pulmonary disease, oxycodone hydrochloride/paracetamol (since Apr 2019) and duloxetine (since 14 Sep 2020) for peripheral neuropathy, apixaban (since 13 Oct 2020) for paroxysmal atrial fibrillation, diltiazem (since 13 Oct 2020) for hypertension, torsemide (since Oct 2020) for heart failure with preserved ejection fraction, and acetylsalicylic acid (since Oct 2020) for health maintenance. He also received influenza vaccine (on 01 Oct 2020). On 08 Oct 2020 (Day 31), the subject went to the emergency department (ED) after he experienced dizziness associated with syncope. The subject reported that while he was walking across a room he suddenly became extremely dizzy. He sat down on his couch and the next thing he recalled was waking up on the floor. It was unclear how long he was unconscious as the event was unwitnessed. The fall resulted in an abrasion on his forehead and nose, left side anterior chest discomfort (pleuritic in nature) and left shoulder discomfort with movement. He denied any shortness of breath; however, he stated that he had poor oral intake due to decreased appetite. The subject reported that he has had several episodes of dizziness with falls since Sep 2020. Additionally, it was also reported that the intermittent dizziness upon standing was also associated with paraesthesia in his arms and feet since Sep 2020. The subject refused computed tomography angiography (CTA) of his chest to rule out embolus. He was admitted for further work-up and cardiology was consulted. Based on the subject's symptoms, exam findings, and laboratory results which were notable for acute kidney injury (AKI) and hypovolemia (first episode; reported as nonserious adverse event with an onset date of 08 Oct 2020 [Day 31]). Cardiology felt the subject's symptoms might be secondary to dehydration and poor oral intake. He was hydrated with intravenous fluids (normal saline) and started on heparin for deep vein thrombosis prophylaxis. During the hospitalization, the subject was noted to be in atrial fibrillation with rapid ventricular response on 08 Oct 2020 (Day 31), which required IV diltiazem infusion. He responded to this treatment and was switched to oral diltiazem 120 mg daily. Additionally, metoprolol was also initiated and titrated up to 50 mg twice a day (BID). Apixaban was started for anticoagulation. Laboratory results on 08 Oct 2020 (Day 31) showed a hemoglobin A1C (Hb A1C) of 7.2% (normal range [NR]: 4.0%-6.0%); a CT of the head, facial bones, and spine was unremarkable except for advanced multilevel degenerative changes of the spine. On 09 Oct 2020 (Day 32), the thyroid stimulating hormone was 0.425 µIU/mL (NR: 0.0358- 3.740 µIU/mL) and magnesium was 1.9 mg/dL (NR: 1.5-2.3 mg/dL). On the same day (Day 32), an electrocardiogram (ECG) revealed tachycardic rhythm and atrial fibrillation with repolarization abnormalities; a 2D completed echocardiogram revealed mild concentric hypertrophy with an estimated ejection fraction of 55% to 60%, normal cavity size, systolic function, and wall motion of the left and right ventricle, and Grade 2 diastolic dysfunction was noted. Aortic valve regurgitation was mild to moderate and mitral valve regurgitation was mild. Left atrium was moderately to markedly dilated and right atrium was mildly dilated. Estimated systolic pulmonary artery peak pressure was 35-40 mmHg that was considered extracardiac with no pericardial effusion. On 10 Oct 2020(Day 33), the subject's vitamin B12 was 146 pg/mL (NR: 193-986 pg/mL), and folate was 11.60 ng/mL (NR: 3.10-17.50 ng/mL). On 13 Oct 2020 (Day 36), the subject's potassium was 4.0 mmol/L (NR: 3.5-5.1 mmol/L) and sodium was 137 mmol/L (NR: 136-145 mmol/L). Based on the imaging and laboratory results, it was reported that the subject did not have any acute distress and the atrial fibrillation, hypovolemia (first episode), and syncope were considered resolved on 13 Oct 2020 (Day 36). Subsequently, he was discharged from the hospital. A COVID-19 test was not performed during this hospitalization. On 18 Oct 2020 (Day 41), the subject, while on apixaban treatment from his previous hospitalization, experienced dizziness accompanied by a fall and went to the ED. Upon arrival, he was initially found to be hypotensive, and there was initial concern for a possible infectious etiology related to a diabetic foot ulcer. Apparently, the subject had a recent right third toe infection that he did not have medically treated and had since felt weaker than his baseline along with poor oral intake. In the ED, the subject was

Narrative Comment
treated with 0.9% sodium chloride 1000 mL oral and oxycodone/acetaminophen 5/325 mg 1 tablet. The subject was thought to be hypovolemic (second episode) with orthostatic hypotension. The subject was hospitalized for monitoring and evaluation. As part of the work-up, an ECG was conducted which revealed an unknown rhythm, irregular rate, nonspecific repolarization abnormalities in diffuse leads, and a prolonged QT interval; CT of the spine without contrast revealed no acute cervical spine abnormality, advanced multilevel degenerative changes and spinal canal narrowing; a chest x-ray revealed no acute findings; and CT of the head without contrast revealed no acute intracranial findings. The laboratory tests showed Hb A1C of 7.2%, white blood cell count of 12.1 × 10^3/mm^3 (NR: 4.0-10.5 × 10^3/mm^3), red blood cell count of 4.22 M/µL (NR: 4.3-5.86 M/µL), platelet count of 431 × 10^3/mm^3 (NR: 154-393 × 10^3/mm^3), absolute neutrophil count of 9.5 × 10^3/mm^3 (NR: 2.0-7.3 × 10^3/mm^3), chloride of 97 mmol/L (NR: 98-107 mmol/L), sodium of 133 mmol/L, blood urea nitrogen (BUN) of 54 mg/dL (NR: 7-18 mg/dL), creatinine of 3.4 mg/dL (NR: 0.6-1.3 mg/dL), prohormone brain natriuretic peptide of 4021 pg/mL (NR: ≤450 pg/mL), and troponin of <0.015 (NR: 0.045-0.600, unit not reported). The initial diagnosis after preliminary examination was reported as "suspect multifactorial involving poor hydration, possible infection and recent increase in beta-blocker. Concern for potential osteomyelitis of foot wounds with elevated erythrocyte sedimentation rate and C-reactive protein". The subject was again noted to have AKI though his creatinine level had improved since prior hospitalization (but not back to baseline). Further work-up of the diabetic foot ulcer was conducted. On 19 Oct 2020 (Day 42), ankle-brachial index at rest was normal bilaterally, a left foot x-ray revealed no evidence of obstruction, and right foot x-ray revealed that the second toe had been resorbed or partially resected and some degenerative findings were observed that required a magnetic resonance imaging (MRI) for evaluation of osteomyelitis. On 22 Oct 2020 (Day 45), podiatry was consulted for evaluation of early osteomyelitis or reactive osteitis and a MRI of the right foot with contrast showed partially absent second toe and bone marrow edema representing reactive osteitis versus early osteomyelitis in the third toe distal phalanx. Soft tissue swelling and myositis and muscle atrophy was noted with no evidence of fluid collection or marrow infiltration. On the same day (Day 45), cardiology was consulted because of difficulty in controlling the atrial fibrillation, resulting in intermittent episodes of rapid ventricular rate as well as hypotension. He had an unsuccessful attempt at cardioversion and eventually the heart rate was controlled after treatment with amiodarone and carvedilol. The subject was also started on midodrine 5 mg BID and the beta-blocker was discontinued secondary to the subject's hypotension. Lisinopril and torsemide were withheld secondary to his AKI; however, the subject continued treatment with diltiazem. On 25 Oct 2020 (Day 48), the subject's BUN was 11 mg/dL and creatinine substantially improved at 0.9 mg/dL. On an unknown date, the subject was discharged from the hospital in stable condition with the discharge medications including doxycycline and amoxicillin/clavulanic acid for 14 days for the diabetic foot infection and to follow-up with wound care and podiatry. He was also instructed to continue amiodarone and carvedilol and to stop metoprolol and lisinopril given the recent AKI and low blood pressures. The subject was instructed to follow-up with an interventional cardiologist for a potential watchman device placement or atrioventricular node ablation. During this hospitalization, a SARS-CoV-2 test was negative. On 25 Oct 2020 (Day 48), the hypovolemia (second episode) and orthostatic hypotension were considered resolved. In the opinion of the investigator, there was no reasonable possibility that the syncope and orthostatic hypotension were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	50 kg	19.5 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eye glass wearer	Corrective lens user	1979	Present
myopia	Myopia	1979	Present
postmenopausal state	Postmenopause	2016	Present
recurrent heartburn	Dyspepsia	2019	Present
palpitations	Palpitations	JUL2020	Present
cervical spine degeneration	Spinal osteoarthritis	JUL2020	Present
vitamin D deficiency	Vitamin D deficiency	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	13:35
2	BNT162b2	16OCT2020 (22)	15:23

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CONG	Heart disease congenital	congenital heart anomaly	02NOV2020 (39)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC	Y	Yes	NOT RELATED/OTHER: Congenital heart anomaly	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1131 11311222, a 56-year-old Asian female with a pertinent medical history of palpitations (since Jul 2020), received Dose 1 on 25 Sep 2020 and Dose 2 on 16 Oct 2020 (Day 22). The subject was diagnosed with congenital heart disease on 02 Nov 2020, 17 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of congenital heart disease included metoprolol succinate (since Jul 2020) for palpitations. The subject had been experiencing intermittent chest pain (since Jul 2020), which radiated to the right jaw and arm, worsened with exertion and associated with right arm numbness. On 02 Nov 2020 (Day 39), the subject went to the emergency department (ED) because of her recurrent chest pain. In the ED, she rated her chest pain score as 5-6 on a scale of 10 that was alleviated with nitroglycerin and oral beta blockers. Her troponins and blood creatine phosphokinase MB were negative. The subject stated that she thought her previous episodes of chest pain was because of exertion after exercising on a treadmill; however, she continued to have this pain even at rest. The subject was subsequently hospitalized for congenital heart disease. She underwent computerized tomogram angiogram of her coronary arteries on 03 Nov 2020 (Day 40), which showed "an anomalous origin of the right coronary artery (RCA) from the left coronary cusp. The vessel had an interarterial course between the ascending thoracic aorta and pulmonary artery and demonstrated a small caliber without focal stenosis or atherosclerosis throughout its interarterial course of a length of approximately 1.4 cm. The coronary circulation was right dominant". She had recurrent chest pain and required multiple doses of nitroglycerin and oral beta blockers. The subject wanted to be monitored closely in the cardiac intensive care unit (CICU) as she was concerned that her chest pain might recur. On arrival to CICU, the subject stated that her chest pain score was 2 on a scale of 10, which went up to 5 and she began experiencing right arm numbness. Her symptoms improved with up-titration of nitroglycerin and the blood pressure was under control. The subject was in the hospital for 18 hours and was sent to the clinic where she stayed for 10 days. On 12 Nov 2020 (Day 49), the subject underwent a median sternotomy with unroofing of intramural segment of anomalous RCA. Her postoperative course was complicated by anemia with hemoglobin level of 8 and hematocrit of 23.8 (units and normal ranges not reported). The subject received 1 unit of unpacked red blood cells and the anemia was considered resolved on the same day (Day 49). The subject reported that she was tested for SARS-CoV-2 test 3 times during the duration of these hospital visits and showed negative results. The congenital heart disease was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the congenital heart disease was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	112 kg	35 kg/m2	30JUL2020 (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ETOH abuse	Alcohol abuse	2000	Past
Coronary Artery Disease	Coronary artery disease	2008	Present
Hyperlipidemia	Hyperlipidaemia	2008	Present
Hypertension	Hypertension	2008	Present
Open Heart Surgery	Cardiac operation	2009	Past
Benign Prostate Hyperplasia	Benign prostatic hyperplasia	2012	Present
Congestive Hearth Failure (CHF)	Cardiac failure congestive	2012	Present
Strock (CVA)	Cerebrovascular accident	2014	Past
Ischemic colitis	Colitis ischaemic	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Colectomy Hartman	Colostomy	2017	Past
Bipolar Disorder	Bipolar disorder	2018	Present
Schizophrenia with paranoia	Schizophrenia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	10:08
2	Placebo	21AUG2020 (22)	11:11

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Bipolar disorder	Worsening Bipolar Disorder	24AUG2020 (25)	08:00	04SEP2020 (36)	14:00	12	3
2	NERV	Syncope	Syncope	05OCT2020 (67)	10:00	05OCT2020 (67)	10:00	1	3
3	INFEC	Urinary tract infection	Urinary tract infection	05OCT2020 (67)	10:00	14OCT2020 (76)	10:00	10	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (04SEP2020)	NOT RELATED/OTHER: Psychiatric illness	2	4	Y

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: Urinary tract Infection	2	46	N
3	N	Y	Resolved (14OCT2020)	NOT RELATED/OTHER: Escherichia coli	2	46	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1133 11331006, a 62-year-old white male with a pertinent medical history of alcohol abuse (in 2000), benign prostatic hyperplasia (since 2012); ischemic colitis and colostomy (colectomy Hartman) (both in 2017); bipolar disorder and schizophrenia (both since 2018), received Dose 1 on 31 Jul 2020 and Dose 2 on 21 Aug 2020 (Day 22). The subject experienced worsening bipolar disorder on 24 Aug 2020, 3 days after receiving Dose 2 and was diagnosed with urinary tract infection (UTI) on 05 Oct 2020, 45 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of worsening bipolar disorder and urinary tract infection included acetylsalicylic acid (since 2015) for cardiac prophylaxis. The site staff contacted the subject as the e-diary was incomplete and the subject's wife informed them that on 24 Aug 2020 (Day 25), the subject presented to the emergency room because of worsening bipolar disorder and was hospitalized because of erratic and threatening behaviors and suicidal thoughts. The subject had not been compliant with medications for a week. It was reported that he was treated with intravenous (IV) haloperidol and lorazepam since 24 Aug 2020 (Day 25). The subject stabilized and was discharged from the hospital on 27 Aug 2020 (Day 28). On 31 Aug 2020 (Day 32), the subject developed agitation, psychosis, confusion, and delusions consistent with worsening/decompensated bipolar affective disorder with paranoid schizophrenia and was readmitted for stabilization. The subject was noted to have suicidal ideation and psychosis for which he was treated again with haloperidol and lorazepam (intramuscular and IV). The subject's symptoms were reported to be under control after treatment. On 04 Sep 2020 (Day 36), the worsening bipolar disorder was considered resolved, and the subject was discharged from the hospital. During a follow-up phone call, the subject reported that he was feeling well with no suicidal thoughts. A SARS-CoV-2 test was negative during this hospitalization. On 05 Oct 2020 (Day 67), the subject experienced syncope and went to the emergency room and was later hospitalized for observation. A urine culture was positive for Escherichia coli (>100000 CFU/mL E coli) and blood culture was negative. The subject was diagnosed with a UTI. It was reported that the subject had undergone ileostomy reversal on 23 Sep 2020 (Day 55), which was the predisposing factor for the UTI. The subject was treated with vancomycin 1500 mg in normal saline IV piggy back from 05 Oct 2020 to 06 Oct 2020, IV flush of sodium chloride 0.9% 10 to 30 mL from 05 Oct 2020 to 07 Oct 2020, IV piperacillin sodium/tazobactam sodium 3.375 in sodium chloride 0.9% 100 mL from 05 Oct 2020 to 10 Oct 2020, IV morphine 2 mg/mL on 07 Oct 2020 and oral amoxicillin capsule 125 mg, twice a day from 07 Oct 2020 to 14 Oct 2020 for the UTI. The syncope resolved on the same day (Day 67). On 07 Oct 2020 (Day 69), the subject was discharged from the hospital and the UTI resolved on 14 Oct 2020 (Day 76). A SARS-CoV-2 test was negative during this hospitalization. In the opinion of the investigator, there was no reasonable possibility that the worsening bipolar disorder and urinary tract infection were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the worsening bipolar disorder was most likely coincidental and was associated with known underlying psychiatric conditions. Per Pfizer, the urinary tract infection was most probably a coincidental condition more likely associated with the subject's underlying contributory postsurgical clinical conditions.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	81	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	97.55 kg	29.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Lower Back Pain	Back pain	1972	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2008	Present
Elevated Cholesterol	Blood cholesterol increased	2008	Present
Hypertension	Hypertension	2008	Present
Osteoarthritis (Both Knees and Hands)	Osteoarthritis	2016	Present
Perennial Allergic Rhinitis	Rhinitis perennial	2017	Present
Right Partial Knee replacement	Knee arthroplasty	MAY2017	Past
Prostatitis	Prostatitis	11APR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	17:00
2	Placebo	01SEP2020 (21)	10:18

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Intestinal obstruction	Intestinal Obstruction	20AUG2020 (9)		03SEP2020 (23)		15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (03SEP2020)	NOT RELATED/OTHER: Unknown	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341058, an 81-year-old white male with no pertinent medical history, received Dose 1 on 12 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 21). The subject was diagnosed with an intestinal obstruction on 20 Aug 2020, 8 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the intestinal obstruction included acetylsalicylic acid (since 1995) for cardiac protection; hydrochlorothiazide (since 2008) for hypertension, atorvastatin (since 2008) for elevated cholesterol, finasteride (since 2008) for benign prostatic hyperplasia, and loratadine/pseudoephedrine sulfate (since Jul 2018) for perennial allergic rhinitis. On 20 Aug 2020 (Day 9), the subject felt nauseous and vomited 8 times. On 21 Aug 2020 (Day 10), the subject continued feeling nauseous and vomited again 4 times. The subject presented to the emergency room and he was diagnosed with an intestinal obstruction. He was hospitalized and put on a liquid diet and slowly advanced to a regular diet over the course of a week. On 24 Aug 2020 (Day 13), the subject was discharged from the hospital and the intestinal obstruction was considered resolved on 03 Sep 2020 (Day 23). In the opinion of the investigator, there was no reasonable possibility that the intestinal obstruction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	54.09 kg	23.2 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	1949	Past
appendicitis	Appendicitis	1949	Past
tonsillectomy	Tonsillectomy	1953	Past
tonsillitis	Tonsillitis	1953	Past
rheumatoid arthritis	Rheumatoid arthritis	1970	Present
left fractured femur repair	Fracture treatment	01DEC1971	Past
bunions to left foot	Foot deformity	1979	Past
right hammer toe	Foot deformity	1979	Past
hammer toe repair to right foot	Toe operation	1979	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left hand carpal tunnel syndrome	Carpal tunnel syndrome	1983	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1990	Present
post menopausal	Postmenopause	1994	Present
anxiety	Anxiety	2009	Present
bilateral cataracts	Cataract	2015	Present
left fractured femur	Femur fracture	01DEC2017	Past
gout	Gout	MAR2018	Present
left inner ear infection	Labyrinthitis	12SEP2018	Past
ER visit for kidney stones	Nephrolithiasis	AUG2020	Past
kidney stones	Nephrolithiasis	AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	10:06
2	BNT162b2	24SEP2020 (22)	09:37

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Adrenal gland cancer	ADRENAL ADENOCARCINOMA	20OCT2020 (48)		ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		4	TC	Y	Yes	NOT RELATED/OTHER: IDIOPATHIC	2	27	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	10NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341250, a 76-year-old white female with a pertinent medical history of nephrolithiasis (twice in Aug 2020), received Dose 1 on 03 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 22). The subject was diagnosed with adrenal gland cancer on 20 Oct 2020, 26 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the adrenal gland cancer included hydroxyzine hydrochloride (since 13 Dec 2017) for anxiety, colchicine (since Mar 2018) for gout, acetylsalicylic acid (since 20 Nov 2018) for cardiac prophylaxis, and hydrocodone bitartrate/paracetamol (since 14 Sep 2020) for right-side pain. On 20 Oct 2020 (Day 48), the subject experienced mild dehydration, vomiting, and right-side pain and reported to the emergency room. The subject was hospitalized on 23 Oct 2020 (Day 51) and was diagnosed with probable granular cancer (adrenal gland and lymph nodes on right axillary region) with an onset date of 20 Oct 2020 (Day 48). Relevant laboratory test results were unavailable. The subject was treated with ketorolac tromethamine 5 mg since 20 Oct 2020 (Day 48). The subject was discharged from the hospital on 26 Oct 2020 (Day 54) and the adrenal gland cancer was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the adrenal gland cancer was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was idiopathic. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	83.3 kg	29.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
keloid scar (left knee)	Keloid scar	1966	Present
depression	Depression	1995	Present
cataplexy	Cataplexy	2000	Present
narcolepsy	Narcolepsy	2000	Present
low testosterone	Blood testosterone decreased	2010	Present
erectile dysfunction	Erectile dysfunction	2010	Present
left shoulder injury	Limb injury	2011	Past
left shoulder replacement	Shoulder arthroplasty	2011	Past
pre-diabetic	Glucose tolerance impaired	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2015	Present
circadian rhythm sleep disorder	Circadian rhythm sleep disorder	2018	Present
reading glasses	Corrective lens user	2018	Present
sleep apnea	Sleep apnoea syndrome	2018	Present
overweight/obese	Obesity	2019	Present
hyperlipidemia	Hyperlipidaemia	FEB2020	Present
pulmonary nodule	Pulmonary mass	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	14:57
2	Placebo	09SEP2020 (24)	13:19

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis acute	acute cholecystitis	14OCT2020 (59)		17OCT2020 (62)		4
2	INFEC	Urinary tract infection	urinary tract infection	15OCT2020 (60)		17OCT2020 (62)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (17OCT2020)	NOT RELATED/OTHER: gallstones	2	36	Y
2	1	TC	N	Resolved (17OCT2020)	NOT RELATED/OTHER: bacterial infection	2	37	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
fluzone quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	10OCT2020
shingrix	VARICELLA ZOSTER VACCINE RGE (CHO)	06NOV2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1135 11351143, a 63-year-old white male with a pertinent medical history of impaired glucose tolerance (since 2013), obesity (since 2019), and hyperlipidemia (since Feb 2020), received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject was diagnosed with acute cholecystitis on 14 Oct 2020, 35 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the acute cholecystitis included fluoxetine hydrochloride (since 1999) for depression, modafinil (since 2000) for narcolepsy with cataplexy, sildenafil (since 2010) for erectile dysfunction, testosterone (Adrogel and Vegelxo, since 2010) for low testosterone, metformin (since 2013) for prediabetes, losartan (since 2015) for hypertension, and ezetimibe (since Feb 2020) for hyperlipidemia. After having abdominal pain for 5 days, the subject went to the emergency room on 15 Oct 2020 (Day 60). The subject was hospitalized and the relevant laboratory tests showed an elevated white blood cell count of 14.7 × 103/mm3 (normal range [NR]: 4.0-11.0 × 103/mm3) with absolute neutrophils of 11.33 × 103/mm3 (NR: 1.80-7.70 × 103/mm3). The platelet count was also elevated at 457 × 103/mm3 (NR: 130-400 × 103/mm3). A urinalysis showed trace bacteria and urine protein of 100 mg/dL (2+) (NR: negative). A computerized tomogram of the abdomen and pelvis showed extensive fat surrounding the gallbladder suspicious for acute cholecystitis. The subject was diagnosed with acute cholecystitis with an onset date of 14 Oct 2020 (Day 59). He was also diagnosed with urinary tract infection (reported as a nonserious adverse event) on 15 Oct 2020 (Day 60). On 16 Oct 2020 (Day 61), the subject underwent a laparoscopic cholecystectomy and was treated with famotidine, morphine, ceftriaxone, metronidazole, hydromorphone, dexamethasone, fentanyl, and bupivacaine-epinephrine. On 17 Oct 2020 (Day 62), the acute cholecystitis and urinary tract infection resolved and the subject was discharged from the hospital in stable condition along with a discharge medication of hydrocodone-acetaminophen (from 17 Oct 2020 to 21 Oct 2020). A SARS-CoV-2 test was negative during the hospitalization. In the opinion of the investigator, there was no reasonable possibility that the acute cholecystitis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to gallstones. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1974	Present
Hypertension	Hypertension	1979	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Osteopenia	Osteopenia	2010	Present
Spontaneous Coronary artery dissection	Coronary artery dissection	07DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	14:44
2	BNT162b2	17AUG2020 (20)	09:51

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1			Myocardial Ischemia- Related to spontaneous coronary artery dissection	28AUG2020 (31)		28AUG2020 (31)		1	1	N	N
2	CARD	Coronary artery dissection	Spontaneous coronary artery dissection	28AUG2020 (31)		28AUG2020 (31)		1	4	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (28AUG2020)	NOT RELATED/OTHER: Suffered some myocardial ischemia at the time of dissection	2	12	N
2	Resolved (28AUG2020)	NOT RELATED/OTHER: History of coronary artery dissection	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29JUL2020	
Withdrawn	VACCINATION	28AUG2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	17SEP2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1140 11401002, a 64-year-old white female with a pertinent medical history of hypertension (since 1979), hyperlipidemia (since 2000), and coronary artery dissection (from 07 Dec 2019 to 31 Dec 2019), received Dose 1 on 29 Jul 2020 and Dose 2 on 17 Aug 2020 (Day 20). The subject was diagnosed with a coronary artery dissection on 28 Aug 2020, 11 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the coronary artery dissection included rosuvastatin calcium (since 2000) for hyperlipidemia; cetirizine hydrochloride (since 2000) for seasonal allergies; alendronate sodium (since 2010) for osteopenia; venlafaxine hydrochloride (since 2010) for menopausal symptoms; carvedilol, acetylsalicylic acid, and clopidogrel bisulfate (all since 07 Dec 2019) for coronary artery dissection; losartan potassium (since 07 Dec 2019) for hypertension; omeprazole (since 07 Dec 2019) for gastrointestinal irritation prevention; and montelukast sodium (since 2019) for seasonal allergies. The subject called the study site and informed the investigator that she wanted to withdraw from the study because of a recent recurrence of a coronary artery dissection. On 28 Aug 2020 (Day 31), the subject was hospitalized for spontaneous coronary artery dissection. Her previous coronary dissection occurred in Dec 2019 and she had been doing well since then. During this admission, she stated she had a cardiac catheterization, which was “clean” for arteriosclerotic plaque. Apparently, when the dissection occurred there was some impedance of blood flow and it was reported that she may have suffered myocardial ischemia-related to spontaneous coronary artery dissection. The subject recovered from the coronary artery dissection and myocardial ischemia on 28 Aug 2020 (Day 31). A SARS-CoV-2 test on 08 Sep 2020 (Day 42) was negative. The subject remained hospitalized at the time of the last available report The subject requested withdrawal from the study on 17 Sep 2020. In the opinion of the investigator, there was no reasonable possibility that the coronary artery dissection was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of coronary artery dissection. Pfizer concurred with the investigator’s causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183.79 cm	102.09 kg	30.2 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	01NOV1985	Present
Allergy to cats	Allergy to animal	01AUG1988	Present
Allergy to bees	Allergy to arthropod sting	01AUG1988	Present
allergy to penicillin	Drug hypersensitivity	01AUG1988	Present
Allergy to shrimp	Food allergy	01AUG1988	Present
Gout	Gout	01SEP2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31JUL2020 (1)	09:28
2	BNT162b2	20AUG2020 (21)	14:57

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	IMMUN	Anaphylactic reaction	Anaphylaxis Status Post Bee Sting	28AUG2020 (29)	14:00	28AUG2020 (29)	20:00	1	4	TC
2	INFEC	Infected bite	Cellulitis Status Post Bee Sting	30AUG2020 (31)	08:00	09SEP2020 (41)	08:00	11	2	TC
3	GENRL	Injection site pain	Injection Site Pain	31JUL2020 (1)	12:00	01AUG2020 (2)	08:00	2	1	N
4	GENRL	Injection site swelling	Injection Site Swelling	31JUL2020 (1)	12:00	01AUG2020 (2)	08:00	2	2	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (28AUG2020)	NOT RELATED/OTHER: Subject with history of allergy to bee venom	2	9	Y
2	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Subject with history of allergy to bee venom	2	11	N
3	N	Resolved (01AUG2020)	Study Treatment	1	1	N
4	N	Resolved (01AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	17SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1140 11401009, a 40-year-old white male with a pertinent medical history of asthma (since 01 Nov 1985) and multiple allergies including to animals (cats) and arthropod stings (bees), drug hypersensitivity (penicillin), and food allergy (shrimp) (all, since 01 Aug 1988), received Dose 1 on 31 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 21). The subject was diagnosed with an anaphylactic reaction on 28 Aug 2020, 8 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the anaphylactic reaction included salbutamol sulfate (since 01 Nov 1985) for asthma, montelukast sodium (since 01 Sep 2012) for asthma, and allopurinol (since 01 Sep 2014) for gout. During his follow-up visit on 17 Sep 2020, the subject reported that he was stung by a bee on his second right toe on 28 Aug 2020 (Day 29) which resulted in a visit to the emergency department (ED). He initially attempted to treat the sting by applying ice and taking diphenhydramine. However, he developed a high-pitched voice and his epinephrine medication at home was expired. He was subsequently taken to the ED for anaphylaxis treatment. The anaphylactic reaction was considered as life-threatening. While in the ED, the subject was noted to have stridor and was treated with epinephrine, famotidine, and methylprednisolone sodium succinate. His condition improved after treatment and the anaphylactic reaction resolved on the same day (Day 29) which resulted in the subject being discharged from the ED. On 30 Aug 2020 (Day 31), the subject developed infected site (cellulitis status post bee sting) and was treated with Keflex. No relevant tests were reported. On 09 Sep 2020 (Day 41), the infected site resolved. In the opinion of the investigator, there was no reasonable possibility that the anaphylactic reaction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of allergy to bee venom. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.8 cm	104.45 kg	34.9 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	01OCT1965	Past
lung cancer	Lung neoplasm malignant	01OCT2011	Past
cardiac catheterization	Catheterisation cardiac	07DEC2011	Present
hyperlipidemia	Hyperlipidaemia	07DEC2011	Present
R upper lung lobectomy	Lung lobectomy	11JAN2012	Past
diminished lung function due to lung surgery	Pulmonary function test decreased	01FEB2012	Present
Gallbladder Attacks	Gallbladder disorder	2013	Present
hypertension	Hypertension	01APR2018	Present
pre-diabetes	Glucose tolerance impaired	01APR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	12:20
2	Placebo	28AUG2020 (22)	10:20

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Cholecystitis acute	Acute Cholecystitis	16SEP2020 (41)	08:00	30SEP2020 (55)		15	4	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30SEP2020)	NOT RELATED/OTHER: Subject with history of gallstones and associated gallbladder wall thickening	2	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	25SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1140 11401078, a 73-year-old white male with a pertinent medical history of hyperlipidemia (since 07 Dec 2011), and gallbladder disorder (since 2013), received Dose 1 on 07 Aug 2020 and Dose 2 on 28 Aug 2020 (Day 22). The subject was diagnosed with acute cholecystitis on 16 Sep 2020, 19 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the acute cholecystitis included omeprazole (since 01 Dec 1999) for gastroesophageal reflux disease, pravastatin sodium (since 01 Nov 2011) for hyperlipidemia, acetylsalicylic acid (since 01 Nov 2011) as a blood thinner, umeclidinium bromide/vilanterol trifenatate (since 01 Apr 2015) for diminished lung function, metoprolol tartrate (since 01 Apr 2018) for hypertension, and metformin (since 01 Apr 2019) for prediabetes. On 16 Sep 2020 (Day 41), the subject presented to the emergency room with severe pain due to worsening of a gallbladder disorder that was ongoing for 7 years. The subject was subsequently hospitalized because of acute cholecystitis. During the hospitalization, on 18 Sep 2020 (Day 43), a bile duct stent was placed. The subject was treated with amoxicillin/clavulanic acid since 22 Sep 2020 (Day 47). On 27 Sep 2020 (Day 52), a SARS-CoV-2 test was negative. On 30 Sep 2020 (Day 55), the subject underwent a cholecystectomy after which the acute cholecystitis was deemed to be resolved. The subject was still hospitalized at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the acute cholecystitis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of gallstones and associated gallbladder wall thickening. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.66 cm	69.27 kg	26.8 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intravenous pyelogram dye allergy	Contrast media allergy	1956	Present
hypertension	Hypertension	01SEP1995	Present
post-menopausal (19yrs)	Postmenopause	2001	Present
hyperlipidemia	Hyperlipidaemia	01SEP2005	Present
GI Cramping	Gastrointestinal pain	2012	Present
Cholecystectomy	Cholecystectomy	01SEP2012	Past
breast cancer bilateral	Breast cancer	24JUN2015	Past
breast lumpectomy	Breast conserving surgery	01AUG2015	Past
Macular degeneration	Macular degeneration	01DEC2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	13:45
2	BNT162b2	25SEP2020 (24)	10:37

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Gastrointestinal pain	Worsening GI Cramping	08SEP2020 (7)	08:00	20SEP2020 (19)		13	3	N	N
2	GASTR	Small intestinal obstruction	Small Bowel Obstruction	08SEP2020 (7)		20SEP2020 (19)		13	3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (20SEP2020)	NOT RELATED/OTHER: Subject has history of intermittent GI issues	1	7	N
2	Resolved (20SEP2020)	NOT RELATED/OTHER: Pre-existing condition (GI cramping). See Med Hx	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	23OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1140 11401244, a 67-year-old white female with a pertinent medical history of hyperlipidemia (since 01 Sep 2005), gastrointestinal pain (since 2012), cholecystectomy (on 01 Sep 2012), and Roux-en-Y bypass procedure (unknown date), received Dose 1 on 02 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 24). The subject was diagnosed with a small intestinal obstruction on 08 Sep 2020, 6 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the small intestinal obstruction included ramipril (since 01 Aug 2002) for hypertension, amlodipine besilate (since 01 Aug 2010) for hypertension, and pravastatin sodium (since 01 Sep 2017) for hyperlipidemia. On 08 Sep 2020 (Day 7), the subject experienced an acute worsening of his chronic gastrointestinal pain; she experienced abdominal cramps which was associated with decreased bowel movements and one episode of vomiting. The symptoms progressed resulting in the subject's hospitalization. It was reported that the subject had experienced intermittent bouts of abdominal pain in recent years. On 10 Sep 2020 (Day 9), a computerized tomography scan of the abdomen showed small bowel obstruction at the Roux-en-Y anastomotic site of the proximal jejunum concerning for a closed loop obstruction with unchanged mild mesenteric edema associated with proximal small bowel loops. On 12 Sep 2020 (Day 11), an upper gastrointestinal x-ray showed no evidence of obstruction; however, there was concern for bowel obstruction due to scar tissue and adhesions causing a stricture in the bowel. The subject reported that she had no pain after a few days of bowel rest and could tolerate a clear liquid diet. On 14 Sep 2020 (Day 13), an endoscopy was planned; however, the result was unknown. An exploratory laparotomy was also scheduled. On 20 Sep 2020 (Day 19), the gastrointestinal pain and small intestinal obstruction resolved. On 09 Oct 2020 (Day 38), a SARS-CoV-2 test (nasal swab) was negative. The subject denied ever having fever, shakes, chills, diarrhea, cough, shortness of breath, nor any known exposure to an individual with SARS-CoV-2 infection. In the opinion of the investigator, there was no reasonable possibility that the small intestinal obstruction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the pre-existing condition (gastrointestinal cramping). Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	73.64 kg	23.9 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cerebral vascular accident	Cerebrovascular accident	25AUG2017	Past
Paroxysmal atrial fibrillation	Atrial fibrillation	19JAN2018	Present
Hiatal hernia	Hiatus hernia	09APR2018	Present
Hypertension	Hypertension	09APR2018	Present
Hypercholesterolemia	Hypercholesterolaemia	12JUL2018	Present
Migraines	Migraine	12JUL2018	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	20MAY2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	13:58
2	Placebo	28AUG2020 (26)	11:48

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	VASC	Orthostatic hypotension	Possible postural hypotension	31AUG2020 (29)	14:00	31AUG2020 (29)	16:00	1	4	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (31AUG2020)	NOT RELATED/OTHER: Neurology noted indicated likely postural hypoperfusion	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	25SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1142 11421032, a 70-year-old white male with a pertinent medical history of cerebrovascular accident (on 25 Aug 2017), atrial fibrillation (since 19 Jan 2018), hypertension (since 09 Apr 2018), and hypercholesterolemia (since 12 Jul 2018), received Dose 1 on 03 Aug 2020 and Dose 2 on 28 Aug 2020 (Day 26). The subject was diagnosed with orthostatic hypotension on 31 Aug 2020, 3 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the orthostatic hypotension included hydrochlorothiazide (from 12 Jul 2018 to 31 Aug 2020) for hypertension; rivaroxaban and flecainide acetate (both since 13 Nov 2018) for atrial fibrillation; fenofibrate and lovastatin (both since 21 Dec 2018) for hypercholesterolemia; sumatriptan (since 21 Dec 2018) for migraines; pantoprazole (since 29 Nov 2019) for gastroesophageal reflux disease; valacyclovir (since 21 Aug 2020) for shingles; and sildenafil citrate (since 31 Aug 2020) for erectile dysfunction. On 31 Aug 2020 (Day 29), the subject experienced dizziness immediately after a bowel movement and presented to the emergency department; however, the subject reported that the dizzy sensation lasted for 2 hours and did not recur. The subject was evaluated with imaging and was subsequently hospitalized for an overnight neurological observation. His urinalysis was abnormal and glucose was 202 mg/dL (normal range: 70-110 mg/dL). A SARS-CoV-2 test was negative. A computerized tomogram (CT) of the head and CT angiogram of the head and neck were normal. The orthostatic hypotension was considered resolved on the same day (Day 29). On 01 Sep 2020 (Day 30), per the neurological observation, the dizziness was likely due to postural cerebral hypoperfusion. On 02 Sep 2020 (Day 31), a magnetic resonance imaging of the brain was normal and the subject was discharged from the hospital with a diagnosis of possible transient cerebral hypoperfusion in the setting of postural hypotension. On 16 Sep 2020 (Day 45), during a cardiology visit, the subject reported that he had taken sildenafil citrate 2 hours prior to the symptom onset. He also reported that treatment with hydrochlorothiazide was permanently discontinued upon hospitalization, and he had not taken either medication since hospitalization. The cardiologist felt that the subject's hypotension was likely due to treatment with both the diuretic and sildenafil citrate. The orthostatic hypotension did not recur. In the opinion of the investigator, there was no reasonable possibility that the orthostatic hypotension was related to the study intervention or clinical trial procedures, but rather it was related to postural hypoperfusion and the concomitant medications-sildenafil citrate and hydrochlorothiazide. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	70.59 kg	22.9 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to penicillin	Drug hypersensitivity	1947	Present
Hysterectomy	Hysterectomy	1973	Past
Hypertension	Hypertension	12JUL2007	Present
Atrial fibrillation	Atrial fibrillation	11APR2015	Present
Recurrent Blepharitis	Blepharitis	23AUG2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	10:22
2	BNT162b2	29AUG2020 (25)	09:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Colitis	Colitis	05SEP2020 (32)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: Recent antibiotic use	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	28SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1142 11421044, a 73-year-old white female with a pertinent medical history of hypertension (since 12 Jul 2007) and atrial fibrillation (since 11 Apr 2015), received Dose 1 on 05 Aug 2020 and Dose 2 on 29 Aug 2020 (Day 25). The subject was diagnosed with colitis on 05 Sep 2020, 7 days after receiving Dose 2. On 05 Sep 2020 (Day 32), the subject had nausea, vomiting, and diarrhea and presented to the emergency department requiring hospitalization. A computerized tomogram of the abdomen performed on the same day (Day 32), showed diffuse colonic edematous wall thickening, sigmoid diverticulosis, gastric antral wall and bladder wall thickening, hepatic steatosis, and trace of pericholecystic fluid that confirmed the diagnosis of colitis. The colitis was reported to be possibly related to recent antibiotic use; however, the concomitant medications taken by the subject were unknown. A SARS-CoV-2 rapid test was negative. The subject was discharged on 07 Sep 2020 (Day 34). The colitis was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the colitis was related to the study intervention or a clinical trial procedure, but rather it was related to recent antibiotic use. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	82 kg	28.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Major Depressive Disorder	Major depression	2018	Present
Schizophrenia	Schizophrenia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	13:41
2	Placebo	04SEP2020 (24)	15:20

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INJ&P	Craniocerebral injury	Closed head injury	19AUG2020 (8)		19AUG2020 (8)		1	3
2	PSYCH	Suicidal ideation	Suicidal Ideation	19AUG2020 (8)		21AUG2020 (10)		3	4

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Subject was in "an altercation"	1	8	N
2	TC	Y	Resolved (21AUG2020)	NOT RELATED/OTHER: History of Major Depressive Disorder	1	8	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	04NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1142 11421084, a 41-year-old white male with a pertinent medical history of major depression and schizophrenia (both since 2018), received Dose 1 on 12 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 24). The subject had suicidal ideation on 19 Aug 2020, 7 days after receiving Dose 1.

On 19 Aug 2020 (Day 8), the subject was arrested for an assault on his roommate. While he was detained in a psychiatric holding cell, the subject began punching his head and told the police officers that he wanted to end his life. He was taken to the emergency room after the altercation for evaluation of closed head injury, which occurred during the assault. On the same day (Day 8), the closed head injury was considered resolved. On 20 Aug 2020 (Day 9), the subject reported right orbit injury, and was hospitalized for psychiatric evaluation. He was feeling better after treatment with aspirin, acetaminophen, fluoxetine hydrochloride, and aripiprazole. On 21 Aug 2020 (Day 10), the suicidal ideation was considered resolved, and the subject was discharged that same day. A SARS-CoV-2 test on 19 Aug 2020 (Day 8) was negative.

The subject was withdrawn from the study on 04 Nov 2020 since he no longer met the eligibility criteria.

In the opinion of the investigator, there was no reasonable possibility that the suicidal ideation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of major depressive disorder. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	68.18 kg	21.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Poison ivy allergy	Dermatitis contact	1973	Present
Bactrim allergy	Drug hypersensitivity	1985	Present
Depression, well-controlled	Depression	2010	Present
Right hip replacement	Hip arthroplasty	2015	Past
palpitation	Palpitations	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	12:32
2	Placebo	17SEP2020 (21)	10:35

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Pericardial effusion	small pericardial effusion	08OCT2020 (42)		ONGOING			2	N	N
2	CARD	Tachycardia	tachycardia	07OCT2020 (41)	10:00	08OCT2020 (42)	12:00	2	3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: the volunteer has been having the tachycardia events in the past	2	22	N
2	Resolved (08OCT2020)	NOT RELATED/OTHER: patient has history of palpitation for the past 4 months	2	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1145 11451056, a 67-year-old white female with a pertinent medical history of palpitations (since 2019), received Dose 1 on 28 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 21). The subject experienced tachycardia on 07 Oct 2020, 20 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the tachycardia included bupropion (since 2010) for depression. On 12 Oct 2020 (Day 46), the subject informed the site that she developed tachycardia on 07 Oct 2020 (Day 41) and called an ambulance. Her heart rate was 143 beats per minute (bpm) in the ambulance. An electrocardiogram (ECG) performed in the ambulance showed possible atrial flutter/junctional rhythm, which spontaneously resolved upon arrival at the hospital. According to the medical records, the subject complained of intermittent palpitations since 2019 though with increased frequency over the past few months. The subject reported that the palpitations typically resolved after rest and deep breathing, but on this occasion they lasted longer. The subject was hospitalized for observation. Upon admission, the physical examination was normal. An ECG performed in the hospital showed normal sinus rhythm with a heart rate of 89 bpm. A chest x-ray of anteroposterior view showed no active disease (lungs clear and expanded, no demonstration of pleural abnormality, and normal cardiomediastinal silhouette). SARS CoV-2 polymerase chain reaction (PCR); coronavirus 229E, HKU1, NL63, and OC43; adenovirus PCR; influenza H1N1; influenza H3N2; influenza A; influenza B; parainfluenza 1, 2, 3, and 4; respiratory syncytial virus; human metapneumovirus; human rhino/enterovirus PCR; Chlamydia pneumoniae; and Mycoplasma pneumoniae tests were negative. On 08 Oct 2020 (Day 42), laboratory results were normal with sodium of 139 mmol/L, potassium of 3.7 mmol/L, blood urea nitrogen of 15 mg/dL, creatinine of 0.96 mg/dL, hemoglobin of 13.7 g/dL, and white blood cell count of 5.7 × 109/L (normal ranges were not provided). A transthoracic echocardiography (TTE) revealed a small pericardial effusion without any signs of tamponade. The pericardial effusion was reported as a nonserious adverse event. The subject was treated with diltiazem 120 mg once daily. On 08 Oct 2020 (Day 42), the tachycardia resolved. The subject was discharged from the hospital on the same day (Day 42) and was advised to follow-up with a cardiologist and repeat the TTE in 2 months. The pericardial effusion was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the tachycardia was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of palpitations for the past 4 months. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	66.36 kg	22.2 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Wisdom teeth removal	Wisdom teeth removal	2003	Past
Depression, controlled	Depression	2016	Present
Hypothyroidism, controlled	Hypothyroidism	2017	Present
Seasonal allergies	Seasonal allergy	2017	Present
c-section delivery	Delivery	10JAN2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Dizziness	dizziness	24SEP2020 (25)		25SEP2020 (26)		2	2
2	MUSC	Intervertebral disc protrusion	disc herniation	14SEP2020 (15)		ONGOING			2
3	NERV	Paraesthesia	Paresthesias of Skin	21SEP2020 (22)		28SEP2020 (29)		8	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (25SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	25	N
2	TC	N	Yes	NOT RELATED/OTHER: Disc Herniation at L5-S1	1	15	N
3	TC	Y	Resolved (28SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1145 11451063, a 34-year-old white female with a pertinent medical history of hypothyroidism (since 2017) and nerve compression (pinched nerve; unknown date) received Dose 1 on 31 Aug 2020. The subject reported paresthesia on 21 Sep 2020, 21 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the paresthesia included bupropion (since 2016) for depression, levothyroxine (since 2017) for hypothyroidism, and loratadine (since 2018) for seasonal allergies. On 14 Sep 2020 (Day 15), the subject began experiencing back pain, which was described as spasms with mild tingling in her right foot (as if something was beneath her skin) and occasionally in her calves. The subject was prescribed ibuprofen as needed for the back pain. On the same day (Day 15), the subject was noted to have intervertebral disc protrusion (reported as nonserious adverse event). On 18 Sep 2020 (Day 19), the subject visited her primary care physician (PCP), who felt the symptoms were likely due to a mechanical problem and potential nerve impingement from prolonged sitting. The subject was treated with methylprednisolone dose pack and cyclobenzaprine from 19 Sep 2020 to 24 Sep 2020. On 21 Sep 2020 (Day 22) the subject developed intermittent twitching that migrated to her lower extremities, upper extremities, and abdomen, and paraesthesia was reported. The subject was scheduled for her second vaccination on 22 Sep 2020 (Day 23), but this was held due to her illness. On 22 Sep 2020 (Day 23), the subject visited a neurologist, who ordered blood tests that were unremarkable and she was advised to undergo a magnetic resonance imaging (MRI). She visited her PCP again because of worsening of symptoms. On 24 Sep 2020 (Day 25), the subject had 2 episodes of dizziness, which prompted her to go to the emergency department (ED). The subject was in the ED overnight to undergo an MRI of her back and spine. She also had a neurology consultation, and a neurological examination was normal including strength, reflexes, sensation, and proprioception. She had normal gait and her vital signs were unremarkable. Laboratory results showed slightly low hemoglobin of 11.6 g/dL (normal range [NR]: 12-15 g/dL), normal calcium of 9.8 mg/dL (NR: 8.4-10.5 mg/dL), normal potassium of 4.1 mEq/L (NR: 3.5-5.1 mEqL), and normal thyroid stimulation hormone of 1.28 IU/mL (NR: 0.5-4.5 IU/mL). Other laboratory parameters like chemistry and metabolic panel results were unremarkable at the time. A computed tomography (CT) of the head without contrast was normal with no evidence of intracranial hemorrhage, mass edema, or midline shift and no definite evidence of infarction. On 25 Sep 2020 (Day 26), an MRI of the brain was normal with no evidence of acute cranial pathology. An MRI of the spine showed no suspicious enhancement, mild disk bulging of C-spine and T-spine, desiccation at the T7-8 and T8-9 and broad-based disc herniation at the L5-S1. An MRI of C-spine with/without contrast showed no significant central or neural foraminal compromise at any level throughout the cervical spine and mild multilevel disc bulging. An MRI of the T-spine with/without contrast showed disc desiccation, loss of intervertebral disc height at the T7-8 and T8-9 levels, with minimal disc bulging at these levels; no evidence of significant central canal or neural foraminal complex throughout the thoracic spine and no abnormal enhancements were seen. An MRI of the L-spine with/without contrast showed broad based disc herniation at the L5-S1 level with no evidence of central canal stenosis or neural foraminal compromise, and no suspicious enhancement. The subject denied any weakness, numbness, and tingling. Notably, the tingling in her right foot, which started on 14 Sep 2020, was resolved. The subject did have twitching multiple times a minute. According to medical records and the subject, her symptoms improved while she was in the hospital and the symptoms were attributed to a reaction to the medications; either the steroids, cyclobenzaprine or, less likely the bupropion. The concomitant medications methylprednisolone and cyclobenzaprine were permanently discontinued on 24 Sep 2020 (Day 25). On 25 Sep 2020 (Day 26), the dizziness resolved and the subject was discharged from the hospital. On 28 Sep 2020 (Day 29), the paresthesia resolved. The intervertebral disc protrusion was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the paresthesia was related to the study intervention or clinical trial procedures, but rather it was related to concomitant medications (methylprednisolone and cyclobenzaprine). Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	99.55 kg	30.5 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Clot Right Leg	Thrombosis	1972	Past
Pulmonary Embolism	Pulmonary embolism	1978	Past
High Cholesterol	Blood cholesterol increased	2016	Present
DVT	Deep vein thrombosis	15DEC2018	Past
benign tumor of thymus	Benign neoplasm of thymus	JUL2019	Past
Thymectomy	Thymectomy	JUL2019	Past
cyst of the thymus gland	Thymic cyst	JUL2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	09:26
2	BNT162b2	21SEP2020 (22)	13:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Atelectasis	Bibasilar Atelectasis on chest xray	10SEP2020 (11)		10OCT2020 (41)		31	1
2	RESP	Interstitial lung disease	Interstitial Pneumonitis	09SEP2020 (10)		09SEP2020 (10)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (10OCT2020)	NOT RELATED/OTHER: low inspiratory effort	1	11	N
2	N	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: ideopathic origin	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1146 11461161, a 66-year-old white male with a pertinent medical history of pulmonary embolism (in 1978); deep vein thrombosis (on 15 Dec 2018); and thymic cyst, benign neoplasm of thymus, and thymectomy (all in Jul 2019), received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject was diagnosed with interstitial lung disease on 09 Sep 2020, 9 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the interstitial lung disease included atorvastatin (since 2018) for elevated cholesterol, ciclosporin (since an unknown date) for dry eye, and apixaban (since an unknown date) for deep vein thrombosis/pulmonary embolism. The subject revealed at his 1-month Follow-up Visit that he had interstitial lung disease on 09 Sep 2020 (Day 10), which resulted in hospitalization. When the subject was followed-up medically for a left lower lobe pulmonary nodule, it was reported that the computed axial tomography scan performed on 09 Jun 2020 (Day -83) showed sub pleural opacity with adjacent pleural thickening of 27 × 1.6 cm. On 02 Jul 2020 (Day -60), the subject underwent an ultrasound guided fine needle aspiration and core biopsy which was sent for cytology. The ultrasound guided fine needle biopsy showed lung alveolar parenchyma with focal atypical epithelial lining cells. Histologic differential of ultrasound guided core biopsy showed atypical adenomatous hyperplasia; however, well-differentiated adenocarcinoma with lepidic pattern could not be excluded. Apparently, the subject failed to report any of the underlying pulmonary issues during the prior visits. A SARS-CoV-2 test was negative on 06 Sep 2020 (Day 7). On 09 Sep 2020 (Day 10), the subject was hospitalized and underwent a left lower lobe resection, which revealed both benign and interstitial pneumonitis with no evidence of neoplasm. On 09 Sep 2020 (Day 10), the interstitial lung disease was considered resolved. On an unspecified date, the subject was discharged from the hospital. On 10 Sep 2020 (Day 11), a chest x-ray showed bibasilar atelectasis (reported as nonserious adverse event). On 10 Oct 2020 (Day 41), the bibasilar atelectasis resolved. In the opinion of the investigator, there was no reasonable possibility that the interstitial lung disease was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was idiopathic. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	87.73 kg	28.5 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasovagal Syncope	Syncope	2000	Present
High Cholesterol	Blood cholesterol increased	2003	Present
Depression	Depression	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	09:45
2	BNT162b2	25SEP2020 (23)	11:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrioventricular block first degree	1 Degree AV block	27SEP2020 (25)		27SEP2020 (25)		1	2
2	CARD	Bradycardia	Acute Bradycardia	27SEP2020 (25)		28SEP2020 (26)		2	3
3	NERV	Loss of consciousness	Loss of consciousness	27SEP2020 (25)	10:00	29SEP2020 (27)	16:00	3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (27SEP2020)	NOT RELATED/OTHER: Idiopathic origin	2	3	N
2	TC	Y	Resolved (28SEP2020)	NOT RELATED/OTHER: Vasovagal response	2	3	Y
3	N	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: History of vasovagal syncope	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1146 11461200, a 51-year-old white male with a pertinent medical history of vasovagal syncope (since 2000), blood cholesterol increased (since 2003), and depression (since 2005), received Dose 1 on 03 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 23). The subject developed acute bradycardia and had loss of consciousness on 27 Sep 2020, 2 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the acute bradycardia and loss of consciousness included simvastatin (since 2003) for blood cholesterol increased and escitalopram oxalate (since 2018) for depression. On 27 Sep 2020 (Day 25), the subject had moved 2 dumbbells weighing 20 pounds, after which he began feeling dizzy and lightheaded, followed by loss of consciousness at around 10:00 AM, and was brought to the emergency services (ES). Upon arrival at ES, he had bradycardia (heart rate [HR] was 37 beats per minute [bpm]), and was treated with 0.5 mg atropine. The subject was hospitalized because of a concussion; his HR remained in the range of 30-40 bpm without any recurrent symptoms. On the same day (Day 25), the subject was diagnosed with first degree atrioventricular block (reported as nonserious adverse event), which was considered to be resolved that same day. During hospitalization, an echocardiogram was unremarkable with an ejection fraction of 65%; a computerized tomogram of the head was normal with no acute intracranial abnormality; and troponin was <0.02 ng/mL and potassium was 139 (unit and normal ranges not provided). A chest x-ray performed showed no acute disease. On 27 Sep 2020 (Day 25), a SARS-CoV-2 test was negative. On 28 Sep 2020 (Day 26), the subject's condition was stable, and the acute bradycardia was considered resolved; he was discharged from the hospital on the same day with the primary discharge diagnosis as syncope. The subject had no other syncopal episodes during hospitalization. The discharge summary also noted that the patient may have had a component of dehydration contributing to his loss of consciousness. The loss of consciousness was considered to be resolved on 29 Sep 2020 (Day 27). In the opinion of the investigator, there was no reasonable possibility that the acute bradycardia and loss of consciousness were related to the study intervention, concomitant medications, or clinical trial procedures, but rather these were related to a history of vasovagal syncope. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	102.91 kg	33.9 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post traumatic stress disorder	Post-traumatic stress disorder	2014	Present
Total left hip replacement	Hip arthroplasty	2015	Past
Hypertension	Hypertension	2016	Present
insomnia	Insomnia	2016	Present
Osteoarthritis	Osteoarthritis	2016	Present
Chronic pain syndrome	Pain	2016	Present
Surgical repair of the right bicep	Muscle operation	2017	Past
Tear of the right bicep	Muscle rupture	2017	Past
Depressive disorder	Depression	02SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	13:21
2	BNT162b2	14OCT2020 (20)	12:37

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary embolism	Pulmonary Emboli	08NOV2020 (45)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: unknown-pending full report	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1146 11461264, a 58-year-old black or African American male with a pertinent medical history of hypertension (since 2016), received Dose 1 on 25 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 20). The subject was diagnosed with pulmonary embolism on 08 Nov 2020 (Day 45), 25 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the pulmonary embolism included zolpidem tartrate (since 2016) for insomnia; amlodipine, furosemide, and enalapril (all since 2016) for hypertension; oxycodone hydrochloride/paracetamol (since 2016) for osteoarthritis; methadone (since 2016) for pain; and sertraline hydrochloride and quetiapine fumarate (both since 02 Sep 2020) for depression. On 08 Nov 2020 (Day 45), the subject visited the emergency room for flu-like symptoms, and was subsequently hospitalized. On 09 Nov 2020 (Day 46), the subject's D-dimer was elevated at 0.84 µg/mL (normal range: 0.00-0.45 µg/mL), which required further evaluation. On the same day (Day 46), a computer tomography scan of the chest showed small segmental pulmonary emboli in the right lower lobe; a SARS-CoV-2 polymerase chain reaction test was negative. The subject was treated with heparin bolus, followed by heparin drip and was started on 0.9% sodium chloride for hydration. The subject did not attend Visit 3 (1-month Follow-up Visit). The subject continued to be hospitalized and the pulmonary embolism was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	57.73 kg	21.8 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	14SEP2012	Present
seasonal allergies	Seasonal allergy	03DEC2012	Present
Anxiety	Anxiety	13SEP2018	Present
menopause	Menopause	2019	Present
mennorrhagia	Menorrhagia	18APR2019	Present
IRREGULAR MENSTRUAL CYCLE	Menstruation irregular	18APR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	12:46
2	Placebo	30SEP2020 (21)	11:57

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal pain lower	Left Lower Quadrant Pain	25SEP2020 (16)		ONGOING		
2	INV	Blood chloride decreased	Decreased Chloride (94)	24SEP2020 (15)		ONGOING		
3	INV	Blood sodium decreased	Decreased Sodium (131)	24SEP2020 (15)		ONGOING		
4	INV	High density lipoprotein increased	Increased HDL (95)	18SEP2020 (9)		ONGOING		
5	REPRO	Ovarian mass	Ovarian Mass	21SEP2020 (12)		ONGOING		
6	INV	Urine ketone body present	Trace Ketones (Urinalysis)	24SEP2020 (15)		ONGOING		
7	INV	White blood cells urine positive	Trace Leukocytes in Urinalysis	24SEP2020 (15)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TCN	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	16	N
2	1	N	N	Yes	NOT RELATED/OTHER: Not related to study treatment	1	15	N
3	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study	1	15	N
4	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	9	N

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	2	TCN	Y	Yes	NOT RELATED/OTHER: Ovarian mass of unknown origin	1	12	Y
6	1	N	N	Yes	NOT RELATED/OTHER: Not related to study treatment	1	15	N
7	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	15	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1147 11471239, a 56-year-old white female with a pertinent medical history of menopause (since 2019); menorrhagia and irregular menstruation (both since 18 Apr 2019); family history of prostate cancer (father's history) and leukemia (brother's history), received Dose 1 on 10 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 21). The subject was diagnosed with an ovarian mass on 21 Sep 2020, 11 days after receiving Dose 1. Concomitant medication reported within 2 weeks prior to the onset of the ovarian mass included lisinopril (since 14 Sep 2020) for hypertension. On 25 Sep 2020 (Day 16), the subject experienced left lower quadrant pain, for which she consulted her primary care physician on 28 Sep 2020 (Day 19). She was initially treated with unspecified antibiotics for presumed diverticulitis. A computerized tomogram (CT) scan showed a mass measuring 8 × 7.2 cm between the uterus and rectum. Magnetic resonance imaging (MRI) showed a complex cystic mass and no mural nodularity. Laboratory test results showed cancer antigen 125 of 67 (units and normal range not reported). On 29 Sep 2020 (Day 20), a CT of the abdomen and pelvis with contrast showed persistence of a large complex cystic pelvic mass measuring 7.6 cm that appeared to arise from the left ovary and extended towards the midline into the pelvic cul-de-sac, and demonstrated a slightly thickened wall, but without mural nodularity or significant post-contrast enhancement; these findings were consistent for benign etiology given lack of nodularity and post-contrast enhancement; however, surgical consultation was advised as a malignant cause could not be definitively excluded. On 02 Oct 2020 (Day 23), a pelvic MRI scan with and without contrast showed a circumscribed cystic mass measuring 8 cm in the pelvis; differential diagnosis was ovarian cystic mass versus peritoneal inclusion cyst with an onset date of 21 Sep 2020 (Day 12). On 15 Oct 2020 (Day 36), the subject presented to the emergency department to undergo robotic bilateral salpingo-oophorectomy, hysterectomy, and lysis of left side adhesions; there was no visible excrescences; torsion of the left adnexa was noted and the mass was adherent to the posterior cul-de-sac with inflammatory reaction. Hence, the subject underwent a surgical procedure; laparoscopic exploration of the upper abdomen revealed normal diaphragm, omentum, right fallopian tube, ovary, and uterus. There were no obvious peritoneal nodules. The subject tolerated the procedure well and was recovering at the time of last available report; however, a slight swelling on the left side of abdomen was noted, but the subject denied any discomfort. The subject was discharged on 16 Oct 2020 (Day 37) in good clinical condition. The ovarian mass was considered ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the ovarian mass was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	72.8 kg	31.5 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent heart murmur	Cardiac murmur	1954	Present
gabapentin allergy	Drug hypersensitivity	2012	Present
lyrica allergy	Drug hypersensitivity	2012	Present
hernia	Hernia	2013	Present
lumbar degenerative disc disease	Intervertebral disc degeneration	2013	Present
partial denture - WEARER	Denture wearer	2016	Present
left thumb osteoarthritis	Osteoarthritis	2018	Present
right knee osteoarthritis	Osteoarthritis	2018	Present
type 2 diabetes	Type 2 diabetes mellitus	2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
femoral hernia	Femoral hernia	JAN2020	Present
hyperlipidemia	Hyperlipidaemia	JAN2020	Present
hypertension	Hypertension	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	13:20
2	Placebo	15OCT2020 (22)	12:31

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Cough	severe cough	01NOV2020 (39)	08:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: medical	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1149 11491313, a 68-year-old white female with a pertinent medical history of cardiac murmur (since 1954), drug hypersensitivity (gabapentin and Lyrica® allergy, both since 2012), type 2 diabetes mellitus (since 2019), and hypertension (since Jan 2020), received Dose 1 on 24 Sep 2020 and Dose 2 on 15 Oct 2020 (Day 22). The subject reported cough on 01 Nov 2020, 17 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the cough included metformin (since Jan 2020) for diabetes; amlodipine, labetalol, losartan potassium and clonidine (all since Jan 2020) for hypertension; and atorvastatin (since Jan 2020) for hyperlipidemia. On 01 Nov 2020 (Day 39), the subject was hospitalized for a severe cough and a COVID-19 test was negative. The subject remained in the hospital for further testing and the cough was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the cough was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	88.09 kg	28.6 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Pancreatitis	Pancreatitis chronic	2014	Present
Sinusitus	Sinusitis	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	14:07
2	BNT162b2	09SEP2020 (24)	09:08

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Myalgia	General Muscle Pain	17AUG2020 (1)	18:00	19AUG2020 (3)		3
2	GASTR	Pancreatitis	Worsening Pancreatitis	21AUG2020 (5)		23SEP2020 (38)		34

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (19AUG2020)	Study Treatment	1	1	N
2	3	N	Y	Resolved (23SEP2020)	NOT RELATED/OTHER: Pancreatitis	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1150 11501001, a 45-year-old white male with a pertinent medical history of chronic pancreatitis (since 2014), received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject was diagnosed with worsening of pancreatitis on 21 Aug 2020, 4 days after receiving Dose 1. Concomitant medication reported within 2 weeks prior to the onset of the worsening of pancreatitis included azelastine hydrochloride (since Jul 2020) for sinusitis. On 21 Aug 2020 (Day 5), the subject visited the emergency room with severe abdominal pain, vomiting, nausea, and diarrhea. On the same day (Day 5), a computerized tomogram of the abdomen and pelvis with contrast showed diffuse peripancreatic edema consistent with pancreatitis; a chest x-ray showed no active cardiopulmonary disease and was normal; laboratory test results showed blood calcium of 10.5 mg/dL (normal range (NR): 8.5-10.2 mg/dL), blood creatinine of 1.31 mg/dL (NR: 0.73-1.22 mg/dL), blood glucose of 140 mg/dL (NR: 74-99 mg/dL), eosinophil count of 0.20 × 103/mm3 (normal low 0.46 × 103/mm3), glomerular filtration rate of 760 and 59 (units and normal range not reported), lipase of 73000 IU/L (NR: 16-61 IU/L), white blood cell count of 19.85 × 103/mm3 (NR: 3.70-11.00 × 103/mm3) with lymphocytes 12% (NR not reported), monocyte count of 1.39 × 103/mm3 (NR: <0.87 × 103/mm3), monocytes 7% (NR not reported), neutrophils 80% (NR not reported), neutrophil count of 15.88 × 103/mm3 (NR: 1.45-7.50 × 103/mm3), and total protein of 8.3 g/dL (NR: 6.3-8 g/dL). On 21 Aug 2020 (Day 5), a SARS-CoV-2 test was negative; the liver function tests, electrolytes, anion gap, complete blood count, and troponin T were within the normal limits. Blood cultures were negative. The subject was discharged from the hospital on 25 Aug 2020 (Day 9) and the worsening of pancreatitis was considered resolved on 23 Sep 2020 (Day 38). In the opinion of the investigator, there was no reasonable possibility that the worsening of pancreatitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	82.45 kg	27.2 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arthroscopic surgery left knee	Knee operation	1970	Past
osteoarthritis	Osteoarthritis	1971	Present
anxiety	Anxiety	1972	Present
Bipolar depression	Bipolar disorder	1972	Present
nervous breakdoen	Mental disorder	1972	Past
allergy to codeine	Drug hypersensitivity	1983	Present
allergy to thorazine	Drug hypersensitivity	1983	Present
arthroscopic surgery left knee	Knee operation	1985	Past
dyspepsia	Dyspepsia	1989	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroid	Hypothyroidism	1990	Present
hyoid bone removed	Ostectomy	1990	Past
arthroscopic surgery left knee	Knee operation	1991	Past
seborrheic dermatitis	Seborrhoeic dermatitis	1995	Present
Type II diabetes	Type 2 diabetes mellitus	1995	Past
colitis	Colitis	2000	Past
irritable bowel	Irritable bowel syndrome	2000	Present
hypertension	Hypertension	2008	Present
insomnia	Insomnia	2010	Present
cervical disc disease	Intervertebral disc disorder	2010	Past
cervical disc surgery	Intervertebral disc operation	2010	Past
gastric bypass	Gastric bypass	2012	Past
thoracic spine disc disease	Intervertebral disc disorder	2013	Past
surgery T-3 disc	Intervertebral disc operation	2013	Past
anemia	Anaemia	2014	Past
arthroscopic surgery right knee	Knee operation	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:42
2	Placebo	10SEP2020 (23)	10:51

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Bipolar disorder	worsening of bipolar disorder	29OCT2020 (72)		06NOV2020 (80)		9	3
2	RESP	Cough	cough	03NOV2020 (77)		06NOV2020 (80)		4	1
3	RENAL	Pollakiuria	urinary frequency	06OCT2020 (49)		01NOV2020 (75)		27	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: historical condition with variability	2	50	Y
2	N	N	Resolved (06NOV2020)	NOT RELATED/OTHER: unknown	2	55	N
3	N	N	Resolved (01NOV2020)	NOT RELATED/OTHER: unknown	2	27	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521095, a 67-year-old white male with a pertinent medical history of mental disorder (nervous breakdown, in 1972); anxiety and bipolar disorder (since 1972); hypothyroidism (since 1990); type 2 diabetes mellitus (in 1995), insomnia (since 2010); and hospitalization for bipolar disorder (in 2018), received Dose 1 on 19 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 23). The subject was diagnosed with worsening of bipolar disorder on 29 Oct 2020, 49 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the worsening of bipolar disorder included lorazepam (since 1972) for anxiety; selenium sulfide (since 1995) for seborrheic dermatitis; losartan potassium (since 2008) for hypertension; gabapentin (since 2010) and loxapine (since 2015), for insomnia. The subject was contacted after COVID-19 symptoms were entered in the e-diary, and the subject reported that his chronic cough had worsened with a hoarse voice on 03 Nov 2020 (Day 77). When the subject was asked to do a self-swab test, he reported that he could not do the test since he was hospitalized since 29 Oct 2020 (Day 72) for worsening of bipolar disorder and had started new medications for bipolar disorder. Some of the medications were changed during the hospitalization, but subsequently he was put back on the previous medications which he had been on at admission. The subject also reported that he was feeling better. The site had information related to a medical history of depression, but did not know that he had bipolar disorder. The worsening of bipolar disorder and cough were considered resolved on 06 Nov 2020 (Day 80), and the subject was discharged from the hospital on the same day. In the opinion of the investigator, there was no reasonable possibility that the worsening of bipolar disorder was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of bipolar disorder. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	174.55 kg	56.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	DEC1952	Present
tonsillectomy	Tonsillectomy	1961	Past
morbid obesity	Obesity	1980	Present
hiatal hernia repair	Hernia hiatus repair	1988	Past
hiatal hernia	Hiatus hernia	1988	Past
hypertension	Hypertension	1997	Present
hypercholesterolemia	Hypercholesterolaemia	2006	Present
failed prostatectomy	Procedural failure	2007	Past
prostate cancer	Prostate cancer	2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
prostatism	Prostatism	2007	Present
low back pain	Back pain	2010	Present
diabetic neuropathy	Diabetic neuropathy	2018	Present
Type II diabetes	Type 2 diabetes mellitus	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	09:59
2	Placebo	21SEP2020 (22)	08:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Malignant melanoma	melanoma left shoulder	04SEP2020 (5)		08OCT2020 (39)		35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: unknown	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521260, a 67-year-old white male with a pertinent medical history of prostate cancer (from 2007 to 2008); prostatism (since 2007); failed prostatectomy (in 2007); back pain (since 2010); diabetic neuropathy (since 2018); and type 2 diabetes mellitus (since Mar 2020), received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject was diagnosed with malignant melanoma on 04 Sep 2020, 4 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the malignant melanoma included acetylsalicylic acid (since 2000) as cardiovascular prophylaxis; atorvastatin (since 2000) for hypercholesterolemia; hydrochlorothiazide (since 2006) for hypertension, duloxetine hydrochloride (since 2010) for lower back pain, atenolol (since 2015) for hypertension; tamsulosin and finasteride (since 2018) for prostatism; gabapentin (since Jan 2020) for diabetic neuropathy; insulin and glipizide (since Mar 2020) for type 2 diabetes; and fluticasone propionate/salmeterol xinafoate (since Mar 2020) for asthma. On 04 Sep 2020 (Day 5), the subject had a biopsy of a mole on his left shoulder. On 22 Sep 2020 (Day 23), the subject was informed that the biopsy confirmed melanoma. On 08 Oct 2020 (Day 39), the subject had an outpatient procedure for excision of the lesion and the doctor reported that some lymph nodes were also excised. Following the procedure, the subject did not have a ride home and was hospitalized. On 08 Oct 2020 (Day 39), the malignant melanoma resolved. The subject was discharged from the hospital on an unknown date. In the opinion of the investigator, there was no reasonable possibility that the malignant melanoma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.59 cm	60.59 kg	21.5 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Brazil Nut Allergy	Food allergy	1964	Present
Penicillin Allergy	Drug hypersensitivity	1965	Present
Dislocated Left Shoulder	Joint dislocation	1978	Past
Left Shoulder Surgery	Shoulder operation	25DEC1979	Past
Dislocated Right Shoulder	Joint dislocation	1996	Past
Right Shoulder Surgery	Shoulder operation	OCT2000	Past
Right Hip Osteoarthritis	Osteoarthritis	2008	Past
Right Hip Surgery	Hip surgery	AUG2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Correct Failed Right Shoulder Surgery	Shoulder operation	2017	Past
Right Shoulder Surgery	Shoulder operation	OCT2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	16:58
2	BNT162b2	08SEP2020 (21)	14:57

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Arthropathy	WIDENINNG OFACROMIOCLAVICULAR JOINT SPACE (GRADE 1)	06OCT2020 (49)		ONGOING			2	TC	N
2	INJ&P	Facial bones fracture	FRACTURE OF ROOF OF RIGHT ORBITAL (GRADE 3)	06OCT2020 (49)		ONGOING			3	TC	Y
3	INJ&P	Fall	FALL FROM BICYCLE	06OCT2020 (49)	08:20	06OCT2020 (49)	08:20	1	2	N	N
4	INJ&P	Muscle strain	PARTIAL TEAR OF THE RIGHT TRAPEZIUS MUSCLE (GRADE 1)	06OCT2020 (49)		ONGOING			2	TC	N

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
5	RESP	Oropharyngeal pain	SORE THROAT	23AUG2020 (5)		30AUG2020 (12)		8	1	N	N
6	NERV	Subarachnoid haemorrhage	SUBARACHNOID HEMORRHAGE	06OCT2020 (49)	08:20	17OCT2020 (60)		12	4	TC	Y
7	INJ&P	Traumatic intracranial haemorrhage	TRAUMATIC INTRACRANIAL HEMORRHAGE	06OCT2020 (49)		ONGOING			3	TC	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	N
2	Yes	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	Y
3	Resolved (06OCT2020)	NOT RELATED/OTHER: NO UNDERLYING CAUSE	2	29	N
4	Yes	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	N
5	Resolved (30AUG2020)	NOT RELATED/OTHER: UNRELATED NEW MEDICAL CONDITION	1	5	N
6	Resolved (17OCT2020)	NOT RELATED/OTHER: FALL FROM BICYCLE	2	29	Y
7	Yes	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
TETANUS-DIPHTHERIA VACCINE	DIPHTHERIA VACCINE;TETANUS VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561001, a 61-year-old white male with no pertinent medical history, received Dose 1 on 19 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 21). The subject was diagnosed with facial bones fracture, subarachnoid hemorrhage, and traumatic intracranial hemorrhage after falling from a bicycle on 06 Oct 2020, 28 days after receiving Dose 2. On 06 Oct 2020 (Day 49), the subject fell while riding his bicycle, which resulted in significant head trauma that required airlifting to the hospital. The subject was first evaluated at an urgent care facility and a computerized tomogram (CT) scan showed right upper eyelid hematoma with an intracranial hemorrhage, right frontal lobe hemorrhagic contusions and subtle posttraumatic subarachnoid hemorrhage; no brain herniation; no midline shifting; minimal pneumocephalus; comminuted depressed fracture of the right orbit roof with bone fragments abutting the right frontal lobe and rectus muscle; and right frontal bone nondepressed skull fracture. The subarachnoid hemorrhage was considered to be life-threatening by the investigator. The subject reported that he was not wearing a helmet and had right shoulder and right hip pain, and was treated with oxycodone 5 mg every 6 hours as needed and tetanus/diphtheria vaccine was administered. On 07 Oct 2020 (Day 50), a CT of the brain showed maturing small focus of right frontal intraparenchymal hemorrhagic contusion; no new hemorrhage or no midline shift; the previously mentioned subarachnoid hemorrhage was not appreciated on this examination. No COVID-19 test was performed. An orthopedic surgeon and a neurosurgeon determined the injuries to not require surgery, and the subject was discharged from the hospital on 10 Oct 2020 (Day 53) on paracetamol and levetiracetam as prophylaxis. The incidental findings on radiology of possible brachial plexus traction (Grade 1 partial tear of the right trapezius muscle [muscle strain] and widening of acromioclavicular joint space [arthropathy]) would be followed up on an outpatient basis as the subject did not had any neuromuscular deficits at the time. On 17 Oct 2020 (Day 60), the subarachnoid hemorrhage resolved; the traumatic intracranial hemorrhage, facial bones fracture, muscle strain, and arthropathy were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the facial bones fracture, subarachnoid hemorrhage, and traumatic intracranial hemorrhage were related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to the bicycle accident. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.2 cm	74 kg	26.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 1 Diabetes	Type 1 diabetes mellitus	AUG2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	11:44

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	VASC	Deep vein thrombosis	DEEP VEIN THROMBOSIS	31AUG2020 (12)		09SEP2020 (21)		10	3	TC
2	MUSC	Musculoskeletal stiffness	right shoulder stiffness	05SEP2020 (17)		07SEP2020 (19)		3	1	TCN
3	RESP	Pulmonary embolism	PULMONARY EMBOLISM	31AUG2020 (12)		02SEP2020 (14)		3	3	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: MEDICAL HISTORY - TYPE 1 DIABETES	1	12	Y
2	N	Resolved (07SEP2020)	NOT RELATED/OTHER: unknown new medical condition	1	17	N
3	N	Resolved (02SEP2020)	NOT RELATED/OTHER: DEEP VEIN THROMBOSIS	1	12	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	08SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561006, a 45-year-old black/African American male with a pertinent medical history of type 1 diabetes mellitus (since Aug 2014), received Dose 1 on 20 Aug 2020. The subject developed deep vein thrombosis on 31 Aug 2020, 11 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the deep vein thrombosis included insulin (regular) and insulin glargine (both since 10 Dec 2016) for type 1 diabetes mellitus. On 20 Aug 2020 (Day 1), the subject was diagnosed with COVID-19. On 31 Aug 2020 (Day 12), the subject visited the emergency room with complaints of cough and calf pain. The subject was subsequently hospitalized for bilateral calf pain and hyperglycemia due to noncompliance, and insulin regular 15 units was administered subcutaneously. A spiral computerized tomogram (CT) detected a thrombus; a Doppler of the lower extremity was negative; a CT angiogram showed several bilateral segmental to subsegmental pulmonary emboli and bilateral patchy peripheral opacities likely reflecting an infectious process; the subject's C-reactive protein was 8.1 mg/L (normal range [NR]: 0.1-3.0 mg/L) and a SARS-CoV-2 test result was still positive. Given the history of COVID-19 infection; the presence of more consolidative opacity rather than ground glass was atypical, but could indicate some evolution of airspace opacities associated with COVID-19. A concomitant/superimposed infectious process was suspected, and the subject was noted to have pulmonary embolism (nonserious event). During this hospital visit, the subject was mostly asymptomatic and did not require supplemental oxygen, but was started on enoxaparin sodium bridging to apixaban. His blood sugar had been well controlled since he resumed insulin. On 01 Sep 2020 (Day 13), the subject's D-dimer was 1.66 mg/L (NR: 0.0-0.5 mg/L). On 02 Sep 2020 (Day 14), the pulmonary embolism and COVID-19 infection were considered resolved and the subject was discharged on apixaban 10 mg orally twice a day (BID) for 7 days followed by apixaban 5 mg orally BID; acetaminophen 650 mg every 4 hours as needed (PRN), and ibuprofen 600 mg every 8 hours PRN for 14 days. The subject was discontinued from the study intervention on 08 Sep 2020 because he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 09 Sep 2020 (Day 21), the deep vein thrombosis resolved. During a follow-up visit on 16 Sep 2020 the subject stated that all his symptoms had resolved on 09 Sep 2020, and that he would continue apixaban for at least 6 months. In the opinion of the investigator, there was no reasonable possibility that the deep vein thrombosis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to medical history of type 1 diabetes mellitus. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.3 cm	83.6 kg	32.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
C-section	Caesarean section	16MAY2019	Past
Obesity	Obesity	06JUN2019	Present
Menorrhagia	Menorrhagia	03JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	15:26
2	Placebo	10SEP2020 (22)	16:04

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PREG	Abortion spontaneous incomplete	INCOMPLETE SPONTANEOUS ABORTION	04OCT2020 (46)		07OCT2020 (49)		4	3
2	RESP	Haemoptysis	HEMOPTYSIS	04OCT2020 (46)		04OCT2020 (46)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	2	25	Y
2	N	N	Resolved (04OCT2020)	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	2	25	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	12OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561007, a 22-year-old black/African American female with a pertinent medical history of cesarean section (on 16 May 2019), obesity (since 06 Jun 2019), and menorrhagia (on 03 Jan 2020), received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had an incomplete spontaneous abortion on 04 Oct 2020, 24 days after receiving Dose 2. On 20 Aug 2020 (Day 1) and on 10 Sep 2020 (Day 22), the subject's urine human chorionic gonadotropin (HCG) results were negative. On 05 Oct 2020 (Day 47), the subject visited the emergency room (ER) because of pelvic pain and hemoptysis (reported as nonserious event with an onset date of 04 Oct 2020 [Day 46]). On 05 Oct 2020 (Day 47), the serum HCG level was 60666 mIU/mL (normal range: 0-5 mIU/mL) and an ultrasound showed a single intrauterine gestation consistent with a 7 weeks 2 days yolk sac, but embryonic heart tones were not detected. The subject reported no history of smoking, alcohol, or use of any illicit drugs during her pregnancy. The subject had 1 previous pregnancy and 1 other child. The subject's first day of her last menstrual period was on 15 Aug 2020 and the estimated date of conception was in Aug 2020. The subject's estimated due date was on 22 May 2021. On 06 Oct 2020 (Day 48), the subject returned to her primary care physician for continued pelvic pain and discomfort, and she was immediately transferred to the ER for a possible incomplete spontaneous abortion. On the same day (Day 48), an ultrasound performed noted an intrauterine gestational sac measuring 3.6 × 3.2 cm; deformed gestational sac with an echogenic area within the sac was noted, which could be because of a blood clot (measuring 1.5 × 1.5 cm); no fetal pole, yolk sac, or fetal cardiac activity were noted, which was suggestive of an empty intrauterine gestational sac. The subject was found to be 8 weeks pregnant, but she had lost her baby while in the ER. On the same day (Day 48), following confirmation of blighted ovum, the subject underwent suction dilation and curettage to remove the products of conception, and was transferred to the recovery ward. It was confirmed that no COVID-19 test was performed during hospitalization. On 07 Oct 2020 (Day 49), the subject recovered from the incomplete spontaneous abortion and she was discharged from the hospital without any surgical complications. In the opinion of the investigator, there was no reasonable possibility that the incomplete spontaneous abortion was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	64.09 kg	23.6 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis Multiple Joints	Osteoarthritis	2004	Present
Post Menopause	Postmenopause	2010	Present
Depression	Depression	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	09:34
2	BNT162b2	24SEP2020 (23)	09:11

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Transient ischaemic attack	Suspected Transient Ischemic Attack	27OCT2020 (56)	05:30	28OCT2020 (57)	14:00	2	3
2	NERV	Tremor	Tremor	13OCT2020 (42)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: Atherosclerotic vs Embolic disease	2	34	Y
2	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	05NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1157 11571134, a 69-year-old white female with a pertinent medical history of postmenopause (since 2010) and depression (since Jan 2020), received Dose 1 on 02 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 23). The subject had a transient ischemic attack on 27 Oct 2020, 33 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the transient ischemic attack included tramadol (since 2014) for osteoarthritis; duloxetine hydrochloride (since Jun 2020) and trazodone (since 2020), both for depression. On 27 Oct 2020 (Day 56) at 04:30 AM, the subject developed sudden onset of confusion and shaking. Approximately an hour later (~05:30 AM), the subject was driving to work and felt dizzy with slurred speech. The subject was admitted to the hospital. A work-up included: angiogram that showed atherosclerotic changes with mild stenosis of left internal carotid artery; computerized tomogram of the head showed no evidence of acute intracranial abnormality; and a magnetic resonance imaging of the brain performed was consistent with a subacute to chronic infarct in the right midbrain at the pontine junction. Additional work-up included a chest x-ray that showed no evidence of acute abnormality and an echocardiogram showed mild mitral valve annular calcification without stenosis, mild sclerosis and mild stenosis in aortic valve, and a left ventricular ejection fraction of 65%-70%. The subject was treated with acetylsalicylic acid 300 mg once on 28 Oct 2020 and clopidogrel bisulfate 75 mg orally once daily for the transient ischemic attack. On 28 Oct 2020 (Day 57), the transient ischemic attack resolved, and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the transient ischemic attack was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	85	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	90.3 kg	27.9 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis	Osteoarthritis	2010	Present
type II diabetes	Type 2 diabetes mellitus	2010	Present
chronic constipation	Constipation	2012	Present
hypertension	Hypertension	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	12:34
2	Placebo	04NOV2020 (92)	10:57

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INFEC	Pneumonia	pneumonia	11NOV2020 (99)		ONGOING	
2	INV	SARS-CoV-2 test positive	SARS-COV-2 Positive	10NOV2020 (98)	03:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: viral syndrome	2	8	Y
2		3	N	Y	Yes	NOT RELATED/OTHER: viral syndrome	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1161 11611029, an 85-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 2010), and hypertension and arrhythmia (since 2019), received Dose 1 on 05 Aug 2020 and Dose 2 on 04 Nov 2020 (Day 92). The subject had a SARS-CoV-2 positive test on 10 Nov 2020, 6 days after receiving Dose 2 and was diagnosed with pneumonia on 11 Nov 2020, 7 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the positive SARS-CoV-2 test and pneumonia included famotidine (since 01 Jan 2009) for gastroesophageal reflux disease, paracetamol (since 01 Jan 2010) for osteoarthritis, glipizide (since 01 Jan 2011) for type 2 diabetes mellitus, amlodipine (since 01 Mar 2019) for hypertension, acetylsalicylic acid (since 01 Jan 2020) as cardiac prophylaxis, magnesium (since 01 Jan 2020) for chronic constipation, and metformin (since 01 Jan 2020) for type 2 diabetes mellitus. The subject's wife notified the site about the subject's hospitalization because of the positive SARS-CoV-2 test. On 10 Nov 2020 (Day 98), at 0300 hours, the subject experienced breathing difficulty and was hospitalized. On the same day (Day 98), a SARS-CoV-2 test was positive, and the subject was also diagnosed with pneumonia on the next day (Day 99). The pneumonia was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the positive SARS-CoV-2 test and pneumonia were related to the study intervention, concomitant medications, or clinical trial procedures, but rather these were related to a viral syndrome. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	69 kg	23.6 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Type II	Type 2 diabetes mellitus	1999	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Hypertension	Hypertension	2000	Present
Nearsighted	Myopia	2010	Present
smoking	Tobacco user	10AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	11:20
2	Placebo	02SEP2020 (24)	11:57

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Pneumonia	pneumonia	03SEP2020 (25)		13SEP2020 (35)		11	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (13SEP2020)	NOT RELATED/OTHER: unblinded per tx physician physician request sponsor notify of unblinded	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	01OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1162 11621059, a 61-year-old black/African American male with a pertinent medical history of type 2 diabetes mellitus (DM) (since 1999), hyperlipidemia and hypertension (both since 2000), and tobacco user (since 10 Aug 2020), received Dose 1 on 10 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 24). The subject was diagnosed with pneumonia on 03 Sep 2020, 1 day after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the pneumonia included glipizide (since 1998) and metformin (since 2000), both for type 2 DM, lisinopril, (since 2005), metoprolol and hydrochlorothiazide (both since 2015) for hypertension, and atorvastatin (since 2008) for hyperlipidemia. On 03 Sep 2020 (Day 25), the subject experienced breathing difficulty and was subsequently hospitalized requiring intubation and care in the intensive care unit. Laboratory test results included hemoglobin of 6.0 g/dL (normal range not reported); 2 tests for COVID-19 polymerase chain reaction were negative; and a chest x-ray showed modelled glass appearance bilaterally. On 12 Sep 2020 (Day 34), the subject was discharged from the hospital. On 13 Sep 2020 (Day 35), the pneumonia resolved. In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	118.64 kg	37.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present
Anxiety	Anxiety	2010	Present
Hypothyroidism	Hypothyroidism	APR2011	Present
Allergic Rhinitis	Rhinitis allergic	07JUN2016	Present
S/p laparoscopic sleeve gastrectomy	Gastrectomy	10MAY2018	Past
Low Back Pain	Back pain	09JUL2018	Present
Panic Attacks	Panic attack	24JUL2019	Present
Hysterectomy	Hysterectomy	31JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	15:51
2	Placebo	09SEP2020 (24)	11:53

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Cholecystitis acute	Acute Cholecystitis	21AUG2020 (5)		22AUG2020 (6)		2	3	TC/TCN	Y
2	HEPAT	Cholelithiasis	Cholelithiasis	21AUG2020 (5)		22AUG2020 (6)		2	2	TCN	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (22AUG2020)	NOT RELATED/OTHER: Cholelithiasis and sudden weight loss due to baratric surgery 2018	1	5	Y
2	Resolved (22AUG2020)	NOT RELATED/OTHER: Sudden weight loss due to bariatric surgery	1	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluzone (Influenza vaccine)	INFLUENZA VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1167 11671009, a 39-year-old white female with a pertinent medical history of obesity (since 2000), hypothyroidism (since Apr 2011), gastrectomy (laparoscopic sleeve gastrectomy) (on 10 May 2018), and back pain (since 09 Jul 2018), received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject was diagnosed with acute cholecystitis on 21 Aug 2020, 4 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the acute cholecystitis included Synthroid (since 20 Nov 2015) for hypothyroidism, montelukast sodium (since 07 Jun 2016) for allergies, and sertraline hydrochloride (since 24 Jul 2019) for anxiety. On 21 Aug 2020 (Day 5), the subject presented with severe right upper quadrant abdominal pain that radiated to the back and was hospitalized. On 22 Aug 2020 (Day 6), a computerized tomogram of the abdomen/pelvis showed cholelithiasis and acute cholecystitis with gallbladder distention with an elevated white blood cell count of 11.4 × 103/mm3 (normal range: 3.5-10.5 × 103/mm3). A SARS-CoV-2 test was negative. The subject underwent laparoscopic cholecystectomy and was treated with intravenous (IV) normal saline with famotidine and ondansetron, IV piperacillin sodium/tazobactam sodium, and tramadol. Postsurgery, the subject's condition improved and the acute cholecystitis and cholelithiasis were considered resolved on 22 Aug 2020 (Day 6). On 23 Aug 2020 (Day 7), the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the acute cholecystitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	135.45 kg	37.2 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Iron Deficiency anemia	Iron deficiency anaemia	26AUG1998	Present
Lumbar Radiculopathy	Lumbar radiculopathy	2010	Present
Acid Reflux disease	Gastrooesophageal reflux disease	08AUG2012	Present
Paroxysmal Atrial Fibrillation	Atrial fibrillation	24OCT2012	Present
Coronary arteriosclerosis	Arteriosclerosis coronary artery	13AUG2014	Present
Hematochezia	Haematochezia	08OCT2015	Past
Chronic Gout	Gout	30AUG2016	Present
Peripheral Neuropathy	Neuropathy peripheral	30AUG2016	Present
Type 2 Diabetes	Type 2 diabetes mellitus	09MAR2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	28AUG2017	Present
Macular degeneration	Macular degeneration	2018	Present
Benign Hyperplasia Prostate	Benign prostatic hyperplasia	10OCT2018	Present
Hyperlipidemia	Hyperlipidaemia	10OCT2018	Present
Hypothyroidism	Hypothyroidism	10OCT2018	Present
Mild Dementia	Dementia	28JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	09:24
2	Placebo	17SEP2020 (21)	08:30

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Angina unstable	Unstable Angina Pectoris	20OCT2020 (54)		20OCT2020 (54)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (20OCT2020)	NOT RELATED/OTHER: known Coronary artery disease	2	34	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1167 11671085, a 73-year-old white male with a pertinent medical history of iron deficiency anemia (since 26 Aug 1998), gastroesophageal reflux disease (since 08 Aug 2012), atrial fibrillation (since 24 Oct 2012), arteriosclerosis coronary artery (since 13 Aug 2014), chronic gout (since 30 Aug 2016), type 2 diabetes mellitus (since 09 Mar 2017), hypertension (since 28 Aug 2017), and hyperlipidemia and hypothyroidism (both since 10 Oct 2018), received Dose 1 on 28 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 21). The subject was diagnosed with unstable angina on 20 Oct 2020, 33 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the unstable angina included propafenone (since 14 Feb 2011) for atrial fibrillation, levothyroxine (since 04 Apr 2011) for hypothyroidism, allopurinol (since 21 Apr 2011) for chronic gout, ramipril (since 25 Jul 2011) and metoprolol succinate (since 28 Aug 2017) for hypertension, omeprazole (since 08 Aug 2012) for acid reflux disease, oxycodone (since 02 Jun 2015) for back pain, insulin aspart (since 11 Jul 2018) for diabetes, rosuvastatin (since 19 Apr 2019) for hyperlipidemia, and finasteride (since 07 May 2020) for benign prostatic hyperplasia. On 20 Oct 2020 (Day 54), the subject woke up in the middle of the night because of severe chest pain (severity score of 10/10) with shortness of breath. Emergency medical services transported the subject to the emergency room (ER) and treated with nitroglycerin (3 tablets), ticagrelor, and heparin. An electrocardiogram showed no evidence of an ST elevation myocardial infarction. The subject was hospitalized. Troponin was less than 0.02 ng/mL (normal range: 0-0.4 ng/mL) and a SARS-CoV-2 test was negative. The subject underwent a cardiac catheterization, which showed nonobstructive coronary artery disease. On 20 Oct 2020 (Day 54), the subject was diagnosed with unstable angina pectoris which he recovered from on the same day as admission. The subject was discharged after 2 days of hospitalization with a medical management plan for the unstable angina pectoris. In the opinion of the investigator, there was no reasonable possibility that the unstable angina was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to known coronary artery disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	88.64 kg	28 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	1987	Present
smoker	Tobacco user	1990	Present
hyperlipidemia	Hyperlipidaemia	1998	Present
type 2 diabetes	Type 2 diabetes mellitus	1998	Present
type 2 diabetes neuropathy	Diabetic neuropathy	2014	Present
cervicalgia	Neck pain	18SEP2014	Present
attention deficit disorder	Attention deficit hyperactivity disorder	10MAR2017	Present
hypogonadism, testicular	Hypogonadism male	15NOV2019	Present
polycythemia	Polycythaemia	14MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	15:48
2	BNT162b2	29SEP2020 (20)	15:30

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Cerebrovascular accident	Cerebrovascular accident	21OCT2020 (42)		ONGOING			3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: underlying risk factors, smoker, Diabetes, polycythemia	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1167 11671175, a 55-year-old white male with a pertinent medical history of tobacco user (since 1990), hyperlipidemia and type 2 diabetes mellitus (both since 1998), diabetic neuropathy (since 2014), neck pain (since 18 Sep 2014), attention deficit hyperactivity disorder (since 10 Mar 2017), and polycythemia (since 14 May 2020), received Dose 1 on 10 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 20). The subject was diagnosed with a cerebrovascular accident on 21 Oct 2020, 22 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the cerebrovascular accident included fluticasone propionate (since 13 Oct 2003) for allergic rhinitis, fenofibrate (since 03 Oct 2013) for hyperlipidemia, hydrocodone (since 18 Sep 2014) for cervicalgia, atomoxetine hydrochloride (since 10 Mar 2017) for attention deficit disorder, empagliflozin/metformin hydrochloride (since 25 May 2018) and dulaglutide (since 11 Oct 2018) for type 2 diabetes, and clonazepam (since 28 Apr 2020) for dysthymic disorder. On 21 Oct 2020 (Day 42), the subject reported that when he bent down to pick up a pen that he experienced abrupt dizziness, visual loss, and loss of control of his arms associated with nausea and vomiting (twice). The subject was hospitalized, and a computerized tomogram of the head was unremarkable. On 22 Oct 2020 (Day 43), a magnetic resonance imaging showed multiple acute infarctions in bilateral cerebral hemispheres and he was treated with ondansetron, enoxaparin sodium, and intravenous hydration. A SARS-CoV-2 test was negative during this hospitalization. The cerebrovascular accident was ongoing at the time of last available report and the subject was discharged from the hospital on an unspecified date. In the opinion of the investigator, there was no reasonable possibility that the cerebrovascular accident was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	164.2 kg	49.1 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1963	Present
Hypertension	Hypertension	1980	Present
Chronic Deep Vein Thrombosis (DVT)	Deep vein thrombosis	1998	Present
Type II Diabetes	Type 2 diabetes mellitus	1998	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:05
2	Placebo	29SEP2020 (22)	10:06

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Cellulitis	Cellulitis of left lower leg	01OCT2020 (24)		ONGOING			3	TC/TCN	Y
2	INJ&P	Limb injury	Wound of left lower leg	12SEP2020 (5)		30SEP2020 (23)		19	3	TC	N
3	BLOOD	Neutropenia	Neutropenia	01OCT2020 (24)		ONGOING			3	TC/TCN	Y
4	BLOOD	Thrombocytopenia	Thrombocytopenia	01OCT2020 (24)		ONGOING			2	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: underline comorbidities pt with a hx of Type II Diabetes and morbid obesity	2	3	Y
2	Resolved (30SEP2020)	NOT RELATED/OTHER: injury to leg.	1	5	N
3	Yes	NOT RELATED/OTHER: underline comorbidities pt with a hx of Type II Diabetes and morbid obesity	2	3	Y
4	Yes	NOT RELATED/OTHER: Cellulitis	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1170 11701217, a 57-year-old white male with a pertinent medical history of hypertension (since 1980), and type 2 diabetes mellitus and deep vein thrombosis (DVT) (both since 1998), received Dose 1 on 08 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 22). The subject was diagnosed with cellulitis, neutropenia, and thrombocytopenia on 01 Oct 2020, 2 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the cellulitis, neutropenia, and thrombocytopenia included metformin for type 2 diabetes mellitus, lisinopril/hydrochlorothiazide for hypertension, and warfarin sodium for chronic DVT. On 12 Sep 2020, 4 days after receiving Dose 1, the subject developed a left lower leg wound. At Visit 2 (29 Sep 2020), the subject was afebrile but noted to have erythema, swelling, and drainage of the left lower extremity with no other signs of infection, hypotension, tachycardia, malaise, or weakness. As the subject was instructed to seek medical attention, he presented to the emergency room on 01 Oct 2020 (Day 24). The subject was diagnosed with cellulitis of the left lower leg with laboratory results remarkable for neutropenia (white blood cell [WBC] count of 1.8 × 103/mm3; normal range [NR]: 5.0-10.0 × 103/mm3), band neutrophil of 8% [NR: 0%-5%], and neutrophil of 6% [NR: 50%-70%]); and thrombocytopenia (platelet count of 95 × 103/mm3 [NR: 150–450 × 103/mm3]). The C-reactive protein was 4.6 mg/dL (NR: 0.0-0.8 mg/dL) and erythrocyte sedimentation rate was 25 mm/hour (NR: 0–15 mm/hour), and blood cultures were subsequently negative. An ultrasound Doppler showed no evidence of DVT in the left lower leg and an x-ray of limb (tibia/fibula) showed no acute bone/joint abnormality. A SARS-CoV-2 test was negative. The subject was treated with filgrastim (Neupogen) injection, ceftriaxone 1 g in 100 mL of normal saline intravenously (IV) once every 24 hours (total 2 doses) and vancomycin 2000 mg in 500 mL of normal saline IV every 12 hours (total 3 doses). He also received filgrastim (Granix) 300 µg subcutaneously once for neutropenia. However, warfarin was stopped at admission for the treatment of thrombocytopenia. On 02 Oct 2020 (Day 25), the subject's WBC count improved to 4.1 × 103/mm3 and platelet count improved to 107 × 103/mm3 and he was discharged from the hospital with oral antibiotics (cefdinir 300 mg orally and doxycycline 100 mg orally [both twice a day for 5 days]), folic acid 1 mg orally daily, and thiamine 100 mg orally 2 tablets daily. The cellulitis, neutropenia, and thrombocytopenia were ongoing at the time of last available report. In the opinion of the investigator, there was no reasonable possibility that the cellulitis, neutropenia, and thrombocytopenia were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Microdiscectomy Lumbar spine	Intervertebral disc operation	1980	Past
hypercholesterolaemia	Hypercholesterolaemia	2005	Present
hypertension	Hypertension	2005	Present
hypothyroidism	Hypothyroidism	2005	Present
Microdiscectomy Lumbar spine	Intervertebral disc operation	2005	Past
Herniated disc L4-L5	Intervertebral disc protrusion	2005	Past
nephrolithiasis	Nephrolithiasis	2008	Past
Hemorrhoid	Haemorrhoids	2015	Past
Lumbar radiculopathy	Lumbar radiculopathy	2019	Present
left inguinal Hernia repair	Inguinal hernia repair	AUG2019	Past
Hemorrhoidectomy	Haemorrhoid operation	JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	08:53
2	BNT162b2	06OCT2020 (21)	09:57

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Hydronephrosis	Hydronephrosis	02OCT2020 (17)		06OCT2020 (21)		5	2
2	RENAL	Nephrolithiasis	nephrolithiasis	02OCT2020 (17)		06OCT2020 (21)		5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	N	Resolved (06OCT2020)	NOT RELATED/OTHER: Nephrolithiasis	1	17	N
2	TC/TCN	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: Intercurrent illness	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	02SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	05NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1174 11741042, a 71-year-old white male with a pertinent medical history of hypercholesterolemia, hypertension, and hypothyroidism (all since 2005); nephrolithiasis (in 2008); and lumbar radiculopathy (since 2019), received Dose 1 on 16 Sep 2020 and Dose 2 on 06 Oct 2020 (Day 21). The subject was diagnosed with nephrolithiasis on 02 Oct 2020, 16 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the nephrolithiasis included levothyroxine for hypothyroidism, amlodipine (since 2005) for hypertension, acetylsalicylic acid (since 2005) for heart health, and atorvastatin (since 2005) for hypercholesterolemia. On 02 Oct 2020 (Day 17), the subject presented to the emergency room with left flank pain. A computerized tomogram of the abdomen/pelvis without contrast showed obstruction of the left ureter with 7 × 6 mm calculus in the proximal left ureter causing mild hydronephrosis (reported as nonserious adverse event); urinalysis showed large amount of blood (NR: 0-5 hpf). The blood creatinine was 1.5 mg/dL (normal range [NR]: 0.7-1.3 mg/dL) and white blood cell count 14.54 × 103/mm3 (NR: 3.10-9.50 × 103/mm3). On 03 Oct 2020 (Day 18), a ureteral stent was placed and the subject was treated with intravenous (IV) fluids, pain medications, and a single dose of IV ceftriaxone during the stent procedure. On the same day (Day 18), the subject was discharged home on oxybutynin, tamsulosin, oxycodone/acetaminophen, and phenazopyridine as needed for pain. A COVID-19 test was not performed. On 06 Oct 2020 (Day 21), the subject was seen for second dose of study vaccination. The nephrolithiasis and hydronephrosis were considered resolved on the same day (Day 21), and the stent was planned to be removed following the subject's second study visit. In the opinion of the investigator, there was no reasonable possibility that the nephrolithiasis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	78.18 kg	25.4 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	1996	Present
attention deficit disorder	Attention deficit hyperactivity disorder	2000	Present
hypertension	Hypertension	2008	Present
insomnia	Insomnia	2010	Present
neck pain	Neck pain	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	12:31
2	BNT162b2	15SEP2020 (22)	13:55

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Aortic dilatation	Ascending aorta ectasia	10OCT2020 (47)		ONGOING			1
2	GENRL	Injection site pain	injection site tenderness	25AUG2020 (1)	19:00	26AUG2020 (2)	12:00	2	1
3	CARD	Left ventricular dysfunction	Diastolic dysfunction of the left ventricle	11OCT2020 (48)		ONGOING			1
4	NERV	Transient global amnesia	transient global amnesia	10OCT2020 (47)		10OCT2020 (47)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Unknown, possibly hypertension	2	26	N
2	N	N	Resolved (26AUG2020)	Study Treatment	1	1	N
3	N	N	Yes	NOT RELATED/OTHER: Unknown, possibly hypertension	2	27	N
4	N	Y	Resolved (10OCT2020)	NOT RELATED/OTHER: unknown	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781015, a 67-year-old white male with a pertinent medical history of depression (since 1996), attention deficit hyperactivity disorder (since 2000), hypertension (since 2008), and insomnia (since 2010), received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). The subject experienced transient global amnesia on 10 Oct 2020, 25 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the transient global amnesia included lisinopril for hypertension, paracetamol for neck pain, eszopiclone for insomnia, amphetamine aspartate/amphetamine sulfate/dexamphetamine saccharate/dexamphetamine sulphate for attention deficit disorder, and mirtazapine for depression. On 10 Oct 2020 (Day 47), the subject was hospitalized for transient global amnesia characterized by confusion. The subject had a phone conversation with his father that he could not recall. His wife stated that the subject was repetitive and could not remember the date nor the day's events. The subject was normal after an 8-hour period, which he could not remember. The subject was afebrile and normotensive. A computerized tomogram of the head and thorax showed no significant abnormalities and a brain magnetic resonance imaging was normal. A urine drug screen was positive only for amphetamines, which was consistent with his concomitant medication (amphetamine aspartate/amphetamine sulfate/dexamphetamine saccharate/dexamphetamine sulfate), which he was taking for attention deficit disorder. Laboratory test results showed a nonfasting glucose of 116 mg/dL (normal range not provided) and undetectable levels of paracetamol, acetylsalicylic acid, and ethanol. A COVID-19 test was not performed. On 10 Oct 2020 (Day 47), the transient global amnesia resolved. On 11 Oct 2020 (Day 48), the subject was discharged from the hospital with an outpatient electroencephalogram scheduled per his primary care physician. In the opinion of the investigator, there was no reasonable possibility that the transient global amnesia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	86.82 kg	31.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa allergy	Drug hypersensitivity	1945	Present
Endometriosis	Endometriosis	1977	Past
codeine allergy	Drug hypersensitivity	1985	Present
tetracycline allergy	Drug hypersensitivity	1985	Present
hysterectomy	Hysterectomy	1987	Past
diverticulitis	Diverticulitis	1989	Past
Diabetes Type II	Type 2 diabetes mellitus	1990	Present
colon resection	Colectomy	1991	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
esophageal reflux	Gastrooesophageal reflux disease	2017	Present
hypercholesterolemia	Hypercholesterolaemia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:35
2	BNT162b2	16SEP2020 (22)	13:27

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Nephrolithiasis	Kidney stone, worsening	03OCT2020 (39)		16OCT2020 (52)		14	3
2	RENAL	Nephrolithiasis	kidney stones	19SEP2020 (25)	14:00	23SEP2020 (29)		5	3
3	INFEC	Pyelonephritis	Pyelonephritis	03OCT2020 (39)		30OCT2020 (66)		28	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (16OCT2020)	NOT RELATED/OTHER: Supersaturated urine	2	18	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	TC	Y	Resolved (23SEP2020)	NOT RELATED/OTHER: unknown	2	4	Y
3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: Renal stone	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781025, a 79-year-old white female with a pertinent medical history of drug hypersensitivity (sulfa allergy; since 1945, and allergy to codeine and tetracycline; both since 1985), type 2 diabetes mellitus (since 1990), and hypercholesterolemia (since 2017), received Dose 1 on 26 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 22). The subject was diagnosed with nephrolithiasis on 19 Sep 2020, 3 days after receiving Dose 2 and pyelonephritis on 03 Oct 2020, 17 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the nephrolithiasis and pyelonephritis included metformin (since 2013) for type 2 diabetes mellitus, omeprazole (since 2017) for gastroesophageal reflux disease, and ezetimibe (since 2019) for hypercholesterolemia. On 19 Sep 2020 (Day 25), the subject presented to the emergency room with sudden onset of sharp pain in her right abdomen/flank, for which a computerized tomogram (CT) scan revealed multiple renal stones - right hydroureteronephrosis with a 3 mm obstructing stone and a 6 mm non-obstructing stone in the right kidney. The subject was admitted for further evaluation, as she was continuing to pass the stones. She denied any other symptoms or any changes in medications and was kept nil by mouth. Laboratory results were only remarkable for a slight elevation in the lipase level (196 IU/L; normal range not provided) and hematuria. The subject was treated with intravenous fluids, and narcotics such as morphine and hydromorphone, ketorolac tromethamine, ondansetron, and cefuroxime. As it was expected that the stone would pass without any procedural intervention and the subject responded to the conservative measures, the subject was discharged from the hospital on 21 Sep 2020 (Day 27). On 23 Sep 2020 (Day 29), the nephrolithiasis was considered resolved. On 03 Oct 2020 (Day 39), the subject developed symptoms of right abdominal/flank pain, nausea, and vomiting, and was diagnosed with worsening of nephrolithiasis that was subsequently diagnosed with pyelonephritis. On 04 Oct 2020 (Day 40), the subject went to the emergency room where a CT confirmed a solitary renal 6 mm stone that was occluding the right ureter. Her urine was noted to be cloudy and her white blood cell count was 11000 (unit and normal range not provided), so a stent was placed. The subject was afebrile throughout the admission. She was treated with ceftriaxone, hydromorphone hydrochloride, and ondansetron. The subject's pain improved and her nausea and vomiting were considered resolved. On 05 Oct 2020 (Day 41), a SARS-CoV-2 test was negative. On an unspecified date, the subject was discharged from the hospital (hospital stay was for 3 days) with cefalexin 500 mg orally 3 times a day. On 16 Oct 2020 (Day 52), the subject underwent lithotripsy and the nephrolithiasis was considered resolved. A CT scan was negative for kidney stones. On 30 Oct 2020 (Day 66), the urinalysis results were within normal limits and the pyelonephritis was considered resolved. The subject was scheduled for a follow-up on 13 Nov 2020. The investigator considered there was no reasonable possibility that the nephrolithiasis and pyelonephritis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	104.55 kg	38.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1970	Present
sulfa allergy	Drug hypersensitivity	1970	Present
post menopausal	Postmenopause	2005	Present
bipolar disorder	Bipolar disorder	2010	Present
Depression	Depression	2011	Present
attention deficit disorder	Attention deficit hyperactivity disorder	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	11:01
2	Placebo	21SEP2020 (22)	10:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Salivary gland calculus	salivary gland stone	20SEP2020 (21)	18:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC	Y	Yes	NOT RELATED/OTHER: Salivary stone	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781048, a 59-year-old white female with no pertinent medical history, received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject experienced salivary gland calculus on 20 Sep 2020, 20 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the salivary gland calculus included lamotrigine (since 2010) for bipolar disorder, bupropion hydrochloride (since 2011) for depression, and atomoxetine hydrochloride (since 2015) for attention deficit disorder. On 21 Sep 2020 (Day 22), during Visit 2, the subject reported swelling and discomfort of her left submandibular salivary gland which was tender to palpation. The subject reported a similar transient episode about 6 months earlier. On 21 Sep 2020 (Day 22), the subject had an ear, nose, and throat (ENT) consultation and was diagnosed with sialadenitis. On 22 Sep 2020 (Day 23), the subject had increased pain, described as "sore throat" and swelling of her tongue. The subject returned to the ENT clinic and the clinician thought she could be having an allergic reaction and treated her with diphenhydramine 50 mg and famotidine 20 mg. Her ENT prescribed antibiotics and corticosteroids. The subject reported slight improvement in her symptoms, but complained of nausea. The subject denied any other symptoms. The site requested the subject to withhold systemic corticosteroids following Dose 2. On the same day (Day 23), the subject had increased pain and swelling of the left submandibular salivary gland, neck, and tongue and she was hospitalized for further evaluation. The subject had an initial blood pressure of 161/89 mmHg, which dropped to 123/78 mmHg within an hour; and her other vital signs were normal. The subject's physical examination showed a tender, swollen, firm mass in her left submandibular region without fluctuance, which extended anteriorly almost to her submental region. Her laboratory results were unremarkable except for an elevated white blood cell (WBC) count of 16.6 (unit and normal range not provided) and neutrophils of 73% (normal range not provided). A computed tomography (CT) scan revealed a left submandibular salivary gland stone. A neck CT revealed a 2.8 × 5.1 mm calcification which was consistent with a Wharton's duct stone. The submandibular gland was enlarged and hyperemic. The subject was treated with intravenous (IV) clindamycin, morphine sulfate 4 mg IV, ketorolac 15 mg IV, dexamethasone 10 mg IV, and ondansetron 4 mg IV. On 23 Sep 2020 (Day 24), the subject's WBC count improved to 13.3, and a Streptococcus test and blood cultures were negative. The subject denied COVID-19 testing while at the hospital and there was no mention of COVID-19 testing in the medical records. On 24 Sep 2020 (Day 25), the subject was discharged from the hospital with moxifloxacin 400 mg orally once daily for 7 days. On 29 Sep 2020 (Day 30), the subject was scheduled for a follow-up. The salivary gland calculus was ongoing at the time of the last available report. The investigator considered there was no reasonable possibility that the salivary gland calculus was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	115.64 kg	38.7 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2015	Present
diabetes type II	Type 2 diabetes mellitus	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	10:55
2	Placebo	29SEP2020 (20)	13:40

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Coronary artery disease	vascular disease (coronary artery disease)	08OCT2020 (29)		ONGOING			3	TC
2	CARD	Myocardial infarction	Myocardial infarction	08OCT2020 (29)	18:00	19OCT2020 (40)		12	3	N
3	RENAL	Nocturia	nocturia	10SEP2020 (1)	22:00	12SEP2020 (3)		3	1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Yes	NOT RELATED/OTHER: atherosclerosis	2	10	N
2	Y	Resolved (19OCT2020)	NOT RELATED/OTHER: vascular disease (coronary artery disease)	2	10	Y
3	N	Resolved (12SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781138, a 68-year-old white male with a pertinent medical history of hypertension (since 2015) and type 2 diabetes mellitus (since Feb 2020), received Dose 1 on 10 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 20). The subject was diagnosed with a myocardial infarction on 08 Oct 2020, 9 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the myocardial infarction included amlodipine besilate/benazepril hydrochloride (since 2015) for hypertension and metformin (since Feb 2020) for type 2 diabetes mellitus. On 08 Oct 2020 (Day 29), the subject presented to the emergency room (ER) with chest pain, nausea, and nonbloody vomiting 4 times. Initial blood pressure (BP) was 162/80 mmHg and he received acetylsalicylic acid 81 mg orally (5 doses) and sublingual nitroglycerin 0.4 mg (1 dose) on his way to the ER. Upon arrival at the ER, the subject's symptoms improved and he denied fever, chills, diarrhea, and other symptoms. The subject remained hypertensive (165/81 mmHg) with otherwise stable vital signs (97.7 F°, pulse rate of 65 beats per minute, respiration rate of 12 breaths per minute, and oxygen saturation of 100% on room air). Physical examination was unremarkable. Chest x-ray was normal. Laboratory results showed elevated troponin I ultra of 0.211, elevated point of care troponin of 0.15 (units and normal ranges not reported), and low density lipoproteins of 140.8 mg/dL (normal range not reported). On 09 Oct 2020 (Day 30), troponin levels increased to 0.97. The subject's electrocardiogram showed normal sinus rhythm without ischemic changes. The subject was admitted to the intensive care unit for non-ST elevation myocardial infarction and treated with intravenous (IV) heparin, oral amlodipine 10 mg once daily (QD), and clopidogrel 76 mg QD. He underwent a left cardiac catheterization, which revealed severe sclerotic disease in left anterior descending coronary artery (80% proximal) and left circumflex coronary artery (60% proximal and 90% distal), and right coronary artery (80% mid and 80% distal). Transthoracic echocardiogram revealed a left ventricular ejection fraction of 59% and moderate left ventricular concentric hypertrophy. On 13 Oct 2020 (Day 34), the subject underwent 2-vessel coronary artery bypass grafting. On 14 Oct 2020 (Day 35), the subject was extubated. His white blood cell (WBC) counts increased from 10 to 12.4 (units and normal range not reported), and a chest x-ray revealed left basilar atelectasis and his pulmonary toilet was advanced. The subject remained afebrile and the WBC count improved without antibiotics. On 16 Oct 2020 (Day 37), the subject started treatment with atorvastatin 80 mg every night and metoprolol 12 mg BID, and his chest tube was removed. The subject tolerated his postoperative course without incident. On 19 Oct 2020 (Day 40), the myocardial infarction resolved and the subject was discharged from the hospital. A COVID-19 testing was not reported. The subject recovered except for the surgical wound pain. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator’s causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	92.27 kg	30.9 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2010	Present
basal cell cancer, right eye lid	Basal cell carcinoma	MAR2020	Past
basal cell excision, right eye lid	Skin lesion removal	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	13:47
2	BNT162b2	05OCT2020 (22)	12:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis	cholecystitis	09OCT2020 (26)		12OCT2020 (29)		4
2	HEPAT	Cholelithiasis	cholelithiasis (gallstones)	09OCT2020 (26)		11OCT2020 (28)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (12OCT2020)	NOT RELATED/OTHER: gallstones	2	5	Y
2	3	TC/TCN	N	Resolved (11OCT2020)	NOT RELATED/OTHER: Bile	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	20OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781167, a 68-year-old white male with no pertinent medical history, received Dose 1 on 14 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 22). The subject experienced cholecystitis on 09 Oct 2020, 4 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the cholecystitis included amlodipine and hydrochlorothiazide (both since unknown dates) for hypertension. On 09 Oct 2020 (Day 26), the subject woke up with a moderate, diffuse, dull pain in the epigastric or central abdominal region without nausea, vomiting, or any other complaints. The subject was afebrile. On 10 Oct 2020 (Day 27), his pain continued to worsen, and he was hospitalized because of abdominal pain, previous vomiting and anorexia, with no bowel movements for 2 days with stable vital signs (temperature was 98.3F, pulse rate was 81 beats per minute, blood pressure was 124/83 mmHg, and respiratory rate was 20 breaths per minute). On examination, his abdomen was soft, nondistended, and had tenderness over central, right upper quadrant, and right lower quadrants without guarding or rebound. Laboratory results showed creatinine kinase of 1098 mg/dL, lactic acid of 2.81 mmol/L, glucose of 148 mg/dL, sodium of 134 mEq/L, chloride of 88 mEq/L, potassium 3.3 mEq/L, carbon dioxide of 29.9 mEq/L, total bilirubin of 1.81 mg/dL, aspartate aminotransferase of 54 U/L, alanine aminotransferase of 48 U/L, lipase of 124 U/L (normal ranges not reported), and a white blood cell count of 20.19 (units and normal range not reported). A computerized tomography of the abdomen showed a distended gallbladder with thickened walls containing stones and evidence of regional inflammation. The subject was diagnosed with cholecystitis and treated with intravenous (IV) fluids, pain medications, and a dose of piperacillin sodium/tazobactam sodium 3.375 g. The subject became febrile to 103 F°. On 11 Oct 2020 (Day 28), the subject underwent laparoscopic cholecystectomy and his gallbladder was noted to be necrotic and friable, resulting in contamination of the wound with bile and stones. The subject had no complications following the surgery. A SARS CoV-2 test was negative. On 11 Oct 2020 (Day 28), the cholelithiasis resolved. On 12 Oct 2020 (Day 29), the cholecystitis resolved and the subject was discharged from the hospital on pain medications. In the opinion of the investigator, there was no reasonable possibility that the cholecystitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	145 kg	41.9 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pollinosis	Seasonal allergy	01JUL2000	Present
Osteochondrosis	Osteochondrosis	03APR2001	Present
Anxiety disorder	Anxiety disorder	MAY2001	Present
Splay-flat feet	Foot deformity	2002	Present
Depression	Depression	JAN2004	Present
irritable bowel	Irritable bowel syndrome	24AUG2010	Present
Lumbal spine syndrome	Spinal disorder	13OCT2014	Present
fatty liver	Hepatic steatosis	21NOV2014	Present
herniated disc cervical vertebra	Intervertebral disc protrusion	05OCT2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	08:17
2	Placebo	04NOV2020 (20)	08:05

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	MUSC	Intervertebral disc protrusion	herniated disc cervical vertebra	11NOV2020 (27)	13:39	ONGOING			1	N

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: surgery is necessary for diagnosed herniated disc on 05Oct2020	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1195 11951023, a 50-year-old white male with a pertinent medical history of osteochrondosis (since 03 Apr 2001), foot deformity (since 2002), spinal disorder (since 13 Oct 2014), and intervertebral disc protrusion (herniated disc cervical vertebra; since 05 Oct 2020), received Dose 1 on 16 Oct 2020 and Dose 2 on 04 Nov 2020 (Day 20). The subject required surgery for the intervertebral disc protrusion (herniated disc cervical vertebra) on 11 Nov 2020, 7 days after receiving Dose 2. The subject was diagnosed with herniated disc of cervical vertebra on 05 Oct 2020, prior to entry into the study. On 19 Oct 2020 (Day 4), a magnetic resonance imaging of cervical vertebra was performed (results pending) for which the subject was hospitalized on 11 Nov 2020 (Day 27) for the planned surgery. The intervertebral disc protrusion was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the intervertebral disc protrusion was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	American Indian or Alaska	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	118.4 kg	36.5 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Uveitis	Uveitis	JAN2006	Present
Chronic intermittent back pain	Back pain	2012	Present
Seasonal allergies	Seasonal allergy	2012	Present
Syphilis	Syphilis	2013	Past
Foot fracture	Foot fracture	2014	Past
Surgical revision of scar tissue in foot	Scar excision	2014	Past
Anxiety	Anxiety	JUN2016	Past
Syphilis	Syphilis	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	15:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Abscess jaw	Abscess in left jaw	31OCT2020 (16)		ONGOING		
2	INFEC	Meningitis bacterial	Meningitis Bacterial	10NOV2020 (26)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	N	Yes	NOT RELATED/OTHER: Inflammation vs. infection	1	16	N
2	3	TC	Y	Yes	NOT RELATED/OTHER: Bacterial infection	1	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1221 12211007, a 37-year-old American Indian/Alaska native male with a pertinent medical history of uveitis (since Jan 2006), syphilis (in 2013 and in Mar 2020) and dental caries of left upper molar (on 04 Oct 2020), received Dose 1 on 16 Oct 2020. The subject experienced bacterial meningitis on 10 Nov 2020, 25 days after receiving Dose 1. On 04 Nov 2020 (Day 20), during Visit 2, the subject's vaccine administration was delayed due to his acute illness, including facial swelling over the left temple and jaw along with a left temporal headache and he presented to the emergency room (ER). A computerized tomogram (CT) of maxillary facial showed asymmetry of left temporalis muscle due to inflammation versus infection. The subject was treated with ibuprofen along with hot compresses and was advised to return to the clinic in 2 days for follow-up. On 06 Nov 2020 (Day 22), during his follow-up visit, no etiological diagnosis of his facial edema and buccal tenderness was provided. Due to history of unprotected sex, the subject was treated with azithromycin, benzathine benzylpenicillin, and ceftriaxone (all on 06 Nov 2020) for potential sexually transmitted diseases and was advised to visit his dentist for his facial edema or gum pain or headache. On 06 Nov 2020 (Day 22), the subject was referred to another hospital, where he was diagnosed with left otitis externa with associated facial cellulitis, and was treated with amoxicillin/clavulanate 750 mg (from 07 Nov 2020 to 10 Nov 2020). On 10 Nov 2020 (Day 26), the subject experienced excruciating left-sided neck pain extending to his temple and down his neck to the shoulder. The headache prevented him from turning the head to the right and he presented to the ER. His vital signs were stable and a brain CT was negative for intracranial hemorrhage and mass lesion. The subject was treated with cyclobenzaprine 20 mg and paracetamol 325 mg (on 10 Nov 2020) for the headache or neck pain. Later that day, the subject complained of worsened bilateral neck pain and an inability to rotate his head in either direction and he returned to ER at 1300 hours. The subject was afebrile with stable vital signs with otherwise unremarkable laboratory results except an elevated white blood cell count of 11.1 × 103/mm3 (normal range not reported). Due to meningeal symptoms, a lumbar puncture (LP) was attempted 4 times by the ER physician and anesthesiologist without success. The subject was treated with ceftriaxone 2 g intravenously (IV), morphine 4 mg IV, ondansetron 4 mg IV, lorazepam 1 mg IV, and hydromorphone hydrochloride 1 mg intramuscularly. The subject was later transferred to the university hospital at 2000 hours for a possible LP to rule out meningitis. The subject remained in the ER on 11 Nov 2020 (Day 27) waiting for magnetic resonance imaging. On 12 Nov 2020 (Day 28), the subject was admitted to another hospital and diagnosed with bacterial meningitis and an abscess in left jaw. The subject's condition improved with ceftriaxone and also received cyclobenzaprine and gabapentin for neck pain. A peripheral central catheter line was inserted for antibiotic therapy. On 18 Nov 2020 (Day 34), the subject was discharged from the hospital. The bacterial meningitis and abscess in the left jaw were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the bacterial meningitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	84	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	81.64 kg	27.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arthritis	Arthritis	2018	Present
atrial fibrillation	Atrial fibrillation	2018	Present
chronic kidney isease	Chronic kidney disease	2018	Present
coronary artery disease	Coronary artery disease	2018	Present
hyperlipidemia	Hyperlipidaemia	2018	Present
hypertension	Hypertension	2018	Present
hypothyroidism	Hypothyroidism	2018	Present
history of prostate cancer	Prostate cancer	2018	Present
vitamin D deficiency	Vitamin D deficiency	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	19:16
2	Placebo	25SEP2020 (24)	16:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Asthenia	Generalized Weakness	12NOV2020 (72)	15:00	ONGOING		
2	GASTR	Constipation	intermittent constipation	28OCT2020 (57)	00:00	29OCT2020 (58)	00:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: COVID 19	2	49	Y
2	1	TC	N	Resolved (29OCT2020)	NOT RELATED/OTHER: diet	2	34	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231097, an 84-year-old black/African American male with a pertinent medical history of anemia and congestive heart failure (both since 23 Feb 2017), benign prostatic hyperplasia and vitamin B12 deficiency (both since 06 Mar 2017), hypothyroidism (since 20 Jul 2017), and atrial fibrillation, chronic kidney disease, coronary artery disease, hyperlipidemia, hypertension, prostate cancer, and vitamin D deficiency (all since 2018), received Dose 1 on 02 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 24). The subject was diagnosed with asthenia on 12 Nov 2020, 48 days after receiving Dose 2 and COVID-19 on 14 Nov 2020, 50 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the asthenia and COVID-19 included amlodipine besilate/atorvastatin calcium (since 15 Feb 2017) for coronary artery disease, tamsulosin hydrochloride (since 15 Feb 2017) for benign prostatic hypertrophy, cyanocobalamin (since 15 Feb 2017) for vitamin B12 deficiency, carvedilol (since 20 Mar 2017) for hypertension, levothyroxine sodium (since 20 Jul 2017) for hypothyroidism, rivaroxaban (since 2018) for blood clot prevention, and epoetin alfa (since 28 Jun 2018) for anemia. On 12 Nov 2020 (Day 72), the subject presented to the emergency room with complaints of recurrent falls and generalized weakness. Magnetic resonance imaging showed no evidence of ischemic infarct or intracranial hemorrhage. The subject returned home; however, the next day 13 Nov 2020 (Day 73) emergency services were called who found the subject at the top of the stairs at his home, complaining of bilateral upper leg weakness and malaise. It was reported that the subject was alert and oriented, and denied chest pain, short of breath, fever, or chills. The subject was hospitalized for observation and workup. A locally performed SARS-CoV-2 RNA test was positive. A chest x-ray showed increased streaky opacities at the right lung base likely representing an atelectasis versus aspiration/pneumonia. Mild left pleural effusion without pneumothorax or pulmonary edema was noted. The asthenia and COVID-19 were ongoing and the subject remained stable in the hospital at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the asthenia and COVID-19 were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	50.3 kg	21.2 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis	Osteoarthritis	1996	Present
Menopause	Menopause	1998	Present
GERD	Gastrooesophageal reflux disease	2002	Present
Melanoma	Malignant melanoma	2007	Past
Hypertension	Hypertension	2008	Present
Dyslipidemia	Dyslipidaemia	2014	Present
Hypothyroidism	Hypothyroidism	2014	Present
Eustachian Tube Dysfunction	Eustachian tube dysfunction	2017	Present
Cardiovascular prevention	Prophylaxis	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Irritable bowl syndrome	Irritable bowel syndrome	2019	Present
Osteoporosis	Osteoporosis	2019	Present
Monoclonal Gammopathy of Unknown Significance	Hypergammaglobulinaemia benign monoclonal	17AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	15:26
2	BNT162b2	01OCT2020 (22)	15:36

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Pancreatic mass	Mass at Pancreatic Head	05NOV2020 (57)	11:21	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: New development of pancreatic mass	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231159, a 73-year-old white female with a pertinent medical history of gastroesophageal reflux disease (GERD; since 2002), hypothyroidism (since 2014), irritable bowel syndrome (since 2019), and hypergammaglobulinemia benign monoclonal (since 17 Aug 2020), received Dose 1 on 10 Sep 2020 and Dose 2 on 01 Oct 2020 (Day 22). The subject was diagnosed with a pancreatic mass on 05 Nov 2020, 35 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the pancreatic mass included omeprazole (since 2005) for GERD, docusate sodium (since 2010) for irritable bowel syndrome, levothyroxine sodium (since 2014) for hypothyroidism, estradiol (since 2014) for vaginal dryness, atorvastatin (since 2018) for dyslipidemia, amlodipine besilate (since 2018) for hypertension, dicycloverine hydrochloride (since Nov 2019) for irritable bowel syndrome, and famotidine (since 2019) for GERD. On 05 Nov 2020 (Day 57), the subject presented to the emergency room with a 2-week history of epigastric pain, early satiety, weight loss (8 lbs), jaundice, and dark urine for the past 4 days. She denied fever and chills. The laboratory tests showed elevated liver function tests, which included bilirubin of 9.1, direct bilirubin of 7.3, aspartate aminotransferase of 289, alanine aminotransferase of 285, and alkaline phosphate of 1148 along with white blood cell count of 7.4 (units and normal ranges not available). A computerized tomogram of the abdomen and pelvis with contrast showed biliary and pancreatic ductal obstruction likely secondary to a pancreatic mass within the uncinate process, dilation of the pancreatic duct up to 7 mm, along with an ill-defined hypoattenuating structure in the uncinate process of the pancreas measuring 1.7 × 1.7 cm. A magnetic resonance imaging of the abdomen showed a 2.5 cm neoplasm in the head/uncinated process of the pancreas resulting in moderate to severe biliary and pancreatic duct obstruction. On 06 Nov 2020 (Day 58), the subject had a gastrointestinal consultation and underwent endoscopic retrograde cholangiopancreatography and endoscopic ultrasound with biopsy (results pending), and a metallic stent was placed in the common bile duct. The subject was hospitalized to monitor for postprocedure pancreatitis. The pancreatic mass was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the pancreatic mass was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	125.7 kg	38.8 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Mellitus	Diabetes mellitus	2014	Present
Gout	Gout	2014	Present
hypertension	Hypertension	2015	Present
Cerebellar Stroke	Cerebellar stroke	2017	Past
Chronic Kidney Disease	Chronic kidney disease	2018	Present
Depression	Depression	2018	Present
Sleep Apnea	Sleep apnoea syndrome	2018	Present
glaucoma	Glaucoma	2019	Present
left frontal stroke	Cerebrovascular accident	JAN2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	12:56
2	BNT162b2	07OCT2020 (24)	15:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Gout	exacerbation of gout in shoulder	04OCT2020 (21)	08:00	ONGOING			1
2	VASC	Hypertensive urgency	hypertensive urgency	28OCT2020 (45)	22:00	05NOV2020 (53)	03:40	9	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: food and medical history	1	21	N
2	TC	Y	Resolved (05NOV2020)	NOT RELATED/OTHER: hypertension	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231166, a 42-year-old black/African American male with a pertinent medical history of diabetes mellitus (since 2014), hypertension (since 2015), cerebellar stroke (in 2017), chronic kidney disease, sleep apnea syndrome, and depression (all since 2018), glaucoma (since 2019), and cerebrovascular accident (in Jan 2019), received Dose 1 on 14 Sep 2020 and Dose 2 on 07 Oct 2020 (Day 24). The subject was diagnosed with hypertensive urgency on 28 Oct 2020, 21 days after receiving the Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the hypertensive urgency included clonidine (from 2014 to 27 Oct 2020), hydrochlorothiazide (from 2014 to 03 Nov 2020), amlodipine besilate and hydralazine hydrochloride (both from 2014 to 04 Nov 2020), labetalol hydrochloride and losartan potassium (both since 2014) for hypertension; allopurinol (from 2014 to 03 Nov 2020) for gout; acetylsalicylic acid (since 2014) and rosuvastatin calcium (since Jul 2020) for cardiovascular prevention; insulin glargine and insulin lispro (both since 2014) for diabetes; and fluoxetine hydrochloride (since 2018) for depression. On 28 Oct 2020 (Day 45), the subject with a history of poorly controlled hypertension and a history of multiple hospitalizations for hypertensive urgency went to the emergency room with chest pressure and hypertensive urgency. The subject reported that he initially experienced an episode of chest pain and shortness of breath shortly after a court hearing and stated that he was in a fight after getting robbed. Upon arrival, the subject's blood pressure had elevated at 207/106 mmHg. The subject was treated with hydralazine, in addition to multiple antihypertensive medications that he was taking previously at home. The subject was hospitalized because of the hypertensive urgency and the symptoms resolved upon arrival at the hospital. No other symptoms or laboratory findings were available to suggest hypertensive urgency. Troponins were stable and electrocardiogram (ECG) showed normal sinus rhythm, left atrium enlargement, left ventricular hypertrophy with repolarization abnormality without signs of ischemia and deepened T-wave inversions compared to previous ECG, and a stable J-point elevation in the anteroseptal loads. The subject also received verapamil 360 mg sustained release orally (PO) daily, carvedilol 25 mg PO twice a day, the dose of insulin glargine was changed to 15 U every night, and acetaminophen as needed for pain. The concomitant medications allopurinol, hydralazine hydrochloride, clonidine patch, amlodipine besilate, and labetalol hydrochloride were stopped. It was reported that blood pressures initially were very difficult to control and might have been confounded by rebound hypertension after removal of clonidine patch. The hypertensive urgency was considered resolved on 05 Nov 2020 (Day 53) and the subject was discharged from the hospital. The subject consulted the renal specialist and he continued treatment with losartan potassium with follow-up scheduled. In the opinion of the investigator, there was no reasonable possibility that the hypertensive urgency was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to hypertension. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1936	83	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	78.4 kg	27.5 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dislocated shoulder	Joint dislocation	1966	Past
atrial fibrillation	Atrial fibrillation	1998	Present
gastroesophageal reflux	Gastrooesophageal reflux disease	2001	Present
Hypertension	Hypertension	2001	Present
sleep apnea	Sleep apnoea syndrome	2012	Present
barrett's Esophagitus	Barrett's oesophagus	2017	Present
Benign Prostatic Hypertrophy	Benign prostatic hyperplasia	2017	Present
diverticulitis	Diverticulitis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	13:36
2	BNT162b2	09OCT2020 (24)	11:03

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Abscess intestinal	Pericolonic Abscess	13OCT2020 (28)	19:00	ONGOING			4	TC/TCN
2	INFEC	Diverticulitis	progression of diverticulitis	29SEP2020 (14)	13:00	ONGOING			3	TC

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: related to an underlying condition reported in Medical History	2	5	Y
2	Y	Yes	NOT RELATED/OTHER: History of diverticulitis	1	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231182, an 83-year-old white male with a pertinent medical history of gastroesophageal reflux disease (since 2001), Barrett's esophagus (since 2017), and diverticulitis (since 2019), received Dose 1 on 16 Sep 2020 and Dose 2 on 09 Oct 2020 (Day 24). The subject was diagnosed with diverticulitis on 29 Sep 2020, 13 days after receiving the Dose 1 and an intestinal abscess on 13 Oct 2020, 4 days after receiving the Dose 2. Concomitant medications reported within 2 weeks prior to the onset of diverticulitis and intestinal abscess included hydrochlorothiazide and metoprolol succinate (both since 2001) for hypertension, rosuvastatin calcium (since 2001) for hypercholesterolemia, omeprazole (since 2001) for gastroesophageal reflux disease, apixaban (since 2016) for atrial fibrillation, acetaminophen (since 03 Apr 2019) for pain, diazepam (since 01 Oct 2020) for sleep, and tamsulosin hydrochloride (since an unspecified date) for benign prostatic hyperplasia. On 29 Sep 2020 (Day 14), the subject was admitted to the hospital and a computerized tomogram scan on 30 Sep 2020 (Day 15), revealed progression of diverticulitis with perforated diverticular disease and colonic diverticulosis. There was an infiltration of the fat centered around the diverticulum along the superior margin of the proximal sigmoid colon, compatible with acute diverticulitis, numerous foci of free air were seen, indicating perforation. The subject's white blood cell count was normal. The subject was nil by mouth and treated with intravenous fluids, piperacillin/tazobactam, and heparin. After treatment, the subject's abdominal examination showed improvement with no evidence of peritonitis. The subject was then started on an oral diet and had been advanced to low residue. The subject was tolerating this well; however, he had minimal abdominal discomfort; therefore, his treatment was transitioned to oral amoxicillin/clavulanic acid from 07 Oct 2020 to 14 Oct 2020 and he was discharged home on 07 Oct 2020 (Day 22). A SARS-CoV-2 test was negative on 09 Oct 2020 (Day 24). On 10 Oct 2020 (Day 25), the subject had frequent watery diarrhea that persisted. On 13 Oct 2020 (Day 28), the subject presented to the ER with left lower quadrant abdominal pain occasionally radiating to the suprapubic area and was hospitalized. He denied fever, chills, nausea, vomiting, dysuria, chest pain, palpitations, shortness of breath, cough, or wheezing. Brain natriuretic peptide, liver function test, and lipase were normal (values not reported). His white blood cell (WBC) count was elevated at 11.23 (units and normal range not provided) with 83% neutrophils (normal range not provided). Urinalysis showed no protein, no nitrites, 2 white blood cells, and 2 red blood cells. A chest x-ray showed no obvious infiltrate or failure and computerized tomogram scan of the abdomen and pelvis showed persistent acute sigmoid diverticulitis and intestinal abscess. On 16 Oct 2020 (Day 31), the abscess enlarged despite antibiotic treatment and the subject underwent an exploratory laparotomy and drainage of the abscess. The abscess was identified on the medial aspect of the sigmoid mesentery, a large amount of purulent fluid was expressed and cultures were taken. The cavity was completely decompressed and was irrigated copiously. A Jackson-Pratt drain was then placed into the cavity and taken out through a separate stab incision. The bowel resection was performed in order to avoid the need for a colostomy. The subject tolerated the procedure well. On 20 Oct 2020 (Day 35), the abscess culture taken during surgery showed Candida glabrata and was treated with anidulafungin (since 20 Oct 2020). The subject remained hemodynamically stable with no fever and the WBC count was returning to normal. The subject was discharged. The diverticulitis and intestinal abscess were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the diverticulitis and intestinal abscess were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.2 cm	64.5 kg	23.9 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2002	Present
Renal lithiasis	Nephrolithiasis	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	12:00
2	Placebo	01SEP2020 (23)	14:00

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Injection site pain	PAIN AT INJECTION SITE	02SEP2020 (24)		02SEP2020 (24)		1	1	N	N
2	RENAL	Nephrolithiasis	Worsening of nephrolithiasis	09NOV2020 (92)	21:00	11NOV2020 (94)		3	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (02SEP2020)	Study Treatment	2	2	N
2	Resolved (11NOV2020)	NOT RELATED/OTHER: Renal lithiasis (previous renal calculus migration)	2	70	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261067, a 35-year-old white female with a pertinent medical history of nephrolithiasis (since 2017), received Dose 1 on 10 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 23). The subject was diagnosed with worsening of nephrolithiasis on 09 Nov 2020, 69 days after receiving Dose 2. On 09 Nov 2020 (Day 92), the subject experienced pain in the right iliac pit that irradiated to the lumbar region and right flank, accompanied with nausea and went to the emergency room. An abdominal computerized tomogram scan revealed impacted calculus at the bladder-ureteral junction and she was hospitalized for worsening of nephrolithiasis. The subject received tramadol 100 mg intravenously (IV) every 6 hours, metamizole sodium 1 g IV every 12 hours, and ondansetron 4 mg IV every 8 hours. The subject reported partial improvement in pain and nausea and remained hospitalized for further observation. On 10 Nov 2020 (Day 93), an ultrasound scan showed right obstructive ureterolithiasis, nephrocalcinosis right kidney. On the same day (Day 93), the subject underwent a surgical procedure for placement of a urethral tube. A SARS-CoV-2 polymerase chain reaction test performed on 10 Nov 2020 (Day 93) was negative. On 11 Nov 2020 (Day 94), the worsening of nephrolithiasis was considered resolved and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the worsening of nephrolithiasis was related to the study intervention or clinical trial procedures, but rather it was related to previous renal calculus migration. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	97.3 kg	32.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	12:28
2	Placebo	03SEP2020 (23)	09:30

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_SNAP_2MPD2_Safety_Narratives_Other_SAE_CSR/profile Date of Generation: 20NOV2020 (21:45)

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Fall	Bicycle fall	20SEP2020 (40)		20SEP2020 (40)		1
2	INJ&P	Forearm fracture	Right forearm fracture	20SEP2020 (40)	14:00	29SEP2020 (49)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	N	Resolved (20SEP2020)	NOT RELATED/OTHER: accidental cause	2	18	N
2	3	TC/TCN	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: fall bike	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261137, a 52-year-old white male with a pertinent medical history of obesity (since 2000), received Dose 1 on 12 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 23). The subject had a right forearm fracture on 20 Sep 2020, 17 days after receiving Dose 2. On 20 Sep 2020 (Day 40), the subject went to the emergency room after he fell from his bike and was evaluated by an orthopedist and an x-ray of the right arm showed right forearm fracture. The subject's arm was immobilized and an appointment was scheduled for corrective surgery. The subject was hospitalized on 28 Sep 2020 (Day 48) and underwent surgery for correction of the fracture. On 29 Sep 2020 (Day 49), the forearm fracture was considered resolved and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the forearm fracture was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.3 cm	102 kg	32.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	10:46
2	BNT162b2	10SEP2020 (23)	10:26

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Appendicitis	01OCT2020 (44)		03OCT2020 (46)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (03OCT2020)	NOT RELATED/OTHER: cause: alimentary	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261282, a 35-year-old white male with a pertinent medical history of obesity (since 2012), received Dose 1 on 19 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 23). The subject was diagnosed with appendicitis on 01 Oct 2020, 21 days after receiving Dose 2. On 01 Oct 2020 (Day 44), the subject experienced abdominal pain, nausea, and vomiting and he self-treated with ciprofloxacin 400 mg 1 tablet twice a day and ketoprofen 100 mg 1 tablet once daily for infection and pain prophylaxis. When the symptoms worsened despite treatment, he went to the hospital. On admission, a computerized tomogram of the abdomen was performed; however, the results were unknown. On the same day (Day 44), the subject underwent surgery for appendicitis. On 03 Oct 2020 (Day 46), the appendicitis was considered resolved and the subject was discharged from the hospital. On 05 Oct 2020 (Day 48), a histopathology report showed acute gangrenous appendicitis, extensive in mesoappendix, and suppurative inflammatory in the surgical margin. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	92.3 kg	30.1 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2000	Present
Vasectomy	Vasectomy	2015	Past
renal lithiasis	Nephrolithiasis	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	09:39
2	BNT162b2	11SEP2020 (23)	08:44

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Conjunctivitis	Conjunctivitis	01SEP2020 (13)		07SEP2020 (19)		7	1
2	RENAL	Renal colic	Renal colic	29AUG2020 (10)	05:00	30AUG2020 (11)	12:00	2	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (07SEP2020)	NOT RELATED/OTHER: possible cause: bacterial	1	13	N
2	TC/TCN	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: Renal lithiasis	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261300, a 44-year-old white male with a pertinent medical history of nephrolithiasis (since Apr 2020), received Dose 1 on 20 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 23). The subject was diagnosed with renal colic on 29 Aug 2020, 9 days after receiving Dose 1. On 01 Sep 2020 (Day 13), the subject informed the site that he was hospitalized on 29 Aug 2020 (Day 10) because of renal colic. The subject received hyoscine butylbromide/metamizole sodium, L-escopolamine/metamizole sodium 1 tablet orally once daily on 29 Aug 2020 and tramadol 100 mg intravenously as needed from 29 Aug 2020 to 30 Aug 2020 during hospitalization. On 30 Aug 2020 (Day 11), an endoscopic uretero lithotripsy was performed and the renal colic was considered resolved; the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the renal colic was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	68.8 kg	24.1 kg/m2	05SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05SEP2020 (1)	15:08
2	BNT162b2	25SEP2020 (21)	09:15

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Cervical vertebral fracture	Fracture of the fourth cervical vertebra	21OCT2020 (47)		30OCT2020 (56)		10
2	INJ&P	Contusion	Bruises in various regions of the body	21OCT2020 (47)		30OCT2020 (56)		10
3	INJ&P	Road traffic accident	hit by motorcycle	21OCT2020 (47)	18:00	21OCT2020 (47)		1
4	INJ&P	Skin abrasion	Excoriations in various regions of the body	21OCT2020 (47)		30OCT2020 (56)		10
5	INJ&P	Spinal cord injury cervical	Cervical spinal cord contusion	21OCT2020 (47)		30OCT2020 (56)		10
6	NERV	Subarachnoid haemorrhage	Subarachnoid hemorrhage	21OCT2020 (47)		30OCT2020 (56)		10
7	RENAL	Subcapsular renal haematoma	Peri-renal hematoma	21OCT2020 (47)		30OCT2020 (56)		10

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
2	2	TC	N	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	N
3	3	N	Y	Resolved (21OCT2020)	NOT RELATED/OTHER: accidental	2	27	Y
4	2	TC	N	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	N
5	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
6	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
7	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261571, a 45-year-old white male with no reported medical history, received Dose 1 on 05 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 21). The subject reported a road traffic accident resulting in cervical vertebral fracture (fracture of the fourth cervical vertebra), cervical spinal cord injury, subarachnoid hemorrhage, and subcapsular renal hematoma on 21 Oct 2020, 26 days after receiving Dose 2. On 21 Oct 2020 (Day 47), the subject was hit by a motorcycle while he was crossing the street, resulting in contusions (bruises in various regions of the body), skin abrasions (excoriations in various regions of the body), cervical vertebral fracture (fracture of the fourth cervical vertebra), cervical spinal cord injury, subarachnoid hemorrhage, and subcapsular renal hematoma. The subject was taken to the emergency room and hospitalized in the intensive care unit on the same day. No surgery was performed. The subject was treated with the following medications from 21 Oct 2020 to 30 Oct 2020: intravenous (IV) dexmedetomidine, IV midazolam, IV haloperidol, IV metamizole sodium, quetiapine 25 mg orally, and IV tramadol, all for subarachnoid hemorrhage, peri-renal hematoma, fracture of the fourth cervical vertebra and cervical spinal cord contusion; and enoxaparin sodium 40 mg subcutaneously for deep vein thrombosis prophylaxis. The subject recovered from the contusions, skin abrasions, fracture of the fourth cervical vertebra, cervical spinal cord injury, subarachnoid hemorrhage, and subcapsular renal hematoma on 30 Oct 2020 (Day 56), and was discharged from the hospital on the same day. A SARS-CoV-2 test was negative during hospitalization. In the opinion of the investigator, there was no reasonable possibility that the road traffic accident, cervical vertebral fracture, cervical spinal cord injury, subarachnoid hemorrhage, and subcapsular renal hematoma were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	61.3 kg	21.7 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	11:33
2	BNT162b2	06OCT2020 (21)	10:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Leydig cell tumour of the testis	Leydig cell tumor in left testicle	23SEP2020 (8)		07OCT2020 (22)		15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: unknown cause	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261745, a 34-year-old white male with no pertinent medical history, received Dose 1 on 16 Sep 2020 and Dose 2 on 06 Oct 2020 (Day 21). The subject was diagnosed with Leydig cell tumor in the left testicle on 23 Sep 2020, 7 days after receiving Dose 1. On 23 Sep 2020 (Day 8), the subject was diagnosed with Leydig cell tumor of the testis, resulting in hospitalization on 06 Oct 2020 (Day 21) and underwent surgery the following day on 07 Oct 2020 (Day 22). Biopsy and pathological anatomy showed Leydig cell tumor measuring in size about 1.8 × 1.8 × 1.6 cm and tumor free margins. On 07 Oct 2020 (Day 22), the Leydig cell tumor of the testis was considered resolved, and the subject was discharged from the hospital without complications. A COVID-19 test was not done. In the opinion of the investigator, there was no reasonable possibility that the Leydig cell tumor of the testis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	49	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
150.3 cm	83.3 kg	36.9 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	2015	Present
low back pain	Back pain	2018	Present
Hysterectomy	Hysterectomy	FEB2019	Past
Perforation of the uterus by IUD	Uterine perforation	FEB2019	Past
Obesity	Obesity	MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17SEP2020 (1)	10:04
2	BNT162b2	07OCT2020 (21)	10:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Idiopathic intracranial hypertension	idiopathic intracranial hypertension	22OCT2020 (36)		30OCT2020 (44)		9	3
2	GENRL	Injection site pruritus	Pruridus at the injection site	17SEP2020 (1)	18:15	20SEP2020 (4)		4	1
3	INFEC	Postoperative wound infection	surgical site infection	03NOV2020 (48)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: idiopathic	2	16	Y
2	N	N	Resolved (20SEP2020)	Study Treatment	1	1	N
3	TC	Y	Yes	NOT RELATED/OTHER: peritoneal loin shunt	2	28	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261769, a 49-year-old white female with a pertinent medical history of obesity (since Mar 2019), received Dose 1 on 17 Sep 2020 and Dose 2 on 07 Oct 2020 (Day 21). The subject developed idiopathic intracranial hypertension on 22 Oct 2020, 15 days after receiving Dose 2 and a postoperative wound infection on 03 Nov 2020, 27 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the idiopathic intracranial hypertension and postoperative wound infection included duloxetine (since Jun 2020) for fibromyalgia. On 22 Oct 2020 (Day 36), the subject presented to the emergency room with severe headache, vomiting, and difficulty with speech and was hospitalized. Magnetic resonance imaging and magnetic resonance angiogram of the brain showed mild global accentuation of the cortical grooves and intracranial fissures; compensatory ectasia of the supratentorial ventricular system. The cerebrospinal fluid (CSF) analysis showed opening pressure of 35 cm H2O, proteins of 27, glucose of 87, blood cells of 90, and lactate of 13 (units and normal ranges not reported); and the CSF culture was negative. While in the hospital, the subject underwent a lumbo-peritoneal shunt. On 30 Oct 2020 (Day 44), the idiopathic intracranial hypertension resolved, and the subject was discharged from the hospital on the same day. A SARS-CoV-2 testing was not reported. On 05 Nov 2020 (Day 50), the subject reported that she had abdominal distension and headache on 03 Nov 2020 (Day 48) and sought emergency care on the same day. It was reported that abdominal distension and headache were symptoms of the surgical site infection (located at the wound site in the lumbar region) from the prior hospitalization. CSF analysis was obtained (results pending). Later, on 04 Nov 2020 (Day 49), the subject was hospitalized because of postoperative wound infection. The subject's symptoms were improving after treatment with intravenous Rocephin (ceftriaxone) 1 g twice a day. As of 10 Nov 2020 (Day 55), the subject remained hospitalized, and the postoperative wound infection was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the idiopathic intracranial hypertension and postoperative wound infection were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	Multiple	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	56 kg	21.6 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral tubal ligation	Female sterilisation	2006	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06OCT2020 (1)	11:40
2	BNT162b2	06NOV2020 (32)	10:16

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Urinary tract infection	Urinary tract infection	18OCT2020 (13)	06:00	22OCT2020 (17)		5

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: urinary infection	1	13	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12262089, a 45-year-old multiracial female with no pertinent medical history, received Dose 1 on 06 Oct 2020 and Dose 2 on 06 Nov 2020 (Day 32). The subject experienced symptoms of a urinary tract infection from 18 Oct 2020, 12 days after receiving Dose 1, which was confirmed after hospitalization on 20 Oct 2020 (Day 15). On 20 Oct 2020 (Day 15), the subject attended the emergency room with symptoms of abdominal pain and dysuria, and was hospitalized. On the same day (Day 15), urine culture showed Escherichia coli (100000 UFC/mL) and urinalysis showed protein ++, nitrite +, hemoglobin ++++, bacteria, red blood cell count of 150000/mL (normal range [NR]: until 10000/mL), and leukocytes of >900000/mL (NR: until 10000/mL). The following day (Day 16) further lab results showed a C-reactive protein of 18.3 mg/L (NR: <5 mg/L);and an ultrasound of the urinary tract showed signs of cystitis. The subject was treated with intravenous ceftriaxone (from 20 Oct 2020 to 22 Oct 2020). On 22 Oct 2020 (Day 17), the urinary tract infection resolved, and the subject was discharged from the hospital. A SARS-CoV-2 reverse transcription polymerase chain reaction test performed on the same day (Day 17) was negative. In the opinion of the investigator, there was no reasonable possibility that the urinary tract infection was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.8 cm	73.2 kg	26.6 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Menopause	Menopause	1993	Present
hypothyroidism	Hypothyroidism	OCT1999	Present
Diabetes mellitus type 2	Type 2 diabetes mellitus	OCT2000	Present
Systemic arterial hypertension	Hypertension	OCT2005	Present
Fracture of left femur	Femur fracture	NOV2019	Past
Osteoporosis	Osteoporosis	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	12:10

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Fall	fall from own height	24OCT2020 (9)		24OCT2020 (9)		1	1	N	N
2	INJ&P	Femur fracture	Fracture of the right femur	24OCT2020 (9)		29OCT2020 (14)		6	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (24OCT2020)	NOT RELATED/OTHER: was knocked down on the street by a dog	1	9	N
2	Resolved (29OCT2020)	NOT RELATED/OTHER: Accidental cause: patient fell after being knocked over by a dog	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12262240, a 76-year-old white female with a pertinent medical history of hypothyroidism (since Oct 1999), type 2 diabetes mellitus (since Oct 2000), hypertension (since Oct 2005), osteoporosis (since Nov 2019), and left femur fracture (from Nov 2019 to Feb 2020), received Dose 1 on 16 Oct 2020. The subject was diagnosed with a right femoral fracture on 24 Oct 2020, 8 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the femoral fracture included levothyroxine sodium (since Oct 1999) for hypothyroidism, metformin (since Oct 2000) and gliclazide (since Oct 2015) for type 2 diabetes mellitus, and losartan (since Oct 2005) for systemic arterial hypertension. On 24 Oct 2020 (Day 9), the subject fell after being knocked down by a dog, and sustained a right femoral fracture. On the same day (Day 9), the subject was hospitalized and underwent a surgery for the fracture on 27 Oct 2020 (Day 12). She was discharged from the hospital on 29 Oct 2020 (Day 14). In the opinion of the investigator, there was no reasonable possibility that the femoral fracture was related to the study intervention, concomitant medications, or clinical trial procedures, but rather, was related to the fall after being knocked down by a dog. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	76.4 kg	24.9 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1960	Past
Inguinal Hernia Repair	Inguinal hernia repair	1995	Past
Inguinal Hernia Repair	Inguinal hernia repair	2005	Past
Hypertension	Hypertension	2007	Present
Bilateral lens replacement	Intraocular lens implant	2010	Past
Gastric Carcinoma	Gastric cancer	OCT2014	Past
Laparotomy for tumour excision	Abdominal operation	27OCT2014	Past
Chemotherapy	Chemotherapy	FEB2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	11:21
2	BNT162b2	16OCT2020 (22)	12:02

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Penile neoplasm	Penile Intra Epithelial Neoplasia	06NOV2020 (43)	16:24	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Neoplasia	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	13NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1230 12301025, a 74-year-old white male with a pertinent medical history of hypertension (since 2007) and gastric cancer (in Oct 2014) for which he underwent a laparotomy for excision of the tumor (on 27 Oct 2014), and chemotherapy (in Feb 2015). The subject received Dose 1 on 25 Sep 2020 and Dose 2 on 16 Oct 2020 (Day 22), and was diagnosed with a penile neoplasm on 06 Nov 2020, 21 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the diagnosis of penile neoplasm included hydrochlorothiazide (since 2007) for hypertension. On 13 Nov 2020 (Day 50), during Visit 3, the subject informed the investigator about the diagnosis of the penile neoplasm, which the investigator considered to be an important medical event. A histology report dated 06 Nov 2020 (Day 43), confirmed high grade penile intraepithelial neoplasia. The penile neoplasm was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the penile neoplasm was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	54.5 kg	23 kg/m2	14AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	12:55
2	Placebo	03SEP2020 (21)	09:23

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Ulna fracture	Left arm olecranon fracture	17SEP2020 (35)	20:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Car crash	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311205, a 29-year-old white female with no reported medical history, received Dose 1 on 14 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 21). The subject was diagnosed with left arm olecranon fracture on 17 Sep 2020, 14 days after receiving Dose 2. On 17 Sep 2020 (Day 35), the subject was involved in a car accident (as a passenger), and was brought to the emergency room, where she was diagnosed with fracture of her left olecranon and a cast was applied to her left elbow. On 23 Sep 2020 (Day 41), the subject was hospitalized and underwent an unspecified orthopedic surgical procedure. The subject was discharged from the hospital on 24 Sep 2020 (Day 42). A second surgery was planned based on her evolution, and on 13 Nov 2020 (Day 92), the subject reported that she was feeling well, without any complications. The left arm olecranon fracture was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the left arm olecranon fracture was related to the study intervention or clinical trial procedures but rather was related to the car accident. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	19	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	69.2 kg	23.9 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	11:10
2	BNT162b2	04SEP2020 (21)	10:45

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	acute appendicitis	18SEP2020 (35)	09:00	06OCT2020 (53)	15:00	19
2	INV	Electrocardiogram QT prolonged	QT interval prolongation	18SEP2020 (35)	14:00	18SEP2020 (35)	20:00	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: unknown	2	15	Y
2	1	N	N	Resolved (18SEP2020)	NOT RELATED/OTHER: Unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311281, a 19-year-old white female with no reported medical history, received Dose 1 on 15 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 21). The subject was diagnosed with appendicitis on 18 Sep 2020, 14 days after receiving Dose 2. On 18 Sep 2020 (Day 35), the subject experienced abdominal pain and nausea, she self-prescribed pargeverine 1 mg and pantoprazole (dose unknown). After 3 hours of persistent symptoms, she visited the emergency room. Laboratory test results showed a white blood cell count of 14980 cells/mL and neutrophils of 79% (normal ranges not reported), and an abdominal ultrasound showed an inflammatory process in the right lower quadrant; an electrocardiogram showed sinus rhythm and prolonged QT (QTc: 531 mms; which was recorded as a nonserious adverse event), and a chest x-ray was unremarkable. The subject was diagnosed with acute appendicitis and hospitalized, she underwent an appendectomy on the same day (Day 35) and was treated with unspecified intravenous antibiotics. On 19 Sep 2020 (Day 36), the subject was discharged from the hospital on oral ciprofloxacin 500 mg twice a day and metronidazole 500 mg 3 times a day for 7 days. The pathology report from 22 Sep 2020 (Day 39) showed a resected cecal appendix. The appendicitis resolved on 06 Oct 2020 (Day 53). At an ambulatory follow-up on 07 Oct 2020 (Day 54), the subject was asymptomatic. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	70.8 kg	25.1 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	12:47
2	BNT162b2	03SEP2020 (20)	10:42

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Anaemia	anemia	25SEP2020 (42)	08:00	ONGOING			2
2	NEOPL	Malignant melanoma	Pigmented ephitelioid melanoma of the vagina	25SEP2020 (42)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: probable relationship with vaginal tumor under study	2	23	N
2	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311315, a 41-year-old white female with no reported medical history, received Dose 1 on 15 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 20). The subject was diagnosed with pigmented epithelioid melanoma of the vagina (malignant melanoma) on 25 Sep 2020, 22 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the malignant melanoma included drospirenone/ethinylestradiol (since 13 Aug 2020) for contraception. The subject presented to her gynecologist complaining of genital bleeding on 25 Sep 2020 (Day 42). A pelvic examination revealed a tumoral lesion in the right lateral wall of the vagina and a magnetic resonance imaging scan performed the same day, revealed; a vegetating lesion at third medium level of the posterior and right lateral wall of the vagina, which comprised of all wall layers and extended to the adjacent fat tissue. The subject was also found to have anemia (hemoglobin value not available). On 06 Oct 2020 (Day 53), the subject was admitted to the hospital for gynecological exploratory surgery, she underwent a partial colpectomy and biopsy samples were taken. The histopathological report showed pigmented epithelioid melanoma of the vagina measuring 40 × 30 × 16 mm that involved all the layers of the miocervix wall infiltrating the resection borders,. The subject was discharged from the hospital on 07 Oct 2020 (Day 54). On 27 Oct 2020 (Day 74), a positron emission tomogram/computed tomography report showed nodular image with hypodense center and mild hyper metabolism in the left pelvic obturator region and a non-hypermetabolic nodule measuring 3.8 mm in the posterior basal segment of the inferior left lung. Both the malignant melanoma and anemia were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the malignant melanoma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	86.25 kg	33.3 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	14:55
2	Placebo	04SEP2020 (21)	16:20

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Influenza like illness	Flu like syndrome	20AUG2020 (6)	20:00	22AUG2020 (8)	00:00	3
2	INFEC	Urinary tract infection	high urinary infection	20AUG2020 (6)	10:00	29OCT2020 (76)	08:00	71
3	GASTR	Vomiting	Vomiting	29AUG2020 (15)	08:30	01SEP2020 (18)	23:00	4

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	N	Y	Resolved (22AUG2020)	NOT RELATED/OTHER: unknown	1	6	Y
2	2	TC	N	Resolved (29OCT2020)	NOT RELATED/OTHER: unknown	1	6	N
3	1	N	N	Resolved (01SEP2020)	NOT RELATED/OTHER: unknown	1	15	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311352, a 45-year-old white female with no pertinent medical history, received Dose 1 on 15 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 21). The subject experienced an influenza-like illness on 20 Aug 2020, 5 days after receiving Dose 1. On the night of 20 Aug 2020 (Day 6), the subject experienced malaise, muscular pain, dry cough, fatigue, and had a temperature of 39.2ºC. She visited the emergency room on 21 Aug 2020 (Day 7), because of these flu-like symptoms and was hospitalized. During the hospitalization, a SARS-CoV-2 test was negative. On 22 Aug 2020 (Day 8), the subject reported via telephone that she was discharged after 1 day of hospitalization because of clinical improvement; the discharge diagnosis was flu syndrome and she did not receive any medications during the hospitalization. The influenza-like illness was reported as resolved on 22 Aug 2020 (Day 8). On 24 Aug 2020 (Day 10), the subject reported via telephone that she was feeling better except for an occasional dry cough. On 28 Aug 2020 (Day 14), the subject was contacted again and she reported that she was feeling better, but had a mild occasional dry cough treated with bromhexine 16 mg as needed. A urinary tract infection (reported as nonserious adverse event), also started simultaneously on 20 Aug 2020 (Day 6) and resolved on 29 Oct 2020 (Day 76). In the opinion of the investigator, there was no reasonable possibility that the influenza-like illness was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	68.6 kg	24.6 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16AUG2020 (1)	14:36
2	BNT162b2	07SEP2020 (23)	13:47

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GASTR	Gastritis	Acute gastritis	17OCT2020 (63)	10:00	03NOV2020 (80)	10:00	18
2	INJ&P	Hand fracture	closed fracture first phalanx right little finger	14SEP2020 (30)	19:30	15OCT2020 (61)	11:57	32

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown	2	41	Y
2	1	TC/TCN	N	Resolved (15OCT2020)	NOT RELATED/OTHER: hit with a clay pot	2	8	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311579, a 68-year-old white male with no reported medical history, received Dose 1 on 16 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 23). The subject reported gastritis on 17 Oct 2020, 40 days after receiving Dose 2. On 17 Oct 2020 (Day 63), the subject experienced diffuse colicky abdominal pain, for which he took propinox 10 mg 3 times a day (TID) and followed a bland and astringent diet. The pain persisted until 21 Oct 2020 (Day 67), his physician prescribed omeprazole 20 mg once daily (QD) and trimebutine 200 mg plus simethicone 120 mg TID. On 25 Oct 2020 (Day 71), the subject visited the emergency room because of worsening pain and was hospitalized for further investigation and treatment of acute gastritis. A blood test (on 25 Oct 2020 [Day 71]), abdominal ultrasound (on 26 Oct 2020 [Day 72]), and computed tomography of the abdomen and pelvis (on an unspecified date) were all unremarkable; and an acute surgical inflammatory process was ruled out. The subject was treated with scopolamine butylbromide 20 mg intravenously (IV) and ranitidine 50 mg IV. On 27 Oct 2020 (Day 73), the subject was discharged from the hospital on omeprazole 20 mg QD and gastroenterology follow-up. On 28 Oct 2020 (Day 74), the subject was feeling well and attended his follow-up with the gastroenterologist. A colonoscopy was performed; however, the result was pending. The subject's condition was stable and the gastritis resolved on 03 Nov 2020 (Day 80), all treatment was discontinued. In the opinion of the investigator, there was no reasonable possibility that the gastritis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	63.5 kg	23.6 kg/m2	17AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	11:10
2	Placebo	07SEP2020 (22)	12:45

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Urosepsis	Urosepsis	15SEP2020 (30)	16:00	22SEP2020 (37)	17:00	8

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (22SEP2020)	NOT RELATED/OTHER: unknown	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311711, a 52-year-old white male with no reported medical history, received Dose 1 on 17 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 22). The subject was diagnosed with urosepsis on 15 Sep 2020, 8 days after receiving Dose 2. On 17 Sep 2020 (Day 32), the subject contacted the study emergency number and informed that he had been admitted to hospital due to suspected COVID-19 disease. The subject had a history of 36 hours (onset date 15 Sep 2020 [Day 30]) of malaise, dry cough (neither were considered severe) and a body temperature of 37.8ºC and decided to attend the emergency room. In the context of the SARS-CoV-2 pandemic, the physician requested a SARS-CoV-2 reverse transcription polymerase chain reaction test, blood panel, chest x-ray (CXR), and a computerized tomography (CT) scan. The subject remained in-house in isolation to rule out COVID-19, he remained eupneic and with normal oxygen saturation. It was further reported that on the same day (Day 32), during the hospitalization, the subject developed a low fever of 38.2 (T max), with dysuria and pollakiuria. For this reason, a blood sample and a urine sample were taken for hemoculture and urine culture tests. On the same day (Day 32), empiric intravenous antibiotic treatment was prescribed: ceftriaxone and vancomycin, both at unknown doses, as sepsis was suspected (focus unidentified). Diagnostic investigation results received on 18 Sep 2020 (Day 33) revealed: a SARS-CoV-2 swab test was negative, white blood cell count was 20000 cells/mL, neutrophil count was 78.7%, and lymphocyte count was 11.6% (normal ranges not reported); blood and urine cultures had no bacterial growth up to that point; a chest CT scan and CXR results were unremarkable. On 18 Sep 2020 (Day 33), a CT of the abdomen and pelvis was unremarkable. On the same day (Day 33), the subject was afebrile, had normal breathing with no additional oxygen support, and a persistent dry cough. Urinary sepsis was suspected and treatment with ceftriaxone was continued whilst vancomycin was discontinued. On 21 Sep 2020 (Day 36), the subject remained asymptomatic and responded well to the treatment. On 22 Sep 2020 (Day 37), the urosepsis resolved and the subject was discharged from the hospital. On 07 Oct 2020 (Day 52), the sub-investigator received the subject's hospital discharge summary that confirmed negative blood and urine cultures and a diagnosis of sepsis (probably urinary focus). In the opinion of the investigator, there was no reasonable possibility that the urosepsis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	99.5 kg	40.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
laparoscopic cholecystectomy	Cholecystectomy	APR2011	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	13:39
2	BNT162b2	07SEP2020 (22)	16:35

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Biliary colic	biliary colic	30OCT2020 (75)	19:00	03NOV2020 (79)	11:00	5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown	2	54	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12311766, a 44-year-old white female with a medical history of laparoscopic cholecystectomy (on 01 Apr 2011), received Dose 1 on 17 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 22). The subject was diagnosed with biliary colic on 30 Oct 2020, 53 days after receiving Dose 2.

On 30 Oct 2020 (Day 75), at 1900 hours, the subject experienced moderate colicky abdominal pain, this worsened the following day (31 Oct 2020 [Day 76]) and was associated with vomiting, which led the subject to attend hospital. She remained under observation until 04:00 AM on 01 Nov 2020 (Day 77) when she was transferred to another hospital for surgery. On an unknown date, a blood test and an image study under intravenous contrast were performed; however, the results were unknown. The subject reported that she was feeling better and her abdominal pain had completely subsided on 02 Nov 2020 (Day 78), at 2000 hours, and she discharged herself against medical advice on 03 Nov 2020 (Day 79). It was considered that the biliary colic had completely resolved on 03 Nov 2020 (Day 79). The site did not have the hospital discharge summary or any results at the time of this report.

In the opinion of the investigator, there was no reasonable possibility that the biliary colic was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	78.85 kg	26.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Colon Cancer	Colon cancer	03APR2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	17:46
2	Placebo	07SEP2020 (22)	14:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Foot fracture	Hallux fracture and second toe of the right foot	16SEP2020 (31)	08:00	20OCT2020 (65)	19:00	35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (20OCT2020)	NOT RELATED/OTHER: work accident	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311834, a 55-year-old white male with no pertinent medical history, received Dose 1 on 17 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 22). The subject was diagnosed with a right foot fracture (hallux fracture and second toe of the right foot) on 16 Sep 2020, 9 days after receiving Dose 2. On 16 Sep 2020 (Day 31), the subject had an accident at work and was taken to the trauma center, where x-ray of the right foot showed a fracture of the hallux and second toe, which was considered to be an important medical event by the investigator. The wound was sutured, and the subject was prescribed oral ketorolac 10 mg three times a day and cefalexin 1 g 4 times a day for a week. On 21 Sep 2020 (Day 36), an outpatient surgery for reconstruction of the hallux and second toe of the right foot with placement of nails was performed and the subject was discharged home on the same day with a walker boot and analgesics. On 07 Oct 2020 (Day 52), the subject had an orthopedic consultation and x-rays of the right foot were performed, but the results were unknown. On 20 Oct 2020 (Day 65), the subject underwent surgery for nail removal without complications and the foot fracture was considered resolved. On 13 Nov 2020 (Day 89), the subject reported that he was feeling well and was doing therapeutic exercises. In the opinion of the investigator, there was no reasonable possibility that the foot fracture was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	27	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	70 kg	24.2 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	01JUL2000	Present
Diabetes type 1	Type 1 diabetes mellitus	01JUL2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	18:10
2	Placebo	07SEP2020 (22)	14:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Hypoglycaemia	severe hipoglycemia	16OCT2020 (61)	15:30	16OCT2020 (61)	15:35	1
2	NERV	Seizure	seizure	16OCT2020 (61)	15:30	16OCT2020 (61)	15:35	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (16OCT2020)	NOT RELATED/OTHER: Diabetes type 1	2	40	Y
2	3	N	N	Resolved (16OCT2020)	NOT RELATED/OTHER: hypoglycemia	2	40	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311844, a 27-year-old white female with a pertinent medical history of hypothyroidism (since 01 Jul 2000) and type 1 diabetes mellitus (since 01 Jul 2011), received Dose 1 on 17 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 22). The subject experienced hypoglycemia on 16 Oct 2020, 39 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the hypoglycemia included levothyroxine sodium (since 01 Aug 2000) for hypothyroidism, and insulin glargine (32 IU subcutaneously [SC] once daily [QD] since 01 Jul 2011) and insulin aspart (15 IU SC QD, since 17 Aug 2011) for type 1 diabetes mellitus. On 17 Oct 2020 (Day 62), the subject informed the site that she had an episode of severe hypoglycemia on 16 Oct 2020 (Day 61), and was found unconscious and having seizures (type unknown) by her mother. The seizures lasted for about 5 minutes, but the subject did not require a visit to the emergency room or the physician's office. The symptoms improved when the subject was given a soda. The hypoglycemic episode was considered to be medically significant by the investigator. The subject confirmed that she contacted her diabetologist after the episode, and her insulin doses were reduced. The episode resolved on the same day, and the subject reported that there were no further episodes of hypoglycemia as of 17 Oct 2020 (Day 62). In the opinion of the investigator, there was no reasonable possibility that the hypoglycemia was related to the study intervention or clinical trial procedures; but rather it was related to concomitant medications (insulin glargine and insulin aspart) for pre-existing diabetes mellitus. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	68 kg	24.1 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arterial hypertension	Hypertension	02JUL2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	12:19
2	Placebo	08SEP2020 (22)	14:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Syncope	Syncope	11SEP2020 (25)	10:00	12SEP2020 (26)	15:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (12SEP2020)	NOT RELATED/OTHER: unknown	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311946, a 68-year-old white male with a pertinent medical history of hypertension (since 02 Jul 2002), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject experienced syncope on 11 Sep 2020, 3 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the syncope included hydrochlorothiazide/valsartan (since 03 Mar 2010), amlodipine (since 02 Nov 2011), alprazolam (since 08 Nov 2017), and nebivolol (since 01 Feb 2020) all for arterial hypertension. On 11 Sep 2020 (Day 25), the subject had a transient loss of consciousness while he was working, which lasted for a minute or 2 and had no associated symptoms such as physical movements or bladder or bowel incontinence. His recovery was complete and rapid; however, the cause of syncope was unknown. The subject visited the emergency room and his systolic blood pressure was 190 mmHg and diastolic blood pressure was unknown. The subject was treated with enalapril (unknown dose) and was referred to a private clinic where an electrocardiogram (ECG) and vital signs were assessed as normal (as per subject). The subject was referred to another clinic where he was hospitalized for further evaluation. The subject underwent diagnostic tests and a complete blood work-up, which were all within normal ranges. His troponin T-ultra-sensitive was at 9.27 pg/mL (normal range: 3-14 pg/mL), chest x-ray, brain computed tomography scan, echocardiogram, and ECG were unremarkable. Additionally, during the hospitalization, the subject had a cardiology consultation and no further actions were indicated. During the subject's hospital stay, a COVID-19 test was not performed. On 12 Sep 2020 (Day 26), the syncope resolved and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	110 kg	38.1 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	17:56
2	BNT162b2	09SEP2020 (22)	10:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Osteochondritis	Osteochondritis	05SEP2020 (18)	12:00	06SEP2020 (19)	13:31	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	Y	Resolved (06SEP2020)	NOT RELATED/OTHER: unknown	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312390, a 25-year-old white female with no reported medical history, received Dose 1 on 19 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 22). The subject was diagnosed with osteochondritis on 05 Sep 2020, 17 days after receiving Dose 1. On 06 Sep 2020 (Day 19), the subject informed the site that she began experiencing chest pain (unspecified) on 05 Sep 2020 (Day 18). She went to the emergency room on the same day (Day 18), and was hospitalized for further evaluation. The treating physician stated that the following tests were performed: "on 05 Sep 2020, a SARS-CoV-2 test was negative, her cardiac troponin results were unknown but were negative for ischemia, a chest computerized tomogram (CT) was normal and a CT angiography for pulmonary embolism was negative for embolism". On an unspecified date, her electrocardiography was negative for ischemia. On physical examination, the subject had localized costochondral tenderness, and a final diagnosis of osteochondritis was made. On 06 Sep 2020 (Day 19), the osteochondritis resolved, and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the osteochondritis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	59.5 kg	23.2 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	14:05
2	Placebo	09SEP2020 (21)	14:05

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	HEPAT	Cholelithiasis	Gallstones	06NOV2020 (79)	08:00	08NOV2020 (81)	13:30	3	1
2	RENAL	Hydronephrosis	Right hydronephrosis	05NOV2020 (78)	20:30	ONGOING			2
3	RENAL	Renal colic	Renal colic	20OCT2020 (62)	10:00	20OCT2020 (62)	12:00	1	2
4	RENAL	Renal colic	Renal colic	05NOV2020 (78)	20:30	ONGOING			3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (08NOV2020)	NOT RELATED/OTHER: Unknown	2	59	N
2	TC	N	Yes	NOT RELATED/OTHER: Renal colic	2	58	N
3	TC	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Unknown	2	42	N
4	TC	Y	Yes	NOT RELATED/OTHER: Renal colic in october 2020.	2	58	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312576, a 24-year-old white female with no reported medical history, received Dose 1 on 20 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 21). The subject was diagnosed with nephrolithiasis (also reported as renal colic) on 05 Nov 2020, 57 days after receiving Dose 2. On 05 Nov 2020 (Day 78), the subject experienced right lumbar colicky pain radiating to the right flank and visited her physician's office, who prescribed intramuscular diclofenac and ketorolac (doses unknown). On the same day (Day 78), the subject presented to the emergency room as the pain did not subside and was subsequently hospitalized for pain control and further diagnosis. It was reported that the subject had renal colic previously on 20 Oct 2020 (Day 62), which had resolved on the same day. During the hospitalization, a chest-x-ray performed on 05 Nov 2020 (Day 78) was unremarkable. On 06 Nov 2020 (Day 79), the blood test results were within normal limits and an ultrasound of the abdomen/kidney showed mild right uronephrosis and an 11 mm stone in the gallbladder (reported as cholelithiasis, a nonserious adverse event). A computed tomography of the abdomen on an unspecified date showed renal colic secondary to nephrolithiasis, and the subject underwent cystoscopy and a double-J stent was placed in the right ureter. The subject's condition improved, and she was discharged from the hospital on 07 Nov 2020 (Day 80) with the following medications; cephalexin 1 g, 3 times a day (TID) for 7 days, omeprazole 20 mg TID, and acetaminophen 500 mg TID. The cholelithiasis resolved on 08 Nov 2020 (Day 81). On 09 Nov 2020 (Day 82), the subject was readmitted to the hospital because of renal colic. During this hospitalization, the subject was treated with intravenous diclofenac 50 mg TID. A repeat renal ultrasound scan was performed but the results were unknown. Laboratory test results on Day 82 were unremarkable. A urine culture (unspecified date) was negative. An ureteroscopy was scheduled on 12 Nov 2020 (Day 85) and the laboratory test results on Day 85 were also unremarkable. The subject was discharged on 12 Nov 2020 (Day 85). The nephrolithiasis and right hydronephrosis were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the nephrolithiasis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184 cm	119.45 kg	35.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	09APR2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:15
2	BNT162b2	11SEP2020 (23)	18:25

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute coronary syndrome	Acute coronary syndrome without ST-T segment elevation	16SEP2020 (28)	09:15	19SEP2020 (31)	14:00	4	2
2	CARD	Bundle branch block right	right bundle branch block	16SEP2020 (28)	15:20	19SEP2020 (31)	14:00	4	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown	2	6	Y
2	N	N	Resolved (19SEP2020)	NOT RELATED/OTHER: Acute coronary syndrome	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312593, a 43-year-old white male with a pertinent medical history of obesity (since 09 Apr 2002), and stress and insomnia (both since unspecified dates), received Dose 1 on 20 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 23). The subject was diagnosed with acute coronary syndrome without ST-T segment elevation, on 16 Sep 2020, 5 days after receiving Dose 2. The subject's baseline body mass index was 35.3 kg/m2. On 16 Sep 2020 (Day 28), the subject presented to the emergency room with chest pain that started from 09:15 AM, and was hospitalized for further evaluation and treatment. Upon admission, the subject denied any medical history of arterial hypertension, dyslipidemia, diabetes, or smoking. An electrocardiogram revealed complete right bundle bunch block with no ST-T segment elevation and sinus rhythm. A Doppler echocardiography of the left ventricle (LV) showed normal segmental wall motion, ejection fraction of 69%, pulmonary systolic pressure of 20 mmHg and LV low distensibility. The subject's laboratory test results showed elevated and upward trend of cardiac biomarkers (serum troponin ultra-sensitive T) at 34 pg/mL, 47 pg /mL, and 158 pg/mL (time and normal ranges not reported). A chest x-ray was unremarkable and other vital signs were normal. The subject was treated with acetylsalicylic acid and diclofenac, which decreased the intensity of his chest pain. The subject was also started on a continuous intravenous infusion of glyceryl trinitrate until 17 Sep 2020 (Day 29). On 17 Sep 2020 (Day 29), the subject underwent an angiogram with revascularization and a drug eluting stent was placed in the left anterior descending coronary artery. The subject tolerated the procedure well and was hemodynamically stable. Dual-antiplatelet therapy was administered with ticagrelor and prasugrel. The subject was also treated with atorvastatin 40 mg, enoxaparin 100 mg twice a day, bisoprolol 2.5 mg, and pantoprazole sodium sesquihydrate 40 mg. A SARS-CoV-2 polymerase chain reaction test was negative. The subject recovered from the chest pain completely and remained in a stable condition. The right bundle branch block and acute coronary syndrome resolved on 19 Sep 2020 (Day 31) and the subject was discharged from the hospital that day. In the opinion of the investigator, there was no reasonable possibility that the acute coronary syndrome was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	149 kg	50.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sleep apnea	Sleep apnoea syndrome	01JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	13:20
2	BNT162b2	11SEP2020 (22)	10:50

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Arrhythmia supraventricular	Arrhythmia supraventricular	17SEP2020 (28)	11:00	19SEP2020 (30)	10:00	3	4	TC/TCN	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown, but probably corresponds to an accessory intraventricular line	2	7	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12312854, a 44-year-old white male with a pertinent medical history of sleep apnea syndrome (since 01 Jan 2010), obesity and sedentarism (both since unknown dates), received Dose 1 on 21 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 22). The subject was diagnosed with supraventricular arrhythmia on 17 Sep 2020, 6 days after receiving Dose 2.

On 17 Sep 2020 (Day 28), the subject presented to the emergency room with palpitations and jaw pain. An electrocardiogram (ECG) revealed wide QRS, tachyarrhythmia with complete left bundle branch block, and a heart rate (HR) of 180 beats per minute (bpm). Laboratory test results showed troponin of 8.32 ng/mL and creatine phosphokinase of 642 µ/L (normal ranges not reported), a chest x ray was performed (unknown results). The subject was admitted to the intensive care unit and was treated with amiodarone (dose and route unknown), which showed a good clinical response, reverting the tachyarrhythmia to normal sinus rhythm. A repeat ECG after the treatment showed normal sinus rhythm, with HR of 75 bpm, and no evidence of ischemic changes. An accessory pathway was found and was removed by ablation. On 19 Sep 2020 (Day 30), the supraventricular arrhythmia resolved and the subject was discharged on the same day. The supraventricular arrhythmia was considered as life-threatening by the investigator. A COVID-19 test was not performed during the hospitalization stay.

In the opinion of the investigator, there was no reasonable possibility that the supraventricular arrhythmia was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	70.8 kg	27 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	13:40
2	Placebo	08OCT2020 (49)	11:26

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Craniocerebral injury	minor cranioencephalic trauma	08OCT2020 (49)	12:18	08OCT2020 (49)	12:18	1	1	N	N
2	NERV	Syncope	syncope	08OCT2020 (49)	12:18	08OCT2020 (49)	14:06	1	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (08OCT2020)	NOT RELATED/OTHER: Head trauma due to fall from own height after syncope	2	1	N
2	Resolved (08OCT2020)	NOT RELATED/OTHER: syncope of probable vasogenic cause	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	11NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312868, a 43-year-old white female with no reported medical history, received Dose 1 on 21 Aug 2020 and Dose 2 on 08 Oct 2020 (Day 49). The subject was diagnosed with syncope on 08 Oct 2020, on the same day as Dose 2. On 08 Oct 2020 (Day 49), approximately an hour after Dose 2 administration, the subject had loss of consciousness that lasted for 10 seconds, and as a result fell from standing and sustained a minor head injury (cranioencephalic trauma). The subject was placed in the Trendelenburg position and on examination, her vital signs showed blood pressure (BP) of 60/40 mmHg, heart rate (HR) of 65 beats per minute (bpm), oxygen saturation of 96%, and blood glucose of 96 mg/dL (normal range not reported). After 20 minutes, the subject's repeat BP remained 60/40 mmHg; therefore, she was transferred to the emergency room for further management. The subject was started on intravenous (IV) saline 500 mL. Vital signs after the IV infusion were BP of 110/77 mmHg and HR of 89 bpm. An electrocardiogram showed normal sinus rhythm. The syncope was interpreted as secondary to a vasovagal episode. The syncope and cranioencephalic trauma resolved on 08 Oct 2020 (Day 49). The syncope was considered as an important medical event by the investigator. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention or clinical trial procedures, but rather had a probable vasogenic cause. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	103 kg	35.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	16:00
2	Placebo	14SEP2020 (25)	11:00

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Atrioventricular block second degree	Second degree AV block (Mobitz II)	10NOV2020 (82)	10:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	2	58	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12312914, a 50-year-old white male with no reported medical history, received Dose 1 on 21 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 25). The subject was diagnosed with second degree atrioventricular block on 10 Nov 2020, 57 days after receiving Dose 2.

On 29 Oct 2020 (Day 70), the subject tested positive for SARS-CoV-2 and was hospitalized. On 10 Nov 2020 (Day 82), while in the hospital, the subject had symptomatic bradycardia and was transferred to a coronary unit. An electrocardiogram (ECG) showed sinus rhythm, atrioventricular (AV) block second degree (Mobitz II) without ST elevation. The subject's myocardial necrosis marker was negative and he was clinically stable with unremarkable laboratory tests. According to the cardiologist and electrophysiologist, the subject had 2 episodes of asymptomatic AV 2:1 block. A control ECG showed sinus rhythm without blockages, and an echocardiogram was normal. The subject's troponin (unknown subtype) levels were normal at 4.5 ng/L and 2.6 ng/L (normal range not provided) on 11 Nov 2020 (Day 83) and 13 Nov 2020 (Day 85), respectively. On 13 Nov 2020 (Day 85), an ECG showed sinus rhythm (76 beats per minute) with no electrical disturbances. The subject remained stable without oxygen requirement and did not receive any treatment for this transitory episode. He was discharged from the hospital on 14 Nov 2020 (Day 86). A 24 hour-Holter monitoring test was suggested and the second degree atrioventricular block was ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the second degree atrioventricular block was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the second degree atrioventricular block was likely due to subject's underlying contributory factors including COVID-19 positive.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	52.05 kg	18.7 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent gross hematuria	Haematuria	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	14:40
2	Placebo	10SEP2020 (20)	15:35

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Haematuria	haematuria	25AUG2020 (4)	14:00	22SEP2020 (32)	08:00	29
2	RENAL	Urinary bladder polyp	Bladder polyp	18SEP2020 (28)	08:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (22SEP2020)	NOT RELATED/OTHER: Bladder polyp	1	4	N
2	1	TCN	Y	Yes	NOT RELATED/OTHER: Unknow.	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313193, a 54-year-old white female with a pertinent medical history of hematuria (since Jul 2020), received Dose 1 on 22 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 20). The subject was diagnosed with a urinary bladder polyp on 18 Sep 2020, 8 days after receiving Dose 2. On 25 Aug 2020 (Day 4), the subject experienced hematuria (reported as nonserious event). On 18 Sep 2020 (Day 28), a computerized tomogram scan of the abdomen and pelvis showed a polyp (27 mm) on the right lateral wall of the bladder. The subject had an appointment with an urologist and remained asymptomatic. On 22 Sep 2020 (Day 32), the hematuria resolved. On 16 Oct 2020 (Day 56), the subject was hospitalized for polyp removal surgery and was discharged on 17 Oct 2020 (Day 57). On 04 Nov 2020 (Day 75), the subject reported that the biopsy result was still pending. The urinary bladder polyp was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the urinary bladder polyp was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	63 kg	23.7 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	16:09
2	Placebo	15SEP2020 (23)	15:17

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Pulmonary mass	Right pulmonary nodule	24SEP2020 (32)	17:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	26OCT2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	26OCT2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1231 12313621, a 65-year-old white female with a long-term history of smoking (since an unknown date), received Dose 1 on 24 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 23). The subject was diagnosed with a right pulmonary mass on 24 Sep 2020, 9 days after receiving Dose 2. On 24 Sep 2020 (Day 32), during a periodic health check-up, the subject underwent a chest computerized tomogram scan which showed a 24 × 188 mm right lung nodule localized in the medial segment of the inferior right lobe (para hilar), with marginal spiculation and no adenomegalies. The subject was hospitalized on 19 Oct 2020 (Day 57) and was referred to a thoracic surgeon for thoracic surgery (lung nodule biopsy). On the same day (Day 57), the subject was moved to the intensive care unit (ICU) and the biopsy results were unknown. Postsurgery, the subject was admitted to the ICU for monitoring, she did not require supplemental oxygen or inotropic drugs. On 23 Oct 2020 (Day 61), the subject was discharged from the hospital. A COVID-19 test was not performed as the subject had no symptoms. The pulmonary mass was considered medically significant by the investigator and was ongoing at the time of the last available report. The subject requested withdrawal from the study on 26 Oct 2020. In the opinion of the investigator, there was no reasonable possibility that the pulmonary mass was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	71.5 kg	30.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bronchial asthma	Asthma	1967	Present
Hypothyroidism	Hypothyroidism	01JUN1995	Present
low back pain	Back pain	2005	Present
bilteral pleural effusion	Pleural effusion	15APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	17:00
2	Placebo	13SEP2020 (21)	18:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Ischaemic stroke	Ischemic Stroke	06NOV2020 (75)	23:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: unknown	2	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313653, a 54-year-old white female with a pertinent medical history of asthma (since 1967), hypothyroidism (since 01 Jun 1995), and pleural effusion (since 15 Apr 2020), received Dose 1 on 24 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 21), no concomitant medications have been reported. The subject was diagnosed with an ischemic stroke on 06 Nov 2020, 54 days after receiving Dose 2. On 06 Nov 2020 (Day 75), after dinner, the subject had an apparent loss of postural tone and consciousness (possible syncope or lipothymia) with subsequent spontaneous recovery. The subject also reported that she had a headache, left sided facial droop, dysarthria, and mild paresis of the left upper and lower limbs. In the early hours of 07 Nov 2020 (Day 76), the subject was taken to the hospital where a computerized tomogram of brain was performed, which ruled out spontaneous bleeding, electrocardiogram and echocardiogram were performed; however, the results were unknown. On the same day (Day 76), the subject was admitted to another hospital where a new brain scan was performed with unremarkable results. On 08 Nov 2020 (Day 77), the subject reported her paresis and headache improved and she was feeling well; however, mild paresis of the left upper and lower limbs still persisted. The subject was discharged from the hospital on 12 Nov 2020 (Day 81). A neurology consultation was scheduled on 27 Nov 2020 (Day 96). The ischemic stroke was reported as ongoing at the time of the last available report. A SARS-CoV-2 swab test performed whilst admitted as an in-patient was negative. In the opinion of the investigator, there was no reasonable possibility that the ischemic stroke was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	66 kg	23.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sjogren syndrome	Sjogren's syndrome	07JUL1977	Present
insomnia	Insomnia	07JUL1990	Present
Right hip replacement surgery	Hip arthroplasty	19DEC2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	17:45
2	BNT162b2	13SEP2020 (21)	15:58

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Emphysema	Panlobar emphysema	09OCT2020 (47)		ONGOING			1
2	RESP	Pneumonitis	Non-specific Pneumonitis	29SEP2020 (37)	15:30	ONGOING			2
3	INFEC	Sialoadenitis	Left submaxillary sialadenitis	03NOV2020 (72)	08:00	09NOV2020 (78)	20:00	7	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Unknown	2	27	N
2	N	Y	Yes	NOT RELATED/OTHER: unknown	2	17	Y
3	TC	N	Resolved (09NOV2020)	NOT RELATED/OTHER: Sjogren's syndrome	2	52	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313674, a 58-year-old white female with a pertinent medical history of Sjogren's syndrome (since Jul 1977), received Dose 1 on 24 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 21). The subject was diagnosed with nonspecific pneumonitis on 29 Sep 2020, 16 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the pneumonitis included bromazepam (since Jul 1990) and zolpidem (since Jul 2010), both for insomnia (which the subject has reported suffering from since Jul 1990). On 29 Sep 2020 (Day 37), the subject complained of malaise, odynophagia, and diarrhea. An unscheduled visit was performed on 06 Oct 2020 (Day 44) for a SARS-CoV-2 nasopharyngeal swab polymerase chain reaction test which was negative. On 08 Oct 2020 (Day 46), the subject was febrile (maximum body temperature recorded was 38°C) with persistent myalgia in addition to the other symptoms. On 09 Oct 2020 (Day 47), the subject was hospitalized and kept in isolation for further evaluation of suspected COVID-19 pneumonia. A repeat SARS-CoV-2 test was negative and a chest computerized tomogram (CT) showed bilateral ground-glass opacities in the right median lobe and both lung bases with central distribution and panlobular emphysema (main bullae 29 mm). Multiple adenopathies within adenomegalic range were visualized at precarinal and prevascular level and in both armpits. The chest CT findings were interpreted as nonspecific pneumonitis. The additional laboratory tests performed on the same day (Day 47) were unremarkable. During the hospitalization, the subject remained afebrile and hemodynamically stable. On 10 Oct 2020 (Day 48), the subject remained symptomatic (odynophagia and mild myalgia) and was discharged from the hospital on tramadol 50 mg 3 times a day and paracetamol as needed. She was also referred to a rheumatologist. The pneumonitis and emphysema were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the pneumonitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	88 kg	29.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Kidney stones	Nephrolithiasis	01JAN1961	Present
Irritable colon	Irritable bowel syndrome	01JAN2005	Present
Arterial hypertension	Hypertension	2012	Present
L4-L5 disc herniation	Intervertebral disc protrusion	DEC2013	Present
Surgical placement of interspinous spacer at L4-L5	Spinal operation	06DEC2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	20:55
2	BNT162b2	14SEP2020 (22)	20:05

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Intervertebral disc protrusion	Worsening lumbar disc herniation	10SEP2020 (18)	10:00	12NOV2020 (81)	15:00	64	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (12NOV2020)	NOT RELATED/OTHER: Unresolved chronic lumbar disc herniation. spinal surgery performed in 2013	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313783, a 66-year-old white male with a pertinent medical history of intervertebral disc protrusion (L4-L5 disc herniation; since Dec 2013), spinal operation (surgical placement of interspinous spacer at L4-L5; on 06 Dec 2013), spondylolisthesis and osteolysis (both in 2013), and limb asymmetry (since an unknown date), received Dose 1 on 24 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 22). The subject experienced worsening of lumbar disc herniation on 10 Sep 2020, 17 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the worsening of lumbar disc herniation included diclofenac sodium, pridinol and ibuprofen all for lumbar disc herniation. The subject had a pre-existing condition of lumbar disc disease (L4-L5, Grade 1 anterolisthesis, and osteolysis as a consequence of an accident in 2013) and a shortening of 2 cm in the right lower limb. He had limited mobility (used a cane) and was unable to lift any weight. On 10 Sep 2020 (Day 18), the subject experienced worsening of chronic spinal pain after a particular movement. He saw an orthopedic surgeon, who scheduled a spinal procedure (lumbar arthrodesis). On 22 Oct 2020 (Day 60), the subject was hospitalized and underwent arthrodesis. He had a good immediate post-surgery recovery, and remained hospitalized for pain control (he was treated with diclofenac sodium 75 mg 3 times a day and acetaminophen 500 mg as needed). The subject was discharged on 25 Oct 2020 (Day 63). On 29 Oct 2020 (Day 67), he visited the surgeon and a chest x-ray performed was unremarkable. On 12 Nov 2020 (Day 81), the subject had an orthopedic consultation and the surgical stitches were removed. The worsening of lumbar disc herniation was considered resolved on the same day (Day 81). The next day (Day 82), the subject was stable without any complications, started on therapeutic exercises, and was planned for an orthopedic consultation in 15 days. In the opinion of the investigator, there was no reasonable possibility that the worsening of lumbar disc herniation was related to the study intervention, concomitant medications, or clinical trial procedures; but rather it was related to an unresolved chronic lumbar disc herniation and spinal surgery performed in 2013. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	72 kg	27.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	25AUG2010	Present
bilateral oophorectomy	Oophorectomy bilateral	OCT2014	Past
Bilateral adnexal cysts	Adnexa uteri cyst	07OCT2014	Past
Bilateral adnexectomy	Salpingo-oophorectomy bilateral	21OCT2014	Past
allergic rhinitis	Rhinitis allergic	2015	Present
asthma	Asthma	01APR2019	Present
hospitalization for asthmatic crisis	Asthmatic crisis	01JUL2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	17:05
2	BNT162b2	15SEP2020 (22)	18:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Acute coronary syndrome	Acute coronary syndrome	08NOV2020 (76)	17:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314001, a 56-year-old white female with a pertinent medical history of hypothyroidism (since 25 Aug 2010); tobacco user and dyslipidemia (since unknown dates); and a family history of coronary artery disease (details unknown), received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). The subject was diagnosed with acute coronary syndrome on 08 Nov 2020, 54 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of the acute coronary syndrome included levothyroxine (since 25 Aug 2010) for hypothyroidism. On 08 Nov 2020 (Day 76), the subject experienced tachycardia, palpitations, and oppressive chest pain, went to the emergency room, and was subsequently hospitalized. Upon admission, the subject was hemodynamically stable and an electrocardiogram (ECG) was normal. The subject was treated with glyceryl trinitrate and acetylsalicylic acid. On 09 Nov 2020 (Day 77), a rotational coronary angiography and left ventriculography showed anterior descending artery severe obstruction with parietal calcification in the middle third and severe obstruction with great parietal calcification in the proximal third of the diagonal branch. The right coronary artery showed moderate to severe obstruction with great parietal calcification (60%-70%) in the middle third. The circumflex artery showed severe obstruction with great parietal calcification in the latero-ventricular branch. A coronary transluminal angioplasty of the anterior descending artery and diagonal branch with implantation of 2 drug-free stents was performed successfully. On 11 Nov 2020 (Day 79), a secondary coronary transluminal angioplasty of the right coronary artery and circumflex artery with implantation of 2 drug-free stents was done successfully. On an unspecified date, a diagnostic cine coronary angiography was also performed. On 12 Nov 2020 (Day 80), the subject's condition stabilized, and she was discharged from the hospital on the same day. The subject's discharge medications included: omeprazole 20 mg once daily (QD), acetylsalicylic acid 100 mg QD, rosuvastatin 40 mg QD, clonazepam 0.5 mg 3 times a day, and nicotine transdermal patch 35 mg QD, and cardiac follow-up was scheduled. The acute coronary syndrome was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the acute coronary syndrome was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Not Reported	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	79.15 kg	28.7 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Heavy Smoking	Tobacco user	1975	Past
Gastroduodenal Bleeding Ulcer	Gastrointestinal ulcer haemorrhage	1998	Past
Diverticulitis	Diverticulitis	01APR2018	Past
Colon Resection	Colectomy	15APR2018	Past
Dyslipemia	Dyslipidaemia	SEP2018	Present
Acute myocardial infarction	Acute myocardial infarction	21SEP2018	Past
angioplasty with stent placement	Vascular stent insertion	21SEP2018	Past
Arterial Hypertension	Hypertension	23SEP2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	18:45
2	BNT162b2	14SEP2020 (21)	16:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Angina pectoris	Angina Pectoris	20SEP2020 (27)	17:00	24SEP2020 (31)	08:30	5
2	PSYCH	Anxiety	Anxiety Crysis	29SEP2020 (36)	12:00	29SEP2020 (36)	18:30	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (24SEP2020)	NOT RELATED/OTHER: coronary disease	2	7	Y
2	2	N	N	Resolved (29SEP2020)	NOT RELATED/OTHER: Angina Pectoris	2	16	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314035, a 63-year-old (Hispanic/Latino/of Spanish origin) male with a pertinent medical history of previous tobacco use (heavy smoker, in 1975), acute myocardial infarction (from 21 Sep 2018 to 23 Sep 2018), vascular stent insertion (angioplasty with stent placement; on 21 Sep 2018), hypertension (since 23 Sep 2018), and dyslipidemia (since Sep 2018), received Dose 1 on 25 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 21). The subject experienced angina pectoris on 20 Sep 2020, 6 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the angina pectoris included acetylsalicylic acid and atorvastatin (both since 24 Sep 2018) both for cardiovascular prophylaxis; rosuvastatin, omeprazole and alprazolam (all since unknown dates) for unspecified indications. On 14 Sep 2020 (Day 21), after receiving Dose 2, the subject experienced injection site pain, myalgia, and headache. On 20 Sep 2020 (Day 27), the subject presented to the emergency room with mild chest pain that lasted for few minutes and shortness of breath (functional class III). The laboratory test results showed ultrasensitive troponin values of 15.6 pg/mL, 172 pg/mL, and 14 pg/mL at unspecified time intervals (normal range was not reported). An electrocardiogram showed sinus rhythm, inferior sequelae, with no new ischemic changes. The chest x-ray and laboratory test results were unremarkable. On the same day (Day 27), a SARS-CoV-2 polymerase chain reaction test was negative; however, due to the COVID-19 pandemic, the subject was admitted to the intensive care unit for isolation purposes and further evaluation. On an unspecified date, echocardiography showed an ejection fraction of 57%, inferior and septal akinesia, and diastolic filling pattern impaired relaxation. Coronary angiography showed right coronary and anterior descendant arteries, no signs of stenosis permeable stent and that of nonrevascularizable artery disease was found. Circumflex artery of first marginal branch showed mild lesion, small caliber artery disease, and nonrevascularizable artery disease. Medical treatment was optimized and was well tolerated by the subject. The angina pectoris was considered resolved on 24 Sep 2020 (Day 31) and he was discharged on the same day. The subject's discharge medications included pantoprazole 20 mg once daily (QD), acetylsalicylic acid 100 mg QD, clopidogrel 75 mg QD, and bisoprolol. In the opinion of the investigator, there was no reasonable possibility that the angina pectoris was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to coronary disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	91 kg	34.3 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis	Acute Appendicitis	05SEP2020 (11)	22:00	09SEP2020 (15)	14:00	5	3
2	VASC	Orthostatic hypotension	orthostatic hypotension	11OCT2020 (47)	06:30	12OCT2020 (48)	13:00	2	1
3	EAR	Vertigo	Vertigo	07OCT2020 (43)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: unknown	1	11	Y
2	N	N	Resolved (12OCT2020)	NOT RELATED/OTHER: dietary habit change, lower intake.	1	47	N
3	N	N	Yes	NOT RELATED/OTHER: Unknow	1	43	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314216, a 57-year-old white female with no reported medical history or concomitant medications received Dose 1 on 26 Aug 2020. The subject was diagnosed with appendicitis on 05 Sep 2020, 10 days after receiving Dose 1. On 05 Sep 2020 (Day 11), the subject experienced diarrhea and vomiting. A few hours later on 06 Sep 2020 (Day 12), she started experiencing abdominal pain and went to the emergency room. She was hospitalized for 1 day for further evaluation. The laboratory test results were unknown and the surgical pathology report was not available at this time. The cause of acute abdominal pain was confirmed to be acute appendicitis and it was resolved surgically. The subject was discharged from the hospital on an unspecified date and the discharge medications included: amoxicillin/clavulanic acid 1 g twice a day for 7 days, metronidazole 500 mg 3 times a day (TID) for 5 days, and ibuprofen 400 mg TID for 3 days. The appendicitis was considered resolved on 09 Sep 2020 (Day 15). In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	64 kg	23.5 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dengue	Dengue fever	15APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	11:05
2	Placebo	16SEP2020 (21)	14:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Epistaxis	Epistaxis	20SEP2020 (25)	19:30	19OCT2020 (54)	22:00	30
2	INJ&P	Multiple injuries	Polytrauma	20SEP2020 (25)	19:30	ONGOING		
3	VASC	Subgaleal haematoma	subgaleal hematoma	20SEP2020 (25)	19:30	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TCN	N	Resolved (19OCT2020)	NOT RELATED/OTHER: sphenoid fracture	2	5	N
2	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Hit by a vehicle	2	5	Y
3	2	TCN	N	Yes	NOT RELATED/OTHER: road accident	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314407, a 26-year-old white female with no pertinent medical history, or no concomitant medications, received Dose 1 on 27 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 21). The subject experienced multiple injuries (polytrauma) on 20 Sep 2020, 4 days after receiving Dose 2. On 20 Sep 2020 (Day 25), the subject was hit by car as a pedestrian and sustained polytrauma with cranioencephalic trauma requiring an emergency room visit. She was hospitalized and upon admission, she was noted to have a right eye hematoma with normal vision. No other findings were observed. A brain computerized tomogram (CT) scan without contrast showed right frontoparietotemporal subgaleal hematoma; skull facial CT scan without contrast was unremarkable; and CT scan without contrast and magnetic resonance imaging (MRI) of the spine showed C2 vertebral body fracture and anterior oblique T3, T4, and T5 body fracture I was identified. Additionally, the MRI showed no spinal cord compression. An abdominal ultrasound was unremarkable. The subject also had epistaxis (reported as nonserious adverse event) on 20 Sep 2020 (Day 25). Laboratory tests and procedures were performed on an unspecified date which were unremarkable. The subject was discharged from the hospital on 23 Sep 2020 (Day 28) with discharge instructions to rest and a permanent Philadelphia collar. The discharge medications included paracetamol 1 g 3 times a day (TID), tramadol 25 mg TID as needed (PRN) for pain, omeprazole 20 mg once daily, and metoclopramide 10 mg for nausea or vomiting. The subject was instructed to visit a spinal orthopaedic surgeon and ophthalmologist every week. As of 14 Oct 2020 (Day 49), the subject had persistent moderate headache and multiple healing hematomas of the right leg, left knee, and right frontotemporal area. On 17 Oct 2020 (Day 52), a repeat CT scan of the spine without contrast showed no changes and a skull facial CT scan without contrast showed right frontotemporal and sphenoid bone fractures. The final diagnoses included C2, T3, T4, and T5 body fractures; right fronto-parietotemporal subgaleal hematoma; right frontotemporal fracture; and sphenoid bone fracture. The subject was evaluated by the orthopedist and head and neck surgeon and an urgent need for surgery was ruled out for these 2 fractures. On 19 Oct 2020 (Day 54), the epistaxis resolved. On 30 Oct 2020 (Day 65), the subject reported that she was seen by the spinal orthopedist periodically and remained asymptomatic. She was still using a Philadelphia collar and was on acetaminophen 500 mg PRN. Ophthalmologic follow-up details were still pending. The sub-galeal haematoma was reported as resolved on 09 Nov 2020. The polytrauma was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the polytrauma were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	70 kg	25.4 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	14:15
2	Placebo	18SEP2020 (22)	15:00

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Abdominal abscess	Intra-abdominal Abscess	29OCT2020 (63)	12:00	ONGOING			3	TC/TCN	Y
2	INFEC	Appendicitis	appendicitis	16OCT2020 (50)	09:00	24OCT2020 (58)	14:00	9	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: surgical history of appendicitis on 19OCT2020	2	42	Y
2	Resolved (24OCT2020)	NOT RELATED/OTHER: Unknown	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314833, a 49-year-old white male with no reported medical history, or concomitant medications, received Dose 1 on 28 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 22). The subject was diagnosed with appendicitis on 16 Oct 2020, 28 days after receiving Dose 2 and an abdominal abscess on 29 Oct 2020, 41 days after receiving Dose 2. On 16 Oct 2020 (Day 50), at 0900 hours, the subject experienced diffuse abdominal pain. On 17 Oct 2020 (Day 51) at 0430 hours, the subject visited the emergency room (ER) for evaluation. He was treated with saline intravenously (IV) and IV analgesic (unknown drug and dose). The subject remained in the hospital for observation for 12 hours and was discharged. No complementary studies were performed and no summary was provided. The abdominal pain persisted and a few hours later, the pain localized in the lower right quadrant. On an unspecified date, the subject went to a different hospital ER where an abdominal computerized tomogram (CT) scan was performed, but the results were unknown. The subject underwent an appendectomy on 19 Oct 2020 (Day 53) at 1930 hours. The appendicitis was considered resolved on 24 Oct 2020 (Day 58), and the subject was discharged from the hospital on the same day. The subject was asymptomatic and had not used any pain medications. He continued to be on bed rest. On 29 Oct 2020 (Day 63), the subject was febrile without any other symptoms noted and the surgical scar did not show any signs of infection. On 30 Oct 2020 (Day 64), the subject had persistent fever and he visited the ER and was subsequently re-hospitalized. Laboratory tests including abdominal ultrasound and x-rays were performed on an unspecified date with unknown results. On 30 Oct 2020 (Day 64), an abdominal CT scan showed an intra-abdominal collection. The subject had a surgeon's appointment on 31 Oct 2020 (Day 65). The subject reported that because of the abdominal free fluid he underwent a laparoscopic abscess drainage on 01 Nov 2020 (Day 66) at 1200 hours without complications. The intra-abdominal abscess was considered secondary to the appendicitis. An abdominal drain was placed that was removed on 04 Nov 2020 (Day 69). Abscess culture and pathology reports were pending at this time. On 05 Nov 2020 (Day 70), the subject informed the site that he was still hospitalized with mild abdominal pain but overall, he was feeling well. He was started on piperacillin/tazobactam IV and received antibiotics IV until 05 Nov 2020 (Day 70) and later switched to oral amoxicillin until 06 Nov 2020 (Day 71). On 07 Nov 2020 (Day 72), the subject remained hospitalized and a repeat CT scan showed evidence of new intra-abdominal collections. Treatment with IV antibiotics was restarted. After treatment with IV antibiotics, the subject was feeling well with mild surgical scar pain. He received analgesics as needed. On 09 Nov 2020 (Day 74) at 1000 hours, an abdominal ultrasound guided drainage was completed successfully. On 10 Nov 2020 (Day 75), the subject informed the site that there was a persistent retro-vesical collection that would require drainage and had a urinary catheter placed. On the same day (Day 75), a culture of abscess drainage material showed Escherichia coli. The subject was treated with a course of IV ampicillin/sulbactam (unspecified date) and IV ciprofloxacin was added to the treatment regimen since the cultured E. coli was sensitive to quinolones. Local surgical wound healing was also reported. On 11 Nov 2020 (Day 76), the subject underwent an unsuccessful ultrasound guided drainage of the retro-vesical collection. On 13 Nov 2020 (Day 78), the subject was afebrile without pain and was eating normally. On 16 Nov 2020 (Day 81), the subject was discharged from the hospital. He continued to receive local wound follow up. The abdominal abscess was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the appendicitis and abdominal abscess were related to the study intervention or clinical trial procedures, but rather the abdominal abscess was related to the appendectomy performed on 19 Oct 2020 (Day 53). Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	98 kg	32 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent asthma	Asthma	21NOV1963	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	17:50
2	Placebo	16SEP2020 (20)	11:30

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Pneumonia	community acquired pneumonia	03OCT2020 (37)	21:00	15OCT2020 (49)	21:03	13

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: unknown	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1231 12314898, a 56-year-old white male with a pertinent medical history of asthma (since 21 Nov 1963), received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject was diagnosed with pneumonia on 03 Oct 2020, 17 days after receiving Dose 2.

Concomitant medication reported within 2 weeks prior to the onset of the pneumonia included salbutamol (since 01 Sep 1970) for asthma.

On 03 Oct 2020 (Day 37), the subject informed the site that she had odynophagia, low grade fever with a body temperature of 37.8°C, shortness of breath, dyspnea, cough, and dizziness. The subject was advised to seek medical attention if the symptoms worsened. The symptoms did not improve and on 04 Oct 2020 (Day 38), the subject presented to the emergency room with shortness of breath. A physical examination revealed tachypnea with a respiratory rate of 28 breaths per minute, wheezing, and decreased breath sounds. A chest x-ray showed bilateral grounded-glass opacities and an opacity/consolidation in the left inferior lobe. The laboratory tests showed complete blood count results were within normal limits except for the white blood cell count of 15300 × 109/L and neutrophils of 81% (normal ranges [NR] not reported); the arterial blood gas study showed hypoxemia and respiratory alkalosis (values not reported). The subject was hospitalized for acute community acquired pneumonia. During hospitalization the subject's blood work-up was monitored every day, and on an unspecified date his neutrophils were at 88% (NR not reported). The subject was then transferred to the intensive care unit and was placed on high flow supplemental oxygen with a good clinical response. The subject remained in isolation following the COVID-19 pandemic protocol. He was treated with intravenous ampicillin/sulbactam, and clarithromycin until 15 Oct 2020 (Day 49), and additionally received oseltamivir, ivermectin, dexamethasone, and low molecular weight heparin. On 05 Oct 2020 (Day 39), the physician informed the investigator that the subject was clinically improving but required supplemental oxygen. A SARS-CoV-2 nasopharyngeal swab test was negative and treatment with ivermectin was stopped. The subject's condition was clinically improving requiring low flow supplemental oxygen on 07 Oct 2020 (Day 41) and he continued treatment with ampicillin/sulbactam, clarithromycin, oseltamivir, dexamethasone, and salbutamol. On 10 Oct 2020 (Day 44), the subject was discharged from the hospital with fluticasone propionate/salmeterol xinafoate 2 puffs 3 times a day, amoxicillin/clavulanic 1 g twice a day (BID), clarithromycin 500 mg BID, montelukast 10 mg once daily (QD), and meprednisone 40 mg QD and was referred to a pulmonologist for further treatment. On 11 Oct 2020 (Day 45), the subject had improved clinically and did not require further supplemental oxygen. On 15 Oct 2020 (Day 49), the pneumonia resolved and the subject informed the investigator that he was feeling well and was asymptomatic.

In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	61.2 kg	22.8 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Amblyopia of the right eye	Amblyopia	(b) (6) 1968	Present
Left hemicrania migraine	Migraine	01JUN1977	Present
allergic to penicillin	Drug hypersensitivity	26AUG1977	Present
Myopia of the left eye	Myopia	01JAN1986	Present
Depression and anxiety	Depression	01JUN2005	Past
Herpes zoster	Herpes zoster	28DEC2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	16:31
2	BNT162b2	17SEP2020 (20)	16:05

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	EYE	Choroidal neovascularisation	Myopic choroidal neovascular membrane of the left eye	06SEP2020 (9)	17:00	ONGOING			2	N	Y

Adverse Events				
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Complication of high myopia presented by the voluntary as antecedent	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315291, a 52-year-old white female with a pertinent medical history of amblyopia of the right eye (since (b) (6) 1968), left hemicrania migraines (since 01 Jun 1977), and myopia of the left eye (since 01 Jan 1986), received Dose 1 on 29 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 20). The subject was diagnosed with choroidal neovascularization (left eye) on 06 Sep 2020, 8 days after receiving Dose 1. On 06 Sep 2020 (Day 9), the subject experienced a sudden and painless decrease in visual acuity of her left eye with no other ophthalmic or systemic symptoms. On 19 Oct 2020 (Day 52), during an ophthalmologic consultation, the subject was diagnosed with myopic choroidal neovascular membrane of the left eye, which was considered an important medical event. The subject was treated with an intravitreal injection of bevacizumab to the left eye. On 05 Nov 2020 (Day 69), the subject was started on antibiotic prophylaxis with moxifloxacin ophthalmic solution 1 drop 3 times a day (TID) and cleaning of both eyes with an unspecified antiseptic soap TID. On 06 Nov 2020 (Day 70), she received an intravitreal injection of ranibizumab 2 mg/0.2 mL, without any complications. The subject continued antibiotic prophylaxis with moxifloxacin ophthalmic solution on 07 Nov 2020 (Day 71) but her vision remained unchanged. On 12 Nov 2020 (Day 76), the subject reported that she was feeling well without any clinical changes or complications and she was advised for follow-up ophthalmic review on 29 Nov 2020 (Day 93). The choroidal neovascularization was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the choroidal neovascularization was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was a complication of pre-existing myopia. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	125 kg	41.3 kg/m2	30AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Congenital ocular toxoplasmosis	Congenital toxoplasmosis	(b) (6) 1970	Past
Heavy Smoking	Tobacco user	03MAR1986	Past
Obesity	Obesity	1992	Present
ANGIOPLASTY	Angioplasty	JAN2015	Past
STENT PLACEMENT	Stent placement	JAN2015	Past
Myocardial infarction	Myocardial infarction	18JAN2015	Past
Arterial hypertension	Hypertension	19AUG2015	Present
Dyslipidemia	Dyslipidaemia	20AUG2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	12:25
2	BNT162b2	19SEP2020 (21)	09:56

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Angina unstable	Unstable Angina Pectoris	14OCT2020 (46)	18:00	16OCT2020 (48)	11:00	3	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (16OCT2020)	NOT RELATED/OTHER: Unknown cause, history of acute myocardial infarction	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315473, a 50-year-old white male with a pertinent medical history of previous heavy tobacco smoking (from 03 Mar 1986 to 18 Jan 2015), obesity (since 1992), myocardial infarction (from 18 Jan 2015 to 19 Jan 2015), angioplasty and stent placement for posterolateral myocardial infarction (both in Jan 2015), hypertension (since 19 Aug 2015), and dyslipidemia (since 20 Aug 2015), received Dose 1 on 30 Aug 2020 and Dose 2 on 19 Sep 2020 (Day 21). The subject was diagnosed with unstable angina on 14 Oct 2020, 25 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the unstable angina included acetylsalicylic acid (since 21 Aug 2015), bisoprolol (since 19 Aug 2020) and atorvastatin (since 26 Aug 2020), all for secondary prevention of cardiovascular disease. On 14 Oct 2020 (Day 46), the subject experienced chest pain that lasted for a few minutes. On 15 Oct 2020 (Day 47), the chest pain worsened, and the subject went to the emergency room. An electrocardiogram showed sinus rhythm, Q wave on DIII and aVF leads, and an inferolateral ST elevation of 1 mm was recorded. Coronary angiography showed normal coronary arteries and the chest x-ray was unremarkable. The laboratory test results were unremarkable. It was unknown if the troponin test results were available. The subject's condition was interpreted as an episode of unstable angina and was admitted to the intensive care unit. The subject remained stable without heart failure and was hemodynamically stable. On 16 Oct 2020 (Day 48), the unstable angina resolved and the subject was discharged with the following medications: pantoprazole 40 mg once daily (QD), acetylsalicylic acid 100 mg QD, bisoprolol 5 mg QD, rosuvastatin 10 mg QD, ezetimibe 10 mg QD (newly started), and alprazolam 0.5 mg 3 times a day. The subject was referred for follow-up with the cardiologist. In the opinion of the investigator, there was no reasonable possibility that the unstable angina was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of acute myocardial infarction. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	78.5 kg	25.9 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	16:26
2	BNT162b2	19SEP2020 (20)	14:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Gastrooesophageal reflux disease	Gastroesophageal reflux disease	30OCT2020 (61)	08:00	ONGOING	
2	INFEC	Suspected COVID-19	Probable COVID-19 illnes	17OCT2020 (48)	09:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC	N	Yes	NOT RELATED/OTHER: Unknown	2	42	N
2		4	TC	Y	Yes	NOT RELATED/OTHER: unknown	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315632, a 66-year-old white male with no reported medical history, received Dose 1 on 31 Aug 2020 and Dose 2 on 19 Sep 2020 (Day 20). The subject reported suspected (but not confirmed) COVID-19 on 17 Oct 2020, 28 days after receiving Dose 2. On 17 Oct 2020 (Day 48) the subject experienced left shoulder and arm pain. On 18 Oct 2020 (Day 49), at 01:00 AM the subject experienced chest pain and dyspnea and called the emergency system. He was taken to the emergency room by ambulance where they performed: electrocardiogram with no ischemic changes, chest x-ray with unknown results, chest computerized tomogram that showed pneumonia of unknown localization. At the time of reporting the subject had presented with a temperature of 38°C. Blood/laboratory tests were done but results were unreported. In accordance with the hospital COVID-19 pandemic protocol the subject had a SARS-CoV-2 reverse transcription polymerase chain reaction (RT-PCR) swab. The date of discharge from hospital is unknown, however, the site received a discharge summary on 20 Oct 2020 (Day 51) stating the result of the SARS-CoV2 RT-PCR swab was negative. The swab taken for the purposes of the study and analyzed at the central laboratory was also negative. An additional SARS-CoV-2 test performed locally on 28 Oct 2020 was also negative. The cause of the potential COVID-19 illness remains unknown as no other microbiological studies were performed. The suspected (but not confirmed) COVID-19 illness was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the suspected COVID-19 was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	60	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	128 kg	39.9 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT DEAF	Deafness unilateral	01JUL1960	Present
arterial hypertension	Hypertension	01JAN2005	Present
OBESITY	Obesity	01JUL2005	Present
Glaucoma in both eyes	Glaucoma	01JUL2017	Present
ISOLATED HEMATOCHESIS	Haematochezia	15AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	17:10
2	Placebo	19SEP2020 (20)	15:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Ischaemic stroke	Ischemic stroke	12OCT2020 (43)	17:00	16OCT2020 (47)	17:30	5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (16OCT2020)	NOT RELATED/OTHER: unknown	2	24	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	14NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315653, a 60-year-old white male with a pertinent medical history of hypertension (since 01 Jan 2005) and obesity (since 01 Jul 2005), received Dose 1 on 31 Aug 2020 and Dose 2 on 19 Sep 2020 (Day 20). The subject was diagnosed with an ischemic stroke on 12 Oct 2020, 23 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of ischemic stroke included losartan (since 01 Jan 2020) for arterial hypertension. The subject experienced paresthesia in the right upper arm on 12 Oct 2020 (Day 43) and muscle weakness in the right arm with decreased strength and sensitivity in the right side of the body on 14 Oct 2020 (Day 45). The subject's symptoms persisted on 15 Oct 2020 (Day 46) requiring an emergency room visit. The subject was subsequently hospitalized because of a stroke, and the vital signs on admission showed brachial arterial pressure at 160/80 mmHg and heart rate (HR) at 70 beats per minute (bpm). Neurological examination showed mild brachiocrural hemiparesis, Hoover maneuver was positive without pronation, and hypoesthesia of the right side of the body was observed; the rest of the examination was unremarkable. On 15 Oct 2020 (Day 46), blood test results were also unremarkable. An electrocardiogram (ECG) showed sinus rhythm and HR at 60 bpm; a brain computerized tomogram (CT) scan without contrast showed enlargement of the brain sulci and leukoaraiosis; and a chest x-ray showed diffuse bibasilar opacities. A chest CT scan on the same day (Day 46) was performed but the results were unknown. As symptoms started more than 48 hours prior to admission, no thrombolytic therapy was given, instead a conservative therapy was prescribed with acetylsalicylic acid 300 mg once daily (QD) and oral (PO) atorvastatin 40 mg QD. On 16 Oct 2020 (Day 47), the ischemic stroke and neurological symptoms resolved and the subject was discharged. The discharge medications included: acetylsalicylic acid 300 mg QD for 2 weeks (after second week 100 mg QD), atorvastatin 40 mg PO QD and losartan 50 mg PO QD. On 17 Oct 2020 (Day 48), a SARS-CoV-2- test was negative. The subject affirmed that he felt better, had autonomous activity for daily life chores, and he returned to work. He reported notable improvement in the paresis of the right arm and was currently planning to start kinesiology. Doppler echocardiography and echo Doppler of the neck vessels would be performed on 30 Nov 2020 (Day 92). The subject reported that he had scheduled an appointment for review with a neurologist in Dec 2020. In the opinion of the investigator, there was no reasonable possibility that the ischemic stroke was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.5 cm	55.5 kg	23.9 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Breast lump	Breast mass	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	09:26
2	BNT162b2	09SEP2020 (23)	10:33

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	Breast hyperplasia	Atypical intraductal hyperplasia in left breast	29SEP2020 (43)		30SEP2020 (44)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (30SEP2020)	NOT RELATED/OTHER: Breast nodule	2	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411206, a 38-year-old multiracial female with a pertinent medical history of breast mass (since 2018) and left breast nodule (since 06 Feb 2020), received Dose 1 on 18 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 23). The subject was diagnosed with breast hyperplasia on 29 Sep 2020, 20 days after receiving Dose 2. On 29 Sep 2020 (Day 43), the subject was hospitalized because of the breast hyperplasia. She had undergone several tests prior to and after enrollment, which included: a bilateral breast ultrasonography on 27 Dec 2019 and 27 Aug 2020 (Day 10), which showed cystic solid complex, simple cyst in left breast with breast imaging reporting and database system score (BI-RADS) of 4; bilateral mammography on 14 Jan 2020, showed BI-RADS of 1 and a repeat bilateral mammography on 26 Aug 2020 (Day 9), showed BI-RADS of 4 for the left breast and BI-RADS of 1 for the right breast. On 20 Jan 2020, a diagnostic biopsy of the left breast was performed and the report on 06 Feb 2020 showed fibrosis+ ductal ectasia+ atypical intraductal epithelial hyperplasia measuring 0.5 × 0.4 mm. On 29 Sep 2020 (Day 43), the subject underwent elective surgery for removal of left breast nodule. The procedure was performed without complications. The following medications were prescribed after surgery: cefalexin 500 mg every 6 hours (from 30 Sep 2020 to 04 Oct 2020) and metamizole sodium 500 mg once daily (from 30 Sep 2020 to 06 Oct 2020). The breast hyperplasia, considered an intermittent pre-existing condition, was resolved on 30 Sep 2020 (Day 44) and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the breast hyperplasia was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to breast nodule. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155.5 cm	67.9 kg	28.1 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Carpal tunnel syndrome	Carpal tunnel syndrome	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	18:32
2	BNT162b2	24SEP2020 (21)	09:34

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis	Acute cholecystitis with cholelithiasis	24OCT2020 (51)		28OCT2020 (55)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: gallstone	2	31	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411643, a 58-year-old white female with no pertinent medical history, received Dose 1 on 04 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 21). The subject was diagnosed with cholecystitis on 24 Oct 2020, 30 days after receiving Dose 2. Concomitant medication reported within 2 weeks prior to the onset of cholecystitis included benfotiamine (since Mar 2020) for carpal tunnel syndrome. On 24 Oct 2020 (Day 51), the subject went to the emergency room with discreet abdominal pain, fever, jaundice, and dark urine. She was hospitalized for further evaluation of hyperbilirubinemia and increased transaminases. An abdominal ultrasound showed cholelithiasis and the subject was started on ceftriaxone and metronidazole from 25 Oct 2020 until 28 Oct 2020. On 26 Oct 2020 (Day 53), a laparoscopy was performed with a surgical description that included few adherences and mild edema of the gallbladder wall. Blood samples were taken for serological analysis of hepatitis B and C, both of which showed negative results. The abnormal pain, fever, jaundice (hyperbilirubinemia), dark urine, and increased transaminases were considered due to acute cholecystitis with cholelithiasis. Additional treatment included cefuroxime at 500 mg every 12 hours, metronidazole 500 mg every 8 hours, and ondansetron hydrochloride at 4 mg every 8 hours (all from 28 Oct 2020 to 02 Nov 2020). On 28 Oct 2020 (Day 55), the cholecystitis was considered resolved and the subject was discharged from the hospital. The subject did not undergo COVID-19 testing during hospitalization. In the opinion of the investigator, there was no reasonable possibility that the cholecystitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	81.3 kg	28.5 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	DEC2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17SEP2020 (1)	15:31
2	BNT162b2	08OCT2020 (22)	16:14

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	BLOOD	Hypochromic anaemia	HYPOCHROMIC ANEMIA / MICROCYTIC	04NOV2020 (49)		ONGOING			1	N
2	INFEC	Pyelonephritis acute	ACUTE PYELINEPHRITIS	02NOV2020 (47)		ONGOING			2	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Yes	NOT RELATED/OTHER: ANEMIA TO BE CLARIFIED	2	28	N
2	Y	Yes	NOT RELATED/OTHER: POSSIBLE BACTERIA URINARY TRACT INFECTION	2	26	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	09NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411825, a 56-year-old multiracial male with no pertinent medical history, received Dose 1 on 17 Sep 2020 and Dose 2 on 08 Oct 2020 (Day 22). The subject was diagnosed with acute pyelonephritis on 02 Nov 2020, 25 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the acute pyelonephritis included ramipril and hydrochlorothiazide (both since Dec 2018) for systemic arterial hypertension. On 04 Nov 2020 (Day 49), the subject went to the emergency room with lumbar pain, dysuria, and fever between 38.5C° and 39.0C° and was subsequently hospitalized for acute pyelonephritis. The subject's laboratory tests and procedures on 04 Nov 2020 (Day 49) showed a white blood cell count of 16.100, C-reactive protein (CRP) at 121 (units and normal ranges not available); a computed tomography of the abdomen showed inflammatory process/infections. The subject's CRP was 207 and 129 (unit and normal range not available) on 06 Nov 2020 (Day 51) and 07 Nov 2020 (Day 52), respectively. The subject was treated with ceftriaxone at 2 g intravenous once daily (from 04 Nov 2020 to 08 Nov 2020), cefuroxime at 250 mg orally (PO) every 12 hours (since 09 Nov 2020), and metamizole sodium at 1 g PO once (on 04 Nov 2020) for fever. On 08 Nov 2020 (Day 53), the subject was discharged from the hospital. The acute pyelonephritis was ongoing at the time of the last available report. A COVID-19 test was not performed during the hospitalization. In the opinion of the investigator, there was no reasonable possibility that the acute pyelonephritis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was due to possible bacterial urinary tract infection. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	78.5 kg	28.8 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic tension headache	Tension headache	1970	Present
Hemorrhoidal disease	Haemorrhoids	1980	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2000	Present
Systemic arterial hypertension	Hypertension	2005	Present
Allergic rhinitis	Rhinitis allergic	2005	Present
carotid atherosclerotic disease	Carotid arteriosclerosis	2015	Present
dyslipidemia	Dyslipidaemia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15OCT2020 (1)	08:54
2	BNT162b2	06NOV2020 (23)	09:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	Disorientation	Disorientation to clarify	09NOV2020 (26)		12NOV2020 (29)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (12NOV2020)	NOT RELATED/OTHER: to clarify	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1241 12412191, a 65-year-old white male with a pertinent medical history of systemic arterial hypertension (since 2005), dyslipidemia and carotid arteriosclerotic disease (both since 2015), received Dose 1 on 15 Oct 2020 and Dose 2 on 06 Nov 2020 (Day 23). The subject experienced disorientation on 09 Nov 2020, 3 days after receiving Dose 2.

Concomitant medications reported within 2 weeks prior to the onset of the disorientation included omeprazole (since 2000) for gastroesophageal reflux disease, losartan and hydrochlorothiazide (both since 2005) for systemic arterial hypertension, and rosuvastatin (since 2015) for dyslipidemia.

On 09 Nov 2020 (Day 26), the subject experienced dizziness, vomiting, disorientation, and transitional global amnesia and visited the hospital. A computerized tomogram scan of the head without contrast did not show hemorrhagic or ischemic injuries and a chest tomography without contrast showed unspecific ground-glass opacity that might be lungs in expiration. Possible diagnoses were COVID-19, ischemic cerebrovascular disease, or viral meningoencephalitis. On 10 Nov 2020 (Day 27), the result from a SARS-CoV-2 naso-oropharyngeal self-swab reverse transcription polymerase chain reaction test was reported as “not detected”. On 12 Nov 2020 (Day 29), the disorientation was considered resolved and the subject was discharged in good condition.

In the opinion of the investigator, there was no reasonable possibility that the disorientation was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator’s causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	87.05 kg	32.4 kg/m2	29SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy Penicillin	Drug hypersensitivity	1964	Present
Allergy sulfas	Drug hypersensitivity	1964	Present
Hypertension	Hypertension	2008	Present
Vasectomy	Vasectomy	2012	Past
Intermittent headache	Headache	MAY2016	Present
Vision impairment	Visual impairment	MAY2017	Present
Hypercholesterolemia	Hypercholesterolaemia	DEC2018	Present
Depression-stable	Depression	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29SEP2020 (1)	10:40
2	BNT162b2	20OCT2020 (22)	13:11

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Chest pain	Chest pain	10NOV2020 (43)		12NOV2020 (45)		3	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (12NOV2020)	NOT RELATED/OTHER: Hypercholesterolemia and hypertension medical history	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1246 12461035, a 59-year-old white male with a pertinent medical history of hypertension (since 2008) and hypercholesterolemia (since Dec 2018), received Dose 1 on 29 Sep 2020 and Dose 2 on 20 Oct 2020 (Day 22). The subject reported chest pain on 10 Nov 2020, 21 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the chest pain included codeine phosphate/ibuprofen/paracetamol (since May 2016) for headache, and escitalopram oxalate (since Aug 2019) for depression; rosuvastatin calcium (since Dec 2018) for hypercholesterolemia; indapamide/perindopril erbumine (since Dec 2018) for hypertension. On 10 Nov 2020 (Day 43), the subject had a routine evaluation and developed chest pain during a stress electrocardiogram. On 11 Nov 2020 (Day 44), the subject was admitted to the hospital for a coronary angiogram, which confirmed no obstructive disease and minimal luminal irregularities of the circumflex artery. On 12 Nov 2020 (Day 45), a gastroscopy was performed and a hiatus hernia with reflux esophagitis was diagnosed. Rosuvastatin dose was increased to 20 mg daily to prevent progression of arteriosclerosis and commenced on acetylsalicylic acid 100 mg daily and esomeprazole magnesium 40 mg daily. On the same day (Day 45), the chest pain resolved and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the chest pain was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a medical history of hypercholesterolemia and hypertension. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	74	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	119.3 kg	36.8 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin/Sulfa Hives	Urticaria	2010	Present
Stroke	Cerebrovascular accident	2014	Present
Arthritis	Arthritis	2015	Present
Hypertension	Hypertension	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	15:41
2	Placebo	21OCT2020 (41)	13:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Cerebrovascular accident	Mild Stroke	23SEP2020 (13)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: Atherosclerotic cardiovascular disease	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1248 12481120, a 74-year-old black/African American female with a pertinent medical history of cerebrovascular accident (since 2014) and hypertension (since 2017), received Dose 1 on 11 Sep 2020 and Dose 2 on 21 Oct 2020 (Day 41). The subject was diagnosed with a cerebrovascular accident on 23 Sep 2020, 12 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the cerebrovascular accident included acetylsalicylic acid (since 2016) for prevention, lisinopril and amlodipine (both since 2017) for hypertension, and vitamin D3 (since 2020) as a supplement. On 23 Sep 2020 (Day 13) the subject was sleepy and incoherent and was admitted to the hospital for a cerebrovascular accident. At the time of admission, the subject tested negative for COVID-19. A cardiac catheterization was scheduled on 28 Sep 2020 (Day 18), but it was later cancelled because the subject tested positive for SARS-CoV-2 on 27 Sep 2020 (Day 17) although she was asymptomatic. The subject was discharged from the hospital on 29 Sep 2020 (Day 19). The cerebrovascular accident was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the cerebrovascular accident was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to atherosclerotic cardiovascular disease. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.5 cm	56.2 kg	22.4 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High Cholesterol	Blood cholesterol increased	2015	Present
Seasonal Allergy	Seasonal allergy	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	16:38
2	Placebo	05OCT2020 (22)	14:47

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Brain abscess	Brain abscess	10OCT2020 (27)		ONGOING			4
2	NERV	Headache	Headache (R sided headache around R eye)	03OCT2020 (20)		05OCT2020 (22)		3	1
3	INFEC	Sinusitis	Sinusitis	10OCT2020 (27)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Yes	NOT RELATED/OTHER: Sinusitis / blocked sinuses	2	6	Y
2	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: Headache	1	20	N
3	TCN	N	Yes	NOT RELATED/OTHER: Sinusitis/Blocked Sinuses	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1248 12481163, a 74-year-old white female with no pertinent medical history, received Dose 1 on 14 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 22). The subject was diagnosed with a brain abscess on 10 Oct 2020, 5 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the brain abscess included atorvastatin (since 2015) for high cholesterol, alendronate sodium (since 04 Oct 2020) for osteoporosis, and acetylsalicylic acid (since an unknown date) for sinus headache. On 03 Oct 2020 (Day 20), the subject experienced right-sided headache around the right eye. The subject's primary care physician prescribed antibiotics. On 05 Oct 2020 (Day 22), the headache resolved. On 10 Oct 2020 (Day 27), the subject presented to the emergency room, where a computerized tomogram of the head showed blocked sinuses and a brain abscess which confirmed the diagnosis of sinusitis and brain abscess. The brain abscess was surgically drained on 11 Oct 2020 (Day 28). A culture was positive for an unknown organism. The subject remained hospitalized, and the brain abscess and sinusitis were ongoing at the time of the last available report. The brain abscess was considered to be life-threatening by the investigator. In the opinion of the investigator, there was no reasonable possibility that the brain abscess was related to the study intervention or concomitant medications, but rather it was related to sinusitis/blocked sinuses. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	105.45 kg	33.3 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tubal Ligation	Female sterilisation	27FEB1992	Past
Chronic Hepatitis C	Chronic hepatitis C	2009	Present
Hypertension	Hypertension	2010	Present
depression	Depression	2018	Present
Post menopausal	Postmenopause	17OCT2018	Present
R Ankle pain	Arthralgia	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	09:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Hypertension	exacerbation of hypertension	04SEP2020 (11)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: environmental factors, psychiatric factors	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	03NOV2020	PHYSICIAN DECISION
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1251 12511050, a 56-year-old black or African American female with a pertinent medical history of chronic hepatitis C (since 2009), hypertension (since 2010), depression (since 2018), and postmenopausal (since 17 Oct 2018), received Dose 1 on 25 Aug 2020. The subject reported an exacerbation of hypertension on 04 Sep 2020, 10 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the exacerbation of hypertension included amlodipine, hydrochlorothiazide, and metoprolol (all since 2017) for hypertension; ibuprofen and hydrocodone (both since Mar 2020) for right ankle pain; and duloxetine hydrochloride (since Mar 2020) for depression. On 04 Sep 2020 (Day 11), the subject was moving to a new home and was not feeling well. She presented to the emergency room (ER) with an elevated blood pressure (BP); her BP in the ER was 213/133 mmHg. On that same day (Day 11), the subject was hospitalized for observation and she continued treatment with amlodipine, hydrochlorothiazide, and metoprolol. During the admission, the subject reported a history of depression with no prior hospitalization. On 10 Sep 2020 (Day 17), the subject was discharged from the hospital and her BP at the time of discharge was 154/93 mmHg. The exacerbation of hypertension was reported to be ongoing at the time of the last available report. The subject was discontinued from the study intervention on 03 Nov 2020 because of the physician's decision and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exacerbation of hypertension was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to environmental and psychiatric factors. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	69.18 kg	23.5 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
colon cancer	Colon cancer	2010	Past
S/P Colostomy	Colostomy	2010	Past
Hyperlipidemia	Hyperlipidaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	10:23
2	BNT162b2	22SEP2020 (22)	09:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Injection site pain	Soreness at injection site	23SEP2020 (23)	03:30	24SEP2020 (24)	08:00	2	1
2	GENRL	Injection site pain	soreness at injection site	02SEP2020 (2)	04:00	04SEP2020 (4)	04:00	3	1
3	GASTR	Small intestinal obstruction	small bowel obstruction	29OCT2020 (59)		05NOV2020 (66)		8	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N
2	N	N	Resolved (04SEP2020)	Study Treatment	1	2	N
3	TC/TCN	Y	Resolved (05NOV2020)	NOT RELATED/OTHER: small bowel obstruction	2	38	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1260 12601037, a 71-year-old white male with a pertinent medical history of colon cancer and a proctocolectomy with right ileostomy (in 2010), hyperlipidemia (since 2019), and small bowel obstruction (in May 2020), received Dose 1 on 01 Sep 2020 and Dose 2 on 22 Sep 2020 (Day 22). The subject was diagnosed with small intestinal obstruction on 29 Oct 2020, 37 days after receiving Dose 2. On 29 Oct 2020 (Day 59), at 0400 hours, the subject was not feeling well; he emptied his ostomy bag and began to experience light cramping that worsened over the course of the day. He presented to the emergency room (ER) with intense non-radiating abdominal pain and tenderness in his left lower quadrant/suprapubic region. The subject was nauseous during the day and had 1 episode of vomiting, but he had no chills, fever, headache, shortness of breath, or chest pain. In the ER, the subject was treated with an intravenous (IV) pain medication. His temperature was 99ºF and blood lactate was high at 2.1 mmol/L (normal range not reported). On 29 Oct 2020 (Day 59), a SARS-CoV-2 test was negative and a computed tomography of the abdomen and pelvis with IV contrast showed a possibly closed loop bowel obstruction in the lower pelvis with small bowel ileus seen proximal to the obstruction. The subject reported that the pain was worse than the previous small bowel obstruction that occurred in May 2020. Subsequently, the subject was hospitalized, and a surgical intervention was scheduled. On 31 Oct 2020 (Day 61), an abdominal exploration revealed 18 inches of necrotic bowel within the pelvis and a loop of small bowel twisted around itself with a piece of scar tissue in the bowel. The scar tissue was cut, bowel was unraveled, necrotic bowel was removed and an anastomosis was created, followed by abdominal irrigation and skin closure with staples. The subject reported that he had COVID-19 symptoms (no further details reported) on 01 Nov 2020 (Day 62). On 05 Nov 2020 (Day 66), the small intestinal obstruction was considered to be resolved and the subject was discharged with a prescription for home physical therapy. The subject was given apixaban for a new diagnosis of atrial fibrillation (non-serious adverse event) on discharge. In the opinion of the investigator, there was no reasonable possibility that the small intestinal obstruction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	96.3 kg	34.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Former tobacco smoker	Ex-tobacco user	1965	Past
hypercholesteromia	Hypercholesterolaemia	2005	Present
hypertension	Hypertension	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	15:41
2	Placebo	24SEP2020 (21)	13:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Aortic aneurysm	abdominal aortic aneurysm	07OCT2020 (34)	01:09	ONGOING			2
2	INFEC	Appendicitis	acute appendicitis	05OCT2020 (32)		07OCT2020 (34)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: incidential finding on CT scan	2	14	N
2	TC/TCN	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: appendicitis	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccination	INFLUENZA VACCINE	07OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1260 12601069, a 71-year-old white male with a pertinent medical history of ex-tobacco user (in 1965; smoked 1.5 pack per day from age 16 to 50) and hypercholesterolemia and hypertension (both since 2005), received Dose 1 on 04 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 21). The subject was diagnosed with acute appendicitis on 05 Oct 2020, 11 days after receiving Dose 2. On 05 Oct 2020 (Day 32), the subject experienced constant and nonradiating lower quadrant abdominal pain which required an emergency room visit the following day (Day 33). The subject was afebrile, normotensive, and mildly tachycardic in the 100's. Laboratory results showed a white blood cell count of 18.2 × 103/mm3 (high) and sodium level of 131 mEq/L (both normal ranges not provided). On 07 Oct 2020 (Day 34), the subject reported that he felt nauseous and lost his appetite; his last bowel movement was normal in the morning and he denied having any other pain. A computed tomography of the abdomen and pelvis performed on the same day (Day 34) showed acute appendicitis without gross perforation or abscess, a 5.1 cm abdominal aortic aneurysm without rupture (which was considered a nonserious adverse event), and small gallstones. A SARS-CoV-2 test result was negative. The subject was hospitalized for acute appendicitis and on 07 Oct 2020 (Day 34), the subject underwent a laparoscopic appendectomy without any postoperative complications; the appendix was found to be gangrenous with pus. On the same day (Day 34), the appendicitis was considered resolved and the subject was discharged home with a prescription for amoxicillin 875 mg/clavulanic acid 275 mg twice a day as prophylaxis for 5 days. The aortic aneurysm was considered ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	92.9 kg	32.9 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hydrocele Repair	Hydrocele operation	15JUN2009	Past
vasectomy	Vasectomy	15JUN2013	Past
Rash to antibiotics of unclear type	Drug eruption	15JUN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	14:50
2	BNT162b2	17SEP2020 (22)	14:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Abscess	Lip Abscess	23SEP2020 (28)		01OCT2020 (36)		9	3
2	INFEC	Cellulitis	Lip cellulitis	23SEP2020 (28)		01OCT2020 (36)		9	3
3	GENRL	Chills	CHILLS - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1
4	IMMUN	Drug hypersensitivity	Hypersensitivity to antibiotics	26SEP2020 (31)		27SEP2020 (32)		2	3
5	NERV	Headache	HEADACHE - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1
6	MUSC	Myalgia	DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (01OCT2020)	NOT RELATED/OTHER: unrelated medical condition	2	7	Y
2	TC	Y	Resolved (01OCT2020)	NOT RELATED/OTHER: Unrelated medical condition	2	7	Y
3	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
4	TC	Y	Resolved (27SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	10	Y
5	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N
6	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1261 12611006, a 48-year-old white male with a pertinent medical history of drug eruption (rash to antibiotics of unclear type, since 15 Jun 2017), received Dose 1 on 27 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 22). The subject was diagnosed with an abscess and cellulitis on 23 Sep 2020, 6 days after receiving Dose 2 and drug hypersensitivity on 26 Sep 2020, 9 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the abscess, cellulitis, and drug hypersensitivity included loratadine (since 2010) for seasonal allergies and ibuprofen (since 2012) for musculoskeletal pain. On 23 Sep 2020 (Day 28), the subject attempted treating a lip abscess by pricking it with a needle at home. The subject's symptoms worsened and he went to the emergency department (ED). On arrival, he was afebrile, all other vital signs were normal, and he appeared nontoxic. The subject was noted to have a visible erythematous, indurated, swollen lesion of the left lower lip just below the vermilion border. A computerized tomogram (CT) scan confirmed a lip abscess measuring 2.0 cm × 0.9 cm × 1.8 cm with fluid left over in the lower lip; an extensive soft tissue edema involving the lower lip was observed, which was compatible with cellulitis and an abscess. Incision and drainage were performed. The subject was treated with a single dose of ceftriaxone 2 g intravenously (IV), single dose of vancomycin 1.75 mg, morphine sulfate 4 mg IV, and oxycodone 10 mg oral for pain. A wound culture was collected which subsequently grew pan-sensitive Staphylococcus aureus (moderate) and a white blood cell count was 10.5 k/µL (normal range: 3.8-11.0 k/µL). He tolerated the incision and drainage well and was discharged with instructions to complete a 7-day course of amoxicillin/clavulanic acid 875/125 mg 1 tablet twice a day (BID) and doxycycline 100 mg BID. The subject was also prescribed oxycodone/acetaminophen 5/325 mg for pain management. He remained in the ED for less than 24 hours. The cellulitis and abscess were considered as medically significant by the investigator. On 26 Sep 2020 (Day 31), the subject had "itching on his face and back" and symptoms worsened on 27 Sep 2020 (Day 32) with mild wheezing, a "scratchy throat", throat tightness, and upper chest/neck tightness requiring an ED visit. The subject was hospitalized for further treatment of hypersensitivity. He had a history of allergy to clindamycin and a family history of sulfa allergy. It was reported that this hypersensitivity reaction was due to doxycycline hyclate that was prescribed after the abscess drainage during the previous hospitalization. Treatment with doxycycline hyclate was stopped on 26 Sep 2020 (Day 31). The subject was treated with IV vancomycin, methylprednisolone 125 mg/vial, diphenhydramine 50 mg/mL, and famotidine 4 mg/4 mL. The drug hypersensitivity was considered resolved with treatment on 27 Sep 2020 (Day 32), and the subject was discharged on the same day. The subject was instructed to finish the previously prescribed course of amoxicillin/clavulanic acid upon discharge. On 01 Oct 2020 (Day 36), the abscess and cellulitis were considered resolved. In the opinion of the investigator, there was no reasonable possibility that the abscess and cellulitis were related to the study intervention, concomitant medications, or clinical trial procedures. Drug hypersensitivity was considered not related to the study intervention or clinical trial procedures, but rather it was related to the doxycycline. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149.9 cm	81 kg	36 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fallopian tube ligation	Female sterilisation	1998	Past
Irritable bowel syndrome	Irritable bowel syndrome	17JUN2004	Present
Syncope and collapse	Syncope	07OCT2005	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	10APR2006	Present
Chronic abdominal pain	Abdominal pain	17AUG2006	Present
Fatty liver	Hepatic steatosis	18OCT2006	Present
Major depressive disorder, recurrent episode	Major depression	25JAN2007	Present
Single seizure, unspecified type	Seizure	05JUN2007	Past
Sinus tachycardia	Sinus tachycardia	05JUN2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	02NOV2007	Present
Drug allergy - Nexium [Esomeprazole Magnesium]	Drug hypersensitivity	17JAN2008	Present
Generalized anxiety disorder	Generalised anxiety disorder	28FEB2008	Present
Bipolar 1 disorder, mixed, moderate	Bipolar I disorder	26JAN2010	Present
Overactive bladder	Hypertonic bladder	06AUG2010	Present
Colonoscopy with biopsy	Biopsy colon	15NOV2010	Past
Obesity	Obesity	13APR2011	Present
Diabetes mellitus, type 2	Type 2 diabetes mellitus	26MAY2011	Present
Peripheral neuropathy	Neuropathy peripheral	03MAY2013	Present
Dyslipidemia	Dyslipidaemia	27JUN2013	Present
Benign fasciculation cramp syndrome	Cramp-fasciculation syndrome	30AUG2013	Present
Laparoscopic hysterectomy	Hysterectomy	12DEC2013	Past
Laparascopic salpingectomy (bilateral)	Salpingectomy	12DEC2013	Past
Chronic kidney disease, stage 2	Chronic kidney disease	11FEB2014	Present
Colonoscopy with biopsy	Biopsy colon	08JUL2014	Past
Right blepharospasm	Blepharospasm	09OCT2014	Present
Gastroparesis	Impaired gastric emptying	31DEC2014	Present
Laparascopic lysis of intra-abdominal adhesion	Adhesiolysis	15MAY2015	Past
Diagnostic laparoscopy	Laparoscopy	15MAY2015	Past
Asthma	Asthma	16AUG2016	Present
Hypertension	Hypertension	19JAN2017	Present
Chronic pancreatitis	Pancreatitis chronic	19JAN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	12:02
2	Placebo	30SEP2020 (20)	11:53

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	Abdominal pain	25SEP2020 (15)		08OCT2020 (28)		14	2
2	PSYCH	Confusional state	Confusion/altered mental status	28SEP2020 (18)		29SEP2020 (19)		2	2
3	IMMUN	Hypersensitivity	Allergic reaction	30OCT2020 (50)		01NOV2020 (52)		3	1
4	METAB	Hypoglycaemia	Hypoglycemia	12SEP2020 (2)		13SEP2020 (3)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (08OCT2020)	NOT RELATED/OTHER: Suspected irritable bowel syndrome	1	15	N
2	N	N	Resolved (29SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	18	N
3	TC	N	Resolved (01NOV2020)	NOT RELATED/OTHER: None	2	31	N
4	TC	Y	Resolved (13SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flulaval Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	22OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1265 12651101, a 47-year-old white female with a family history of diabetes (father and grandmother) and a pertinent medical history of hepatic steatosis (since 18 Oct 2006), major depression (since 25 Jan 2007), generalized anxiety disorder (since 28 Feb 2008), bipolar I disorder (since 26 Jan 2010), obesity (since 13 Apr 2011), type 2 diabetes mellitus (since 26 May 2011), peripheral neuropathy (since 03 May 2013), dyslipidemia (since 27 Jun 2013), chronic kidney disease (since 11 Feb 2014), and chronic pancreatitis (since 19 Jan 2017), received Dose 1 on 11 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 20). The subject reported hypoglycemia on 12 Sep 2020, 1 day after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of hypoglycemia included fenofibrate (since 25 Sep 2012) for dyslipidemia; lisinopril (since 26 Feb 2013) for hypertension; methocarbamol (since 28 Jul 2014) for myofascial pain syndrome; metformin hydrochloride (since 17 Apr 2016), isophane insulin 50 IU twice a day (BID) and human insulin 40 IU BID (both from 23 Oct 2019 to 12 Sep 2020) for type 2 diabetes mellitus; pantoprazole sodium sesquihydrate (since 21 Oct 2019) for gastroesophageal reflux disease; ziprasidone (since 29 Jan 2020), duloxetine hydrochloride (since 01 Jul 2020) and lorazepam (since 04 Aug 2020) for generalized anxiety disorder, and trazodone hydrochloride (since 23 May 2020) for bipolar I disorder. On 12 Sep 2020 (Day 2), the subject was admitted to a hospital for hypoglycemia, her random blood glucose on admission was 14 mg/dL (normal range: 70 - 140 mg/dL). Following admission, it was noted that the subject was hypoglycemic because of not eating adequately. While in the hospital, the subject was treated with multiple doses of glucose drips (D50 and D10) and her sugars normalized. The subject's human insulin/human insulin injection/isophane doses were reduced to 35/25 units BID until she began eating normally again. On 13 Sep 2020 (Day 3), the hypoglycemia resolved (glucose level was 242 mg/dL) and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the hypoglycemia was related to the study intervention or clinical trial procedures, but rather it was related to concomitant medications: isophane insulin and human insulin. Pfizer did not concur with the investigator's assessment and assessed that there was no reasonable possibility that the hypoglycemia was related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	American Indian or Alaska	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.2 cm	107.7 kg	37.2 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Intermittent Asthma	Asthma	23MAR2017	Present
Allergic Rhinitis	Rhinitis allergic	23MAR2017	Present
Anal Skin Tag	Anal skin tags	21AUG2018	Present
Acne Vulgaris	Acne	16AUG2019	Present
Intermittent Sinus Headache	Sinus headache	25OCT2019	Present
Cyclothymic Disorder	Cyclothymic disorder	17APR2020	Present
Genital Herpes Simplex	Genital herpes simplex	30JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	11:52
2	BNT162b2	30SEP2020 (27)	15:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	APPENDICITIS	20SEP2020 (17)	21:00	22SEP2020 (19)	10:19	3
2	INV	Blood cholesterol increased	Elevated Cholesterol	08OCT2020 (35)	18:41	ONGOING		
3	INV	Low density lipoprotein increased	Elevated Low-Density Lipoprotein	08OCT2020 (35)	18:41	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (22SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	17	Y
2	1	TCN	N	Yes	NOT RELATED/OTHER: Unknown	2	9	N
3	1	TCN	N	Yes	NOT RELATED/OTHER: Unknown	2	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flulaval Quadrivalent 2020-2021 PF (Influenza Vaccine)	INFLUENZA VACCINE INACT SPLIT 4V	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1270 12701069, a 31-year-old American Indian or Alaska native female with no pertinent medical history, received Dose 1 on 04 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 27). The subject was diagnosed with appendicitis on 20 Sep 2020, 16 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the appendicitis included montelukast sodium (since 18 Sep 2018) for asthma and escitalopram oxalate (since 17 Apr 2020) for cyclothymic disorder. On 20 Sep 2020 (Day 17), the subject experienced abdominal pain associated with vomiting and diarrhea. On 21 Sep 2020 (Day 18), the subject visited the emergency room for evaluation of these symptoms. The pain was reported as intermittent, acute, generalized, and crampy, she denied fever, chills, chest pain, shortness of breath, syncope, lightheadedness, numbness, weakness, dysuria, hematuria, edema, or sore throat. A computerized tomogram of the abdomen and pelvis with contrast performed that day was consistent with mild acute appendicitis. On the same day (Day 18), a urinalysis showed bacteria 1/HPF, red blood cells 5/HPF, white blood cells 9/HPF, squamous cells (urinary sediment) 160/HPF, and ketones 80 mg/dL. Laboratory tests showed high blood potassium of 3.4 mEq/L and low carbon dioxide of 22 mEq/L (normal ranges not provided); a SARS-CoV-2 RNA qualitative reverse transcription-nucleic acid amplification test was negative. On 22 Sep 2020 (Day 19), the subject underwent appendectomy, the appendicitis resolved, and she was discharged home in stable condition. The pathological findings showed acute suppurative appendicitis negative for malignancy. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	60.4 kg	22.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Idiopathic thrombocytopenic purpura	Immune thrombocytopenia	01MAR2010	Past
left ovarian cyst	Ovarian cyst	10SEP2019	Past

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	21SEP2020 (1)	12:54
2	Placebo	04NOV2020 (45)	10:05

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	REPRO	Haemorrhagic ovarian cyst	Hemorrhagic cyst of the right ovary	21OCT2020 (31)		ONGOING			1
2	INJ&P	Procedural haemorrhage	Intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy	03OCT2020 (13)	07:30	07OCT2020 (17)	10:00	5	3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Yes	NOT RELATED/OTHER: Unknown	1	31	N
2	TC	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: Laparoscopic surgery	1	13	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44441007, a 35-year-old white female with a pertinent medical history of immune thrombocytopenia (from 01 Mar 2010 to 01 Dec 2010) and a left ovarian cyst (from 10 Sep 2019 to 03 Oct 2020), received Dose 1 on 21 Sep 2020 and Dose 2 on 04 Nov 2020 (Day 45). The subject had an intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy (procedural hemorrhage) on 03 Oct 2020, 12 days after receiving Dose 1. On 03 Oct 2020 (Day 13), the subject was hospitalized for a planned left ovarian cyst surgery. During the surgery, the subject experienced an intraoperative hemorrhage for which a drain was placed and caused her hemoglobin level to drop to 8.7 g/dL (normal range not reported). Bleeding did not recur and a blood transfusion was not required, the procedural hemorrhage was considered resolved on 07 Oct 2020 (Day 17), and the subject was discharged with a prescription for elemental iron 80 mg once daily (QD) and folic acid 1 mg QD for 14 days. The subject had a scheduled follow-up visit with her gynecologist on 16 Oct 2020 (Day 26; no further details provided). During Visit 2, the subject provided the histopathological laboratory reports for the ovarian cyst. The report had macroscopic findings of open and fragmented cystic formation (6×4.5 cm) with smooth and brownish-white surfaces and microscopic findings of ovarian parenchyma with a cystic wall formation lined by the endometrial epithelium. There were also sectors of hemorrhage and multiple deposits of macrophages with intracytoplasmic hemosiderin pigment which recognized ovarian parenchyma with follicular cyst. In the opinion of the investigator, there was no reasonable possibility that the procedural hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	53	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	87.3 kg	29.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	01MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	20:25
2	BNT162b2	12OCT2020 (22)	10:48

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1			Jammed Right inguinal hernia	05OCT2020 (15)	16:00	22OCT2020 (32)	15:00	18	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: complication of right inguinal hernia	1	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	11NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44441249, a 53-year-old white male with a pertinent medical history of right inguinal hernia (from an unknown date in 2010 to 05 Oct 2020), received Dose 1 on 21 Sep 2020 and Dose 2 on 12 Oct 2020 (Day 22). The subject was diagnosed with an incarcerated right inguinal hernia on 05 Oct 2020, 14 days after receiving Dose 1. Concomitant medication reported within 2 weeks prior to the onset of the incarcerated right inguinal hernia included metformin (unknown dose, since 01 Mar 2020) for type 2 diabetes mellitus. On 05 Oct 2020 (Day 15), the subject presented to the emergency room with pain in the right inguinal area. On the same day (Day 15), the subject was hospitalized for an incarcerated inguinal hernia, and an urgent hernioplasty was performed. On 06 Oct 2020 (Day 16), the subject was discharged with a prescription for amoxicillin and clavulanic acid 1 g 3 times a day. On 22 Oct 2020 (Day 32), the subject was seen by his surgeon and no further surgical interventions were required. On the same day (Day 32), the incarcerated right inguinal hernia was considered resolved. In the opinion of the investigator, there was no reasonable possibility that the incarcerated right inguinal hernia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	61 kg	24.1 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	03SEP2014	Present
Anxiety disorder	Anxiety disorder	14SEP2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	17:26
2	Placebo	14OCT2020 (22)	15:42

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Oesophageal food impaction	esophageal impaction with food	28SEP2020 (6)	21:00	29SEP2020 (7)	10:30	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: food impaction	1	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44441748, a 51-year-old white female with a pertinent medical history of hypertension (since Sep 2014) and anxiety disorder (since Sep 2017), received Dose 1 on 23 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 22). The subject experienced an esophageal food impaction on 28 Sep 2020, 5 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of the esophageal food impaction included enalapril (since Sep 2014) for arterial hypertension and clonazepam (since Sep 2017) for anxiety. On 28 Sep 2020 (Day 6), at 09:00 PM, the subject choked on her food (pumpkin peel) and subsequently experienced dysphagia and odynophagia. The subject self-induced vomiting and felt better. On 29 Sep 2020 (Day 7), the subject woke up at 02:00 AM due to severe odynophagia (10/10) and was admitted to the emergency room (ER). A neck x-ray was unremarkable. An esophagogastroduodenoscopy (upper endoscopy) was performed to retrieve the foreign body in the esophagus, which was successful and without complications. Mild superficial erosions were observed at the cricopharyngeal muscle level (20 cm from the dental superior arch) where the foreign body was retrieved. On that same day (Day 7), the esophageal food impaction was considered resolved and the subject was discharged from the ER at 10:30 AM. The esophageal food impaction was considered as an important medical event by the investigator. In the opinion of the investigator, there was no reasonable possibility that the esophageal food impaction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	102.27 kg	37.4 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ragweed Allergy	Seasonal allergy	1977	Present
Tree Pollen Allergy	Seasonal allergy	1977	Present
Glasses Wearer	Corrective lens user	1982	Present
Progressive Bifocals	Corrective lens user	2017	Present
Sleep Apnea	Sleep apnoea syndrome	2018	Present
Type II Diabetes	Type 2 diabetes mellitus	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	09:37
2	Placebo	21AUG2020 (22)	09:05

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31JUL2020 (1)	31JUL2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31JUL2020 (1)	31JUL2020 (1)	SERUM	NEGATIVE
Visit 2	21AUG2020 (22)	21AUG2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25SEP2020 (57)/ 25SEP2020 (57)/ 30SEP2020 (62)	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
COVID Illness Visit 2 / 06NOV2020 (99)/ 05NOV2020 (98)/ ONGOING	NO		Arthralgia
	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	25SEP2020 (57)	25SEP2020 (57)	NASAL_SWAB_SELF	NEGATIVE
2	COVID Illness Visit 2	06NOV2020 (99)	06NOV2020 (99)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	25SEP2020 (57)	25SEP2020 (57)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	06NOV2020 (99)	06NOV2020 (99)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE	RIT	ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	
2	NEGATIVE		OTHER	Unknown right now

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	25SEP2020 (57)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1003 10031122, a 48-year-old white male with a height of 165.1 cm, a weight of 102.27 kg, and a BMI of 37.4 kg/m2, received Dose 1 on 31 Jul 2020 and Dose 2 on 21 Aug 2020 (Day 22). The subject had a reported medical history of seasonal allergy (ragweed and tree pollen allergies; both since 1977), corrective lens user (glasses wearer since 1982; progressive bifocals since 2017), sleep apnea syndrome (since 2018), and type 2 diabetes mellitus (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported arthralgia, chills, fever, and new or increased cough, with the first symptom starting on 05 Nov 2020, 76 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 99) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 99) was negative. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	120.14 kg	33.9 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Erythromycin	Drug hypersensitivity	1990	Present
Allergy to Sulfa	Drug hypersensitivity	1990	Present
Obesity	Obesity	2005	Present
Bilateral Tinnitus Ears	Tinnitus	2005	Present
Chronic Migraines	Migraine	2006	Present
Intolerance to Hydrocodone Anxiety	Anxiety	2007	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	20FEB2009	Present
Hypogonadism	Hypogonadism	2010	Present
Bilateral Hearing Loss	Deafness bilateral	MAY2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	01MAR2011	Present
Obstructive Sleep Apnea	Sleep apnoea syndrome	19DEC2013	Present
Anxiety	Anxiety	13MAR2014	Present
Ocular Graves Disease	Basedow's disease	2015	Present
Intolerance to Percocet	Drug intolerance	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	10:02
2	Placebo	31AUG2020 (21)	08:52

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	11AUG2020 (1)	11AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11AUG2020 (1)	11AUG2020 (1)	SERUM	NEGATIVE
Visit 2	31AUG2020 (21)	31AUG2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06NOV2020 (88)/ 06NOV2020 (88)/ ONGOING	NO		Anosmia
	NO		Dizziness
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06NOV2020 (88)	06NOV2020 (88)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06NOV2020 (88)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061012, a 53-year-old white male with a height of 187.96 cm, a weight of 120.14 kg, and a BMI of 33.9 kg/m2, received Dose 1 on 11 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 21). The subject had a reported medical history of drug hypersensitivity (allergy to erythromycin and sulfa; both since 1990), obesity and tinnitus (both since 2005), migraine (since 2006), intolerance to hydrocodone anxiety (since 2007), gastroesophageal reflux disease (since 20 Feb 2009), hypogonadism (since 2010), deafness bilateral (since May 2010), hypothyroidism (since 01 Mar 2011), sleep apnea syndrome (since 19 Dec 2013), anxiety (since 13 Mar 2014), and Basedow's disease and drug intolerance (intolerance to Percocet) (both since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported anosmia, dizziness, headache, new or increased cough, new or increased muscle pain, and new or increased shortness of breath, with the first symptom starting on 06 Nov 2020, 67 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 88) was positive. No local laboratory SARS-CoV-2-NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	82.82 kg	26.5 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sulfa Allergy	Drug hypersensitivity	2000	Present
Chronic Migraine	Migraine	2001	Present
Asthma	Asthma	2003	Present
Acquired Hypothyroidism	Hypothyroidism	2003	Present
Left Thyroid Mass	Thyroid mass	2004	Present
Post-Surgical Pain Right Shoulder	Procedural pain	2009	Present
Right Shoulder Surgery	Shoulder operation	2009	Past
Anxiety	Anxiety	2017	Present
Depression	Depression	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	10:38
2	Placebo	14SEP2020 (27)	12:47

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	13OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (27)	14SEP2020 (27)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (85)/ 11NOV2020 (85)/ ONGOING	NO		Ear pain
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (85)	COVID-19	11NOV2020 (85)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	11NOV2020 (85)	11NOV2020 (85)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	11NOV2020 (85)	11NOV2020 (85)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	Quidel Sofia SARS Antigen FIA

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11NOV2020 (85)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061066, a 39-year-old white female with a height of 176.53 cm, a weight of 82.82 kg, and a BMI of 26.5 kg/m2, received Dose 1 on 19 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 27). The subject had a reported medical history of drug hypersensitivity (sulfa allergy; since 2000), migraine (since 2001), asthma and hypothyroidism (both since 2003), thyroid mass (since 2004), shoulder operation (in 2009), procedural pain (since 2009), and anxiety and depression (both since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 11 Nov 2020 (Day 85), the subject was diagnosed with COVID-19 and reported ear pain, fatigue, headache, new or increased cough, new or increased sore throat, and nasal congestion, with the first symptom starting on 11 Nov 2020, 58 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 85) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 85) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	66.18 kg	25.4 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	MAR2018	Present
Depression	Depression	MAR2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	16:45
2	Placebo	10SEP2020 (22)	17:01

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (22)	10SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 27OCT2020 (69)/ 27OCT2020 (69)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	27OCT2020 (69)	28OCT2020 (70)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	27OCT2020 (69)	27OCT2020 (69)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	INDETERM		LABCORP COVID-19 RT-PCR TEST	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	27OCT2020 (69)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061084, a 27-year-old white female with a height of 161.29 cm, a weight of 66.18 kg, and a BMI of 25.4 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had a reported medical history of anxiety and depression (both since Mar 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fever and new or increased cough with the first symptom starting on 27 Oct 2020, 47 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of COVID-19 illness on 28 Oct 2020 (Day 70) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 69) was reported as indeterminate. The subject went to her primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	20	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	99.55 kg	36.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	2006	Present
Obesity	Obesity	25JUL2014	Present
Polycystic Ovarian Syndrome	Polycystic ovaries	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	18:55
2	Placebo	11SEP2020 (22)	17:29

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (22)	11SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 01NOV2020 (73)/ 30OCT2020 (71)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	01NOV2020 (73)	COVID-19	30OCT2020 (71)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	01NOV2020 (73)	01NOV2020 (73)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	01NOV2020 (73)	30OCT2020 (71)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	CLIA-Certified Lab

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	01NOV2020 (73)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061091, a 20-year-old Asian female with a height of 165.1 cm, a weight of 99.55 kg, and a BMI of 36.4 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 22). The subject had a reported medical history of asthma (since 2006), obesity (since 25 Jul 2014), and polycystic ovaries (since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 30 Oct 2020 (Day 71), the subject was diagnosed with COVID-19 and reported new or increased cough, new or increased sore throat and nasal congestion, with the first symptom starting on 30 Oct 2020, 49 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Nov 2020 (Day 73) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 71) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	21	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.9 cm	147.05 kg	47.4 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BEE STING ALLERGY	Allergy to arthropod sting	2000	Present
MORBIDLY OBESE	Obesity	2000	Present
Hyperlipidemia	Hyperlipidaemia	23DEC2015	Present
Recurring nasal congestion	Nasal congestion	2016	Present
Elongated Uvula	Enlarged uvula	JUN2016	Present
Nasal Deviated Septum	Nasal septum deviation	JUN2016	Past
Nasal Turbinate Hypertrophy	Nasal turbinate hypertrophy	JUN2016	Present
Repair of Nasal Septum	Nasal septal operation	15DEC2016	Past
SLEEP APNEA	Sleep apnoea syndrome	JAN2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HIGH BLOOD PRESSURE	Hypertension	2018	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	13:57
2	Placebo	16SEP2020 (22)	12:46

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	26AUG2020 (1)	26AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	26AUG2020 (1)	26AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (22)	16SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 23OCT2020 (59)/ 20OCT2020 (56)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	23OCT2020 (59)	COVID-19 Infection	22OCT2020 (58)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	23OCT2020 (59)	23OCT2020 (59)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	23OCT2020 (59)	22OCT2020 (58)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	CLIA-certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	23OCT2020 (59)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061114, a 21-year-old white male with a height of 175.9 cm, a weight of 147.05 kg, and a BMI of 47.4 kg/m2, received Dose 1 on 26 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 22). The subject had a reported medical history of allergy to arthropod sting and obesity (both since 2000), hyperlipidemia (since 23 Dec 2015), nasal septum deviation (in Jun 2016), nasal septal operation (on 15 Dec 2016), nasal congestion (since 2016), enlarged uvula and nasal turbinate hypertrophy (both since Jun 2016), sleep apnea syndrome (since Jan 2017), and hypertension and seasonal allergy (both since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 22 Oct 2020 (Day 58), the subject was diagnosed with COVID-19 and reported new loss of taste or smell, new or increased cough, new or increased muscle pain, new or increased sore throat, and nasal congestion, with the first symptom starting on 20 Oct 2020, 34 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 23 Oct 2020 (Day 59) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Oct 2020 (Day 58) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	55	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	68.73 kg	25.2 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	2010	Present
Ampicillin Allergy	Drug hypersensitivity	2014	Present
Insomnia	Insomnia	2017	Present
Postmenopausal	Postmenopause	2019	Present
Rosacea of face	Rosacea	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	11:16
2	Placebo	01SEP2020 (22)	08:57

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	11AUG2020 (1)	11AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11AUG2020 (1)	11AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (22)	01SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (77)/ 22OCT2020 (73)/ 31OCT2020 (82)	NO		Eye pain
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Nasal dryness
	NO		Sneezing
	NO		Upper-airway cough syndrome

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (77)	26OCT2020 (77)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (77)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081011, a 55-year-old white female with a height of 165.1 cm, a weight of 68.73 kg, and a BMI of 25.2 kg/m2, received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 2010), drug hypersensitivity (ampicillin allergy since 2014), insomnia (since 2017), postmenopause (since 2019), and rosacea (since Mar 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported eye pain, new loss of taste or smell, nasal dryness, sneezing, and upper-airway cough syndrome, with the first symptom starting on 22 Oct 2020, 51 days after receiving Dose 2, and the last symptom resolved on 31 Oct 2020 (Day 82). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 77) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	147.09 kg	57.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sciatica	Sciatica	2003	Present
Tramadol Allergy	Drug hypersensitivity	2010	Present
Cipro Allergy	Drug hypersensitivity	2011	Present
Muscle spasm	Muscle spasms	2013	Present
Deep vein thrombosis	Deep vein thrombosis	2014	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2014	Present
Pulmonary embolism	Pulmonary embolism	2014	Past
Diabetes Type II	Type 2 diabetes mellitus	2014	Present
Chronic pain	Pain	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post traumatic stress disorder	Post-traumatic stress disorder	2015	Present
Anxiety	Anxiety	2016	Present
Depression	Depression	2016	Present
Hypertension	Hypertension	2018	Present
Hysterectomy	Hysterectomy	2018	Past
Uterine Fibroids	Uterine leiomyoma	2018	Past
High Cholesterol	Blood cholesterol increased	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	15:04
2	Placebo	09SEP2020 (24)	08:58

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	17AUG2020 (1)	17AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17AUG2020 (1)	17AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09SEP2020 (24)	09SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details

Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (87)/ 07NOV2020 (83)/ ONGOING	YES	CHILLS	
	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Pyrexia
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (87)	COVID 19	09NOV2020 (85)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11NOV2020 (87)	11NOV2020 (87)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11NOV2020 (87)	09NOV2020 (85)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11NOV2020 (87)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	SWABBED PER (b) (6) EMPLOYEE HEALTH

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081048, a 38-year-old white female with a height of 160.02 cm, a weight of 147.09 kg, and a BMI of 57.3 kg/m2, received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject had a reported medical history of sciatica (since 2003), drug hypersensitivity (tramadol allergy since 2010; cipro allergy since 2011), muscle spasms (since 2013), deep vein thrombosis and pulmonary embolism (both in 2014), gastroesophageal reflux disease and type 2 diabetes mellitus (both since 2014), pain and posttraumatic stress disorder (both since 2015), anxiety and depression (both since 2016), uterine leiomyoma and hysterectomy (both in 2018), hypertension (since 2018) and blood cholesterol increased (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 09 Nov 2020 (Day 85), the subject was diagnosed with COVID-19 and reported chills, fatigue, headache, new loss of taste or smell, new or increased cough, new or increased muscle pain, new or increased sore throat, nasal congestion, pyrexia, and rhinorrhea, with the first symptom starting on 07 Nov 2020, 59 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 87) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 85) was positive. The subject had an unspecified swab test done at (b) (6) employee health (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.93 cm	90 kg	34.2 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin allergy	Drug hypersensitivity	1969	Present
Sulfa allergy	Drug hypersensitivity	1969	Present
Demerol allergy	Drug hypersensitivity	1989	Present
Bilateral tubal ligation	Female sterilisation	1999	Past
Contact dermatitis	Dermatitis contact	2000	Present
Major depression	Major depression	OCT2006	Present
Uterine ablation	Endometrial ablation	2009	Past
High cholesterol	Blood cholesterol increased	MAY2012	Present
Morphine allergy	Drug hypersensitivity	2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	SEP2016	Present
Diabetes type II	Type 2 diabetes mellitus	SEP2016	Present
Restless leg syndrome	Restless legs syndrome	2017	Present
Sleep apnea	Sleep apnoea syndrome	2017	Present
Anemia	Anaemia	2018	Present
Chronic low back pain	Back pain	2018	Present
low back stenosis	Lumbar spinal stenosis	2018	Present
Vitamin D deficiency	Vitamin D deficiency	2018	Present
Back osteoarthritis	Spinal osteoarthritis	AUG2018	Present
Diabetic neuropathy	Diabetic neuropathy	2019	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	10:46
2	Placebo	16SEP2020 (20)	10:44

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (20)	16SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 23OCT2020 (57)/ 17OCT2020 (51)/ 29OCT2020 (63)	NO		Headache
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	23OCT2020 (57)	COVID 19	21OCT2020 (55)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	23OCT2020 (57)	23OCT2020 (57)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	23OCT2020 (57)	21OCT2020 (55)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	23OCT2020 (57)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging					
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify
1	COVID Illness Visit 1	23OCT2020 (57)	21OCT2020	CHEST	
2	COVID Illness Visit 1	23OCT2020 (57)	21OCT2020	CHEST	

Imaging				
Assessment Number	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	X-RAY	NA	NORMAL	
2	CT SCAN	NA	ABNORMAL	infiltrate posterior aspect left lower lobe, no acute pulmonary embolism

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081130, a 52-year-old white female with a height of 161.93 cm, a weight of 90 kg, and a BMI of 34.2 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject had a reported medical history of drug hypersensitivity (penicillin and sulfa allergies, both since 1969; Demerol, since 1989; morphine, since 2016); female sterilization (in 1999); dermatitis contact (since 2000); major depression (since Oct 2006); endometrial ablation (in 2009); blood cholesterol increased (since May 2012); hypertension and type 2 diabetes mellitus (both since Sep 2016); restless legs syndrome and sleep apnea syndrome (both since 2017); anemia, back pain, lumbar spinal stenosis, and vitamin D deficiency (all since 2018); spinal osteoarthritis (since Aug 2018); and diabetic neuropathy and gastroesophageal reflux disease (both since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 21 Oct 2020 (Day 55), the subject was diagnosed with COVID-19 and reported headache and new or increased shortness of breath, with the first symptom starting on 17 Oct 2020, 31 days after receiving Dose 2, and the last symptom resolved on 29 Oct 2020 (Day 63). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 23 Oct 2020 (Day 57) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 21 Oct 2020 (Day 55) was positive. The subject went to the emergency room (once). On 21 Oct 2020 (Day 55), a chest radiograph revealed normal findings and a computed tomographic pulmonary angiography of the chest showed infiltration in the posterior aspect of the left lower lobe and no acute pulmonary embolism.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	83.64 kg	25.7 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	2013	Past
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2016	Present
Bilateral lower extremity benign essential tremors	Essential tremor	2016	Present
Hypertension	Hypertension	2018	Present
High cholesterol	Blood cholesterol increased	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	12:07
2	Placebo	29SEP2020 (22)	10:23

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	29SEP2020 (22)	29SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (63)/ 09NOV2020 (63)/ ONGOING	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (63)	COVID 19	09NOV2020 (63)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (63)	09NOV2020 (63)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (63)	11NOV2020 (65)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (63)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081214, a 62-year-old white male with a height of 180.34 cm, a weight of 83.64 kg, and a BMI of 25.7 kg/m2, received Dose 1 on 08 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 22). The subject had a reported medical history of vasectomy (in 2013), benign prostatic hyperplasia and essential tremor (both since 2016), hypertension (since 2018), and blood cholesterol increased (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 09 Nov 2020 (Day 63), the subject was diagnosed with COVID-19 and reported fever, fatigue, headache, new or increased cough, new or increased muscle pain, and new or increased shortness of breath, with the first symptom starting on 09 Nov 2020, 41 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 63) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 65) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	65.91 kg	24.1 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	1975	Present
High cholesterol	Blood cholesterol increased	1981	Present
Tetracycline allergy	Drug hypersensitivity	1983	Present
Postmenopausal	Postmenopause	1994	Present
Osteopenia	Osteopenia	1995	Present
Hydrocodone allergy	Drug hypersensitivity	2016	Present
Tramadol allergy	Drug hypersensitivity	2016	Present
Right thigh basal cell carcinoma	Basal cell carcinoma	2017	Past
Chronic dry eyes	Dry eye	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right thigh basal cell carcinoma removal	Skin neoplasm excision	2017	Past
Left side of neck basal cell carcinoma removal	Skin neoplasm excision	JUN2020	Past
Left side of neck basal cell carcinoma	Basal cell carcinoma	JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	12:10
2	Placebo	05OCT2020 (22)	10:39

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	14SEP2020 (1)	14SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14SEP2020 (1)	14SEP2020 (1)	SERUM	NEGATIVE
Visit 2	05OCT2020 (22)	05OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06NOV2020 (54)/ 04NOV2020 (52)/ ONGOING	YES	CHILLS	
	NO		Dysphonia
	NO		Fatigue
	NO		Pyrexia
	NO		Rhinorrhoea
	NO		Throat irritation
	NO		Upper-airway cough syndrome

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06NOV2020 (54)	COVID 19	05NOV2020 (53)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	06NOV2020 (54)	06NOV2020 (54)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	06NOV2020 (54)	05NOV2020 (53)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06NOV2020 (54)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081319, a 79-year-old white female with a height of 165.1 cm, a weight of 65.91 kg, and a BMI of 24.1 kg/m2, received Dose 1 on 14 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 1975), blood cholesterol increased (since 1981), drug hypersensitivity (tetracycline allergy since 1983; hydrocodone and tramadol allergies, both since 2016), postmenopause (since 1994), osteopenia (since 1995), basal cell carcinoma and skin neoplasm excision (both in 2017), dry eyes (since 2017), skin neoplasm excision (in Jun 2020), and basal cell carcinoma (in Jul 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 05 Nov 2020 (Day 53), the subject was diagnosed with COVID-19 and reported chills, dysphonia, fatigue, pyrexia, rhinorrhea, throat irritation, and upper-airway cough syndrome, with the first symptom starting on 04 Nov 2020, 30 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 54) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 53) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
16JUL1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	91.82 kg	27.4 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Alopecia	Alopecia	2000	Present
High cholesterol	Blood cholesterol increased	2010	Present
Cardiac stent placement	Coronary arterial stent insertion	2010	Past
Hypertension	Hypertension	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	12:07
2	Placebo	07OCT2020 (22)	10:33

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16SEP2020 (1)	16SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16SEP2020 (1)	16SEP2020 (1)	SERUM	NEGATIVE
Visit 2	07OCT2020 (22)	07OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04NOV2020 (50)/ 31OCT2020 (46)/ 10NOV2020 (56)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	NO		Rhinorrhoea
	NO		Sinus congestion
	NO		Sneezing

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	04NOV2020 (50)	04NOV2020 (50)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	04NOV2020 (50)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1008 10081356, a 63-year-old white male with a height of 182.88 cm, a weight of 91.82 kg, and a BMI of 27.4 kg/m2, received Dose 1 on 16 Sep 2020 and Dose 2 on 07 Oct 2020 (Day 22). The subject had a reported medical history of alopecia (since 2000), coronary arterial stent insertion (in 2010), and blood cholesterol increased and hypertension (both since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported new loss of taste or smell, new or increased cough, rhinorrhea, sinus congestion, and sneezing, with the first symptom starting on 31 Oct 2020, 24 days after receiving Dose 2 and the last symptom resolved on 10 Nov 2020 (Day 56). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 50) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	102.64 kg	37.6 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	1990	Present
HYPOTHYROIDISM	Hypothyroidism	1998	Present
Back Pain	Back pain	2016	Present
Eczema	Eczema	JAN2016	Present
Erectile Dysfunction	Erectile dysfunction	30AUG2016	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present
HYPERTENSION	Hypertension	2019	Present
KEFLEX ALLERGY-HIVES	Urticaria	JAN2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PENICILLIN ALLERGY-HIVES	Urticaria	JAN2019	Present
GASTRIC BYPASS	Gastric bypass	JUN2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	11:09
2	Placebo	16SEP2020 (20)	10:48

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (20)	16SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19OCT2020 (53)/ 15OCT2020 (49)/ ONGOING	YES	CHILLS	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Productive cough

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	19OCT2020 (53)	COVID-19	16OCT2020 (50)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	19OCT2020 (53)	20OCT2020 (54)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	19OCT2020 (53)	16OCT2020 (50)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		LABCORP COVID-19 RT-PCR TEST	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19OCT2020 (53)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1009 10091128, a 51-year-old white male with a height of 165.1 cm, a weight of 102.64 kg, and a BMI of 37.6 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject had a reported medical history of obesity (since 1990); hypothyroidism (since 1998); back pain (since 2016); eczema (since Jan 2016); erectile dysfunction (since 30 Aug 2016); seasonal allergy (since 2018); hypertension (since 2019); urticaria (Keflex allergy-hives and penicillin allergy-hives, since Jan 2019); and gastric bypass (in Jun 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 16 Oct 2020 (Day 50), the subject was diagnosed with COVID-19 and reported chills, new loss of taste or smell, new or increased cough, new or increased muscle pain, new or increased shortness of breath, new or increased sore throat, and productive cough, with the first symptom starting on 15 Oct 2020, 29 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 20 Oct 2020 (Day 54) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 50) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
193 cm	115.9 kg	31.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CAT SCRATCH FEVER	Cat scratch disease	1977	Past
cholecystectomy	Cholecystectomy	1996	Past
GALLSTONES	Cholelithiasis	1996	Past
OBESITY	Obesity	2007	Present
SHINGLES FOREHEAD	Herpes zoster	APR2007	Past
SHINGLES RIGHT TEMPAL	Herpes zoster	APR2007	Past
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2017	Present
HYPERTENSION	Hypertension	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CARDIAC STENT PLACEMENT	Coronary arterial stent insertion	MAY2017	Past
ANXIETY	Anxiety	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	12:14
2	Placebo	15SEP2020 (23)	13:18

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (23)	15SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28SEP2020 (36)/ 25SEP2020 (33)/ 06OCT2020 (44)	YES	CHILLS	
	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28SEP2020 (36)	COVID-19	26SEP2020 (34)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28SEP2020 (36)	28SEP2020 (36)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	28SEP2020 (36)	26SEP2020 (34)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	CORONAVIRUS ANTIGEN/CLIA-certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28SEP2020 (36)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	28SEP2020 (36)	26OCT2020 (64)	Alkaline Phosphatase	1.03	ukat/L	0.57	1.73
			Alanine Aminotransferase	0.45009	ukat/L	0.11669	0.86684
			Aspartate Aminotransferase	0.31673	ukat/L	0.21671	0.65013
			Bilirubin	10.3	umol/L	5.1	17.1
			Creatinine	91.1	umol/L	61.9	114.9
			C Reactive Protein	2.1	mg/L	.	9.9
			Urea Nitrogen	5.71	mmol/L	2.5	8.93
		28SEP2020 (36)	Alkaline Phosphatase	1.18	ukat/L	0.57	1.73
			Alanine Aminotransferase	0.6668	ukat/L	0.11669	0.86684
			Aspartate Aminotransferase	0.58345	ukat/L	0.21671	0.65013
			Bilirubin	0.5	U/L	0.3	1
			Creatinine	92.8	umol/L	61.9	114.9
			C Reactive Protein	1.3	mg/L	0	9.9
			Urea Nitrogen	4.29	mmol/L	2.5	8.93

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	28SEP2020 (36)	26OCT2020 (64)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0.2	10^9/L	0	0.5
			Hematocrit	0.48	L/L	0.37	0.49
			Hemoglobin	150	g/L	126	167
			Lymphocytes	1.8	10^9/L	1	4.8
			Monocytes	0.3	10^9/L	0	0.8
			Platelets	217	10^9/L	139	361
			Erythrocytes	4.85	10^12/L	4	5.65
			Leukocytes	6.6	10^9/L	4.4	10.5
		28SEP2020 (36)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.49	L/L	0.37	0.49
			Hemoglobin	164	g/L	126	167
			Lymphocytes	1.9	10^9/L	1	4.8
			Monocytes	0.2	10^9/L	0	0.8
			Neutrophils	1.7	10^9/L	1.5	7.7
			Platelets	195	10^9/L	139	361
			Erythrocytes	5.26	10^12/L	4	5.65
			Leukocytes	3.8	10^9/L	4.4	10.5

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	28SEP2020 (36)	28SEP2020 (36)	1	120 mmHg	100 mmHg	17 breaths/min	78 beats/min	96 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1013 10131288, a 53-year-old white male with a height of 193 cm, a weight of 115.9 kg, and a BMI of 31.1 kg/m2, received Dose 1 on 24 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 23). The subject had a reported medical history of cat scratch disease (in 1977); cholelithiasis and cholecystectomy (both in 1996); obesity (since 2007); herpes zoster (shingles forehead and shingles right temple, in Apr 2007); hypercholesterolemia and hypertension (both since 2017); coronary arterial stent insertion (in May 2017); and anxiety (since Jun 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 26 Sep 2020 (Day 34), the subject was diagnosed with COVID-19 and reported chills, fatigue, new loss of taste or smell, new or increased cough, new or increased muscle pain, and new or increased shortness of breath, with the first symptom starting on 25 Sep 2020, 10 days after receiving Dose 2, and the last symptom resolved on 06 Oct 2020 (Day 44). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Sep 2020 (Day 36) was positive. The local laboratory SARS-CoV-2 “Coronavirus antigen” test result at the time of the COVID-19 illness on 26 Sep 2020 (Day 34) was positive. The subject had a telephone consultation (once) and had an urgent care visit (once). On 28 Sep 2020 (Day 36), the subject had a heart rate of 78 beats per minute, blood pressure of 120/100 mmHg, respiratory rate of 17 breaths per minute, and oxygen saturation of 96% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	49	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.5 cm	97 kg	30.1 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESE	Obesity	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	09:40
2	Placebo	30SEP2020 (22)	15:16

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	09SEP2020 (1)	09SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09SEP2020 (1)	09SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (22)	30SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (48)/ 22OCT2020 (44)/ 25OCT2020 (47)	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (48)	COVID-19	24OCT2020 (46)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (48)	26OCT2020 (48)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26OCT2020 (48)	24OCT2020 (46)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	RCA Laboratory Services LLC

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (48)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	GOVERNMENT TESTING CENTER

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	26OCT2020 (48)	26OCT2020 (48)	Alkaline Phosphatase	1.15	ukat/L	0.57	1.73
			Alanine Aminotransferase	0.21671	ukat/L	0.11669	0.86684
			Aspartate Aminotransferase	0.28339	ukat/L	0.21671	0.65013
			Bilirubin	6.8	umol/L	5.1	17.1
			Creatinine	89.3	umol/L	53	106.1
			C Reactive Protein	1	mg/L	.	9.9
			Urea Nitrogen	4.64	mmol/L	2.5	8.93

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	26OCT2020 (48)	26OCT2020 (48)	Hematocrit	0.46	L/L	0.34	0.46
			Hemoglobin	138	g/L	114	147
			Lymphocytes	38	%	20	44
			Monocytes	12	%	2	8
			Neutrophils	2.4	10^9/L	1.6	6
			Platelets	157	10^9/L	139	361
			Erythrocytes	4.6	10^12/L	3.75	5
			Leukocytes	4.8	10^9/L	4.4	10.5

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	26OCT2020 (48)	26OCT2020 (48)	1	140 mmHg	102 mmHg	16 breaths/min	90 beats/min	99 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1013 10131475, a 49-year-old white female with a height of 179.5 cm, a weight of 97 kg, and a BMI of 30.1 kg/m2, received Dose 1 on 09 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 22). The subject had a reported medical history of obesity (since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 24 Oct 2020 (Day 46), the subject was diagnosed with COVID-19 and reported fatigue, headache, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 22 Oct 2020, 22 days after receiving Dose 2, and the last symptom resolved on 25 Oct 2020 (Day 47). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 48) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 24 Oct 2020 (Day 46) was positive. The subject went to a government testing center (once). On 26 Oct 2020 (Day 48), the subject had a heart rate of 90 beats per minute, blood pressure of 140/102 mmHg, respiratory rate of 16 breaths per minute, and oxygen saturation of 99% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	23	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	64.18 kg	22.1 kg/m2	29JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
acne	Acne	JUN2010	Present
seasonal allergies	Seasonal allergy	MAR2015	Present
polyp on ovary	Ovarian neoplasm	JUN2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29JUL2020 (1)	11:32
2	Placebo	19AUG2020 (22)	09:52

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	29JUL2020 (1)	29JUL2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29JUL2020 (1)	29JUL2020 (1)	SERUM	NEGATIVE
Visit 2	19AUG2020 (22)	19AUG2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07AUG2020 (10)/ 05AUG2020 (8)/ 05AUG2020 (8)	YES	FEVER	

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 2 / 16OCT2020 (80)/ 14OCT2020 (78)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 2	16OCT2020 (80)	COVID-19	16OCT2020 (80)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	07AUG2020 (10)	07AUG2020 (10)	NASAL_SWAB_SELF	NEGATIVE
2	COVID Illness Visit 2	16OCT2020 (80)	16OCT2020 (80)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 2	16OCT2020 (80)	16OCT2020 (80)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	BD Verifor Plus AnalayerCLIA-certified Lab

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07AUG2020 (10)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	16OCT2020 (80)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	physician to children adolescents clinic

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29JUL2020	
Completed	VACCINATION	16SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161003, a 23-year-old white female with a height of 170.18 cm, a weight of 64.18 kg, and a BMI of 22.1 kg/m2, received Dose 1 on 29 Jul 2020 and Dose 2 on 19 Aug 2020 (Day 22). The subject had a reported medical history of acne (since Jun 2010), seasonal allergy (since Mar 2015), and ovarian neoplasm (in Jun 2016). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 16 Oct 2020 (Day 80), the subject was diagnosed with COVID-19 and reported chills, fever, headache, new loss of taste or smell, and new or increased cough, with the first symptom starting on 14 Oct 2020, 56 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 80) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 80) was positive. The subject went to a children-adolescent's clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	66.18 kg	24.2 kg/m2	29JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
over active bladder	Hypertonic bladder	JUN2014	Past
bladder repair	Bladder repair	OCT2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	11:33
2	BNT162b2	19AUG2020 (22)	16:36

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	29JUL2020 (1)	29JUL2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29JUL2020 (1)	29JUL2020 (1)	SERUM	NEGATIVE
Visit 2	19AUG2020 (22)	19AUG2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 21AUG2020 (24)/ 20AUG2020 (23)/ 17SEP2020 (51)	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nausea
	NO		Rhinorrhoea
COVID Illness Visit 2 / 17OCT2020 (81)/ 15OCT2020 (79)/ 22OCT2020 (86)	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	21AUG2020 (24)	21AUG2020 (24)	NASAL_SWAB_SELF	NEGATIVE
2	COVID Illness Visit 1	21AUG2020 (24)	08SEP2020 (42)	NASAL_SWAB	NEGATIVE
3	COVID Illness Visit 2	17OCT2020 (81)	17OCT2020 (81)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	21AUG2020 (24)	08SEP2020 (42)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	17OCT2020 (81)	17OCT2020 (81)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 2	17OCT2020 (81)	17OCT2020 (81)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		OTHER	CLIA Certified Gravity Dignositics

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
2	POSITIVE			
3	NEGATIVE		BD SARS-COV-2REAGENTS FOR BD MAX SYSTEM	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	21AUG2020 (24)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
COVID Illness Visit 2	17OCT2020 (81)	EMERGENCY ROOM	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		OTHER	YES	1	physician to children clinic

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29JUL2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	18SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161004, a 51-year-old white female with a height of 165.1 cm, a weight of 66.18 kg, and a BMI of 24.2 kg/m2, received Dose 1 on 29 Jul 2020 and Dose 2 on 19 Aug 2020 (Day 22). The subject had a reported medical history of hypertonic bladder (in Jun 2014) and bladder repair (in Oct 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported headache, new loss of taste or smell, new or increased sore throat, and nasal congestion, with the first symptom starting on 15 Oct 2020, 57 days after receiving Dose 2, and the last symptom resolved on 22 Oct 2020 (Day 86). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 17 Oct 2020 (Day 81) was positive. Two local laboratory SARS-CoV-2 NAAT results were obtained at the time of the COVID-19 illness on 17 Oct 2020 (Day 81), one was positive and the other was negative. The subject went to her primary care physician (once) and to a children's clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2001	18	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	66.18 kg	24.2 kg/m2	31JUL2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	12:34
2	Placebo	20AUG2020 (21)	15:11

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31JUL2020 (1)	31JUL2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31JUL2020 (1)	31JUL2020 (1)	SERUM	NEGATIVE
Visit 2	20AUG2020 (21)	20AUG2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09SEP2020 (41)/ 07SEP2020 (39)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09SEP2020 (41)	COVID-19	07SEP2020 (39)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09SEP2020 (41)	09SEP2020 (41)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09SEP2020 (41)	07SEP2020 (39)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		QUIDEL CORPORATION LYRA SARS-COV-2 ASSAY	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09SEP2020 (41)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	22SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161017, an 18-year-old white female with a height of 165.1 cm, a weight of 66.18 kg, and a BMI of 24.2 kg/m2, received Dose 1 on 31 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 21). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Sep 2020 (Day 39), the subject was diagnosed with COVID-19 and reported chills, fever, headache, new loss of taste or smell, and new or increased muscle pain, with the first symptom starting on 07 Sep 2020, 18 days after Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Sep 2020 (Day 41) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Sep 2020 (Day 39) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	57.45 kg	23.9 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral tubal ligation	Female sterilisation	SEP1983	Past
right ruptured disc	Intervertebral disc protrusion	SEP2004	Present
spinal cord stimulator insertion	Spinal nerve stimulator implantation	SEP2004	Present
seizures	Seizure	JUN2006	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	JUN2017	Present
hypercholesterolemia	Hypercholesterolaemia	DEC2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	10:20
2	Placebo	24AUG2020 (21)	10:06

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Gastrooesophageal reflux disease	Worsening of of Gastroesophageal Reflux Disease	09SEP2020 (37)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	N	Yes	NOT RELATED/OTHER: Gastroesophageal Reflux Disease	2	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	04AUG2020 (1)	04AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04AUG2020 (1)	04AUG2020 (1)	SERUM	NEGATIVE
Visit 2	24AUG2020 (21)	24AUG2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (88)/ 29OCT2020 (87)/ 29OCT2020 (87)	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30OCT2020 (88)	covid 19	30OCT2020 (88)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (88)	30OCT2020 (88)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30OCT2020 (88)	30OCT2020 (88)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		LABCORP COVID-19 RT-PCR TEST	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	30OCT2020 (88)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161035, a 70-year-old white female with a height of 154.94 cm, a weight of 57.45 kg, and a BMI of 23.9 kg/m2, received Dose 1 on 04 Aug 2020 and Dose 2 on 24 Aug 2020 (Day 21). The subject had a reported medical history of female sterilization (in Sep 1983); intervertebral disc protrusion and spinal nerve stimulator implantation (both since Sep 2004); seizure (in Jun 2006); gastroesophageal reflux disease (since Jun 2017); and hypercholesterolemia (since Dec 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 30 Oct 2020 (Day 88), the subject was diagnosed with COVID-19 and reported new or increased cough on 29 Oct 2020, 66 days after receiving Dose 2, that resolved on the same day (Day 87). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 88) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 88) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	92.18 kg	33.7 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tubal ligation	Female sterilisation	AUG1991	Past
seasonal allergies	Seasonal allergy	MAR1998	Present
anxiety	Anxiety	AUG1998	Present
carpal tunnel repair	Carpal tunnel decompression	JUN2008	Past
bladder repair	Bladder repair	JUN2010	Past
cholecystectomy	Cholecystectomy	JUN2010	Past
rotator cuff repair	Rotator cuff repair	FEB2012	Past
Hypertension	Hypertension	NOV2019	Present
Type 2 Diabetes	Type 2 diabetes mellitus	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	16:39
2	Placebo	24AUG2020 (21)	16:31

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04AUG2020 (1)	04AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04AUG2020 (1)	04AUG2020 (1)	SERUM	NEGATIVE
Visit 2	24AUG2020 (21)	24AUG2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 06NOV2020 (95)/ 06NOV2020 (95)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	06NOV2020 (95)	covid 19	06NOV2020 (95)	1	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	06NOV2020 (95)	06NOV2020 (95)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	06NOV2020 (95)	06NOV2020 (95)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	nest biothechnology CLIA certified

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	06NOV2020 (95)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	lincoln trial health department drive through clinic

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	21SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161048, a 52-year-old white female with a height of 165.1 cm, a weight of 92.18 kg, and a BMI of 33.7 kg/m2, received Dose 1 on 04 Aug 2020 and Dose 2 on 24 Aug 2020 (Day 21). The subject had a reported medical history of female sterilization (in Aug 1991), seasonal allergy (since Mar 1998), anxiety (since Aug 1998), carpal tunnel decompression (in Jun 2008), bladder repair and cholecystectomy (both in Jun 2010), rotator cuff repair (in Feb 2012), hypertension (since Nov 2019), and type 2 diabetes mellitus (since Jan 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Nov 2020 (Day 95), the subject was diagnosed with COVID-19 and reported new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 06 Nov 2020, 74 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 95) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 95) was positive. The subject went to the Lincoln Trail Health Department drive-through clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	94.09 kg	36.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety	Anxiety	JAN2017	Present
acid reflux	Gastrooesophageal reflux disease	JAN2017	Present
bilateral tubal ligation	Female sterilisation	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	16:20
2	Placebo	15SEP2020 (22)	10:27

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (22)	15SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16OCT2020 (53)/ 16OCT2020 (53)/ 01NOV2020 (69)	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	16OCT2020 (53)	COVID-19	23OCT2020 (60)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	16OCT2020 (53)	16OCT2020 (53)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 1 - Repeat Swab	23OCT2020 (60)	23OCT2020 (60)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	16OCT2020 (53)	23OCT2020 (60)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		QUIDEL CORPORATION LYRA SARS-COV-2 ASSAY	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	16OCT2020 (53)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161183, a 31-year-old white female with a height of 161.29 cm, a weight of 94.09 kg, and a BMI of 36.1 kg/m2, received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). The subject had a reported medical history of anxiety and gastroesophageal reflux disease (both since Jan 2017) and female sterilization (in 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 23 Oct 2020 (Day 60), the subject was diagnosed with COVID-19 and reported chills, diarrhea, fever, headache, new loss of taste or smell, new or increased cough, new or increased muscle pain, new or increased sore throat, and vomiting, with the first symptom starting on 16 Oct 2020, 31 days after receiving Dose 2, and the last symptom resolved on 01 Nov 2020 (Day 69). The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 16 Oct 2020 (Day 53) and 23 Oct 2020 (Day 60) were positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 23 Oct 2020 (Day 60) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	103.64 kg	37.4 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hysterectomy	Hysterectomy	1994	Present
thyroidectomy	Thyroidectomy	JUL2004	Present
irregular heart beat	Heart rate irregular	NOV2015	Present
environmental allergies	Hypersensitivity	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	16:32
2	Placebo	18SEP2020 (22)	09:38

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	18SEP2020 (22)	18SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16OCT2020 (50)/ 14OCT2020 (48)/ ONGOING	YES	CHILLS	
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	16OCT2020 (50)	covid-19	16OCT2020 (50)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	16OCT2020 (50)	16OCT2020 (50)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	16OCT2020 (50)	16OCT2020 (50)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		QUEST SARS-COV-2 RRT-PCR	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	16OCT2020 (50)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161207, a 62-year-old white female with a height of 166.37 cm, a weight of 103.64 kg, and a BMI of 37.4 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 22). The subject had a reported medical history of hysterectomy (in 1994); thyroidectomy (in Jul 2004); heart rate irregular (since Nov 2015); and hypersensitivity (since Jun 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 16 Oct 2020 (Day 50), the subject was diagnosed with COVID-19 and reported chills, fatigue, new or increased cough, new or increased muscle pain, new or increased sore throat, and nasal congestion with the first symptom starting on 14 Oct 2020, 26 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 50) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 50) was positive. The subject went to her primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	85 kg	28.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cold sores	Oral herpes	1980	Present
Bactrim allergy	Drug hypersensitivity	2008	Present
Uterine Ablation	Endometrial ablation	2013	Past
Seasonal Allergies	Seasonal allergy	2015	Present
Presbyopia	Presbyopia	JAN2020	Present
ear infection	Ear infection	10MAY2020	Past
benign Fluid cyst	Cyst	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	14:14
2	Placebo	11SEP2020 (22)	13:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (22)	11SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 05NOV2020 (77)/ 04NOV2020 (76)/ 05NOV2020 (77)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05NOV2020 (77)	05NOV2020 (77)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (77)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1018 10181198, a 50-year-old white female with a height of 172.72 cm, a weight of 85 kg, and a BMI of 28.4 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 22). The subject had a reported medical history of oral herpes (since 1980), drug hypersensitivity (Bactrim allergy, since 2008), endometrial ablation (in 2013), seasonal allergy (since 2015), presbyopia (since Jan 2020), ear infection (on 10 May 2020), and cyst (benign fluid cyst, since Jun 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fever, new or increased cough, and nasal congestion, with the first symptom starting on 04 Nov 2020, 54 days after receiving Dose 2 and the last symptom resolved on 05 Nov 2020 (Day 77). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 77) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	80.82 kg	32.5 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bunion left foot	Foot deformity	1993	Past
bunionectomy left foot	Bunion operation	1998	Past
Eczema	Eczema	1999	Present
Rosacea	Rosacea	1999	Present
Allergic rhinitis	Rhinitis allergic	2003	Present
Sinus Headaches	Sinus headache	2003	Past
Gestational diabetes	Gestational diabetes	FEB2003	Past
Gastric Ulcer	Gastric ulcer	NOV2005	Past
Hemorrhoids	Haemorrhoids	NOV2005	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Recurrent back pain	Back pain	APR2006	Past
Sulfa Allergy	Drug hypersensitivity	2008	Present
tubal Ligation	Female sterilisation	2011	Past
cholelithiasis	Cholelithiasis	2014	Past
Presbyopia	Presbyopia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	09:10
2	Placebo	04SEP2020 (22)	12:02

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	14AUG2020 (1)	14AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14AUG2020 (1)	14AUG2020 (1)	SERUM	NEGATIVE
Visit 2	04SEP2020 (22)	04SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (61)/ 11OCT2020 (59)/ 12OCT2020 (60)	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea
COVID Illness Visit 2 / 08NOV2020 (87)/ 03NOV2020 (82)/ ONGOING	YES	FEVER	
	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 2	08NOV2020 (87)	COVID-19	08NOV2020 (87)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	13OCT2020 (61)	14OCT2020 (62)	NASAL_SWAB_SELF	NEGATIVE
2	COVID Illness Visit 2	08NOV2020 (87)	09NOV2020 (88)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	13OCT2020 (61)	14OCT2020 (62)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	08NOV2020 (87)	08NOV2020 (87)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		OTHER	NALT Unknown
2	POSITIVE	unknown trade name	OTHER	Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	13OCT2020 (61)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	08NOV2020 (87)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1019 10191038, a 47-year-old white female with a height of 157.48 cm, a weight of 80.82 kg, and a BMI of 32.5 kg/m2, received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). The subject had a reported medical history of foot deformity (bunion left foot, in 1993), bunion operation (bunionectomy left foot, in 1998), eczema and rosacea (both since 1999), sinus headache (in 2003), rhinitis allergic (since 2003), gestational diabetes (in Feb 2003), gastric ulcer and hemorrhoids (both in Nov 2005), back pain (in Apr 2006), drug hypersensitivity (sulfa allergy, since 2008), female sterilization (in 2011), cholelithiasis (in 2014), and presbyopia (since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 08 Nov 2020 (Day 87), the subject was diagnosed with COVID-19 and reported fever, fatigue, new loss of taste or smell, and new or increased cough, with the first symptom starting on 03 Nov 2020, 60 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 88) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Nov 2020 (Day 87) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	111.86 kg	38 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Appendectomy	Appendicectomy	1976	Past
Appendicitis	Appendicitis	1976	Past
Allergic Rhinitis	Rhinitis allergic	1976	Present
Fractured Right fifth finger	Hand fracture	1985	Past
Vasectomy	Vasectomy	1997	Past
Recurrent back pain lumbar	Back pain	2000	Present
Lipoma right antecubital	Lipoma	2000	Present
Recurrent back pain cervical region	Neck pain	2000	Present
Right knee meniscus repair	Meniscus operation	2009	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right knee anterior cruciate ligament repair	Ligament operation	2010	Past
Numbness on first two fingers right	Hypoaesthesia	2012	Present
Hypercholesterolemia	Hypercholesterolaemia	2013	Present
Hypertension	Hypertension	2013	Present
Presbyopia	Presbyopia	2014	Present
Cervical Fusion	Spinal fusion surgery	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	09:45
2	Placebo	01OCT2020 (22)	07:54

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	10SEP2020 (1)	10SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	10SEP2020 (1)	10SEP2020 (1)	SERUM	NEGATIVE
Visit 2	01OCT2020 (22)	01OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (57)/ 05NOV2020 (57)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nausea
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	05NOV2020 (57)	COVID-19	05NOV2020 (57)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05NOV2020 (57)	05NOV2020 (57)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	05NOV2020 (57)	05NOV2020 (57)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (57)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1019 10191184, a 52-year-old white male with a height of 171.45 cm, a weight of 111.86 kg, and a BMI of 38 kg/m2, received Dose 1 on 10 Sep 2020 and Dose 2 on 01 Oct 2020 (Day 22). The subject had a reported medical history of appendicitis and appendectomy (both in 1976); rhinitis allergic (since 1976); hand fracture (fractured right fifth finger, in 1985); vasectomy (in 1997); back pain, lipoma (lipoma right antecubital), and neck pain (recurrent back pain cervical region) (all since 2000); meniscus operation (right knee meniscus repair, in 2009); ligament operation (right knee anterior cruciate ligament repair, in 2010); hypoesthesia (numbness in first 2 fingers right, since 2012); hypercholesterolemia and hypertension (both since 2013); presbyopia (since 2014); and spinal fusion surgery (in 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 05 Nov 2020 (Day 57), the subject was diagnosed with COVID-19 and reported new or increased cough, new or increased muscle pain, nausea, and vomiting, with the first symptom starting on 05 Nov 2020, 35 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 57) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 57) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.99 cm	143.73 kg	49 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic constipation	Constipation	1970	Present
irritable bowel syndrome-Constipation	Irritable bowel syndrome	1970	Present
herpes simplex	Herpes simplex	1976	Present
acne	Acne	1980	Present
menorrhagia	Menorrhagia	1981	Past
obesity	Obesity	1981	Present
pre-diabetes	Glucose tolerance impaired	1994	Present
hemorrhoids	Haemorrhoids	1994	Present
hypertension	Hypertension	1994	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cesarean section	Caesarean section	JUL1994	Past
red dye #40 allergy	Reaction to colouring	2000	Present
uterine fibroid	Uterine leiomyoma	AUG2015	Past
hysterectomy	Hysterectomy	25SEP2015	Past
colonoscopy	Colonoscopy	03JUN2019	Past
diverticulitis	Diverticulitis	03JUN2019	Present
heel spur, left	Exostosis	25JUL2019	Present
calcific Achilles tendonitis	Tendonitis	25JUL2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	10:28
2	Placebo	10SEP2020 (21)	15:34

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (21)	10SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (54)/ 10OCT2020 (51)/ 22OCT2020 (63)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	13OCT2020 (54)	COVID 19	13OCT2020 (54)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	13OCT2020 (54)	13OCT2020 (54)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	13OCT2020 (54)	13OCT2020 (54)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	13OCT2020 (54)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1028 10281038, a 53-year-old white female with a height of 170.99 cm, a weight of 143.73 kg, and a BMI of 49 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 21). The subject had a reported medical history of constipation and irritable bowel syndrome (both since 1970); herpes simplex (since 1976); acne (since 1980); menorrhagia (in 1981); obesity (since 1981); glucose tolerance impaired, hemorrhoids, and hypertension (all since 1994); caesarean section (in Jul 1994); reaction to coloring (red dye since 2000); uterine leiomyoma (in Aug 2015); hysterectomy (on 25 Sep 2015); colonoscopy (on 03 Jun 2019); diverticulitis (since 03 Jun 2019); and exostosis (left heel spur) and tendonitis (both since 25 Jul 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 13 Oct 2020 (Day 54), the subject was diagnosed with COVID-19 and reported fever, new or increased cough, new or increased sore throat, and rhinorrhea with the first symptom starting on 10 Oct 2020, 30 days after receiving Dose 2, and the last symptom resolved on 22 Oct 2020 (Day 63). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 54) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 54) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	59.73 kg	23.6 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1975	Past
TONSILITIS	Tonsillitis	1975	Past
Metal ALLERGY	Allergy to metals	1980	Present
Surgical glue ALLERGY	Dermatitis contact	1980	Present
Wisdom teeth extraction	Wisdom teeth removal	1992	Past
Endometriosis	Endometriosis	1997	Past
laparoscopy	Laparoscopy	2000	Past
Hysterectomy	Hysterectomy	2009	Past
laparoscopy	Laparoscopy	2009	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	OCT2010	Present
Depression	Depression	OCT2010	Present
Graves Disease	Basedow's disease	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	08:40
2	Placebo	23SEP2020 (22)	16:21

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	02SEP2020 (1)	02SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	02SEP2020 (1)	02SEP2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (22)	23SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (42)/ 11OCT2020 (40)/ ONGOING	YES	NEW OR INCREASED COUGH	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	13OCT2020 (42)	COVID-19	11OCT2020 (40)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	13OCT2020 (42)	13OCT2020 (42)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	13OCT2020 (42)	11OCT2020 (40)	SWABBED MATERIAL	LOWER RESPIRATORY SYSTEM	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13OCT2020 (42)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1028 10281100, a 47-year-old white female with a height of 158.75 cm, a weight of 59.73 kg, and a BMI of 23.6 kg/m2, received Dose 1 on 02 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 22). The subject had a reported medical history of tonsillitis and tonsillectomy (both in 1975); allergy to metals and dermatitis contact (both since 1980); wisdom teeth removal (in 1992); endometriosis (in 1997); laparoscopy (in 2000); hysterectomy (in 2009); laparoscopy (in 2009); anxiety and depression (both since Oct 2010); and Basedow's disease (since 2016). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 11 Oct 2020 (Day 40), the subject was diagnosed with COVID-19 and reported new or increased cough and rhinorrhea with the first symptom starting on 11 Oct 2020, 18 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 42) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Oct 2020 (Day 40) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.01 cm	89.73 kg	26.2 kg/m2	05SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
right clavicle fracture	Clavicle fracture	1972	Past
right clavicle fracture	Clavicle fracture	1975	Past
asthma	Asthma	1980	Present
squamous cell carcinoma left leg	Squamous cell carcinoma	1985	Past
hyperlipidemia	Hyperlipidaemia	1990	Present
actinic keratosis	Actinic keratosis	2010	Present
basal cell carcinoma left arm	Basal cell carcinoma	2010	Past
squamous cell carcinoma face	Squamous cell carcinoma	2010	Past
left inguinal hernia	Inguinal hernia	2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
right inguinal hernia	Inguinal hernia	2018	Past
bilateral inguinal hernia repair	Inguinal hernia repair	22JUN2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05SEP2020 (1)	10:43
2	Placebo	28SEP2020 (24)	14:45

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	05SEP2020 (1)	05SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	05SEP2020 (1)	05SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (24)	28SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (39)/ 11OCT2020 (37)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Wheezing

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	13OCT2020 (39)	COVID-19	13OCT2020 (39)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	13OCT2020 (39)	13OCT2020 (39)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	13OCT2020 (39)	13OCT2020 (39)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown- CLIA Certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	13OCT2020 (39)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1028 10281132, a 61-year-old white male with a height of 185.01 cm, a weight of 89.73 kg, and a BMI of 26.2 kg/m2, received Dose 1 on 05 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 24). The subject had a reported medical history of clavicle fracture (in 1972 and in 1975); asthma (since 1980); squamous cell carcinoma (left leg in 1985); hyperlipidemia (since 1990); basal cell carcinoma (left arm) and squamous cell carcinoma (face) (both in 2010); actinic keratosis (since 2010); inguinal hernia (right and left, both in 2018); and inguinal hernia repair (bilateral on 22 Jun 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 13 Oct 2020 (Day 39), the subject was diagnosed with COVID-19 and reported chills, fever, new or increased cough, new or increased muscle pain, new or increased sore throat, and wheezing with the first symptom starting on 11 Oct 2020, 13 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 39) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 39) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	73.27 kg	27.2 kg/m2	07SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
adenoidectomy	Adenoidectomy	1992	Past
tonsillectomy	Tonsillectomy	1992	Past
left bunionectomy	Bunion operation	1995	Past
bunion left foot	Foot deformity	1995	Past
nicotine addiction	Nicotine dependence	1998	Past
endometriosis	Endometriosis	2005	Past
tubal ligation	Female sterilisation	26JAN2009	Past
laparoscopy	Laparoscopy	15DEC2016	Past
partial right salpingectomy	Salpingectomy	15DEC2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
laparoscopic hysterectomy	Hysterectomy	10FEB2017	Past
bilateral salpingectomy	Salpingectomy	10FEB2017	Past
tailbone fracture	Fractured coccyx	01JAN2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07SEP2020 (1)	09:31
2	Placebo	29SEP2020 (23)	08:14

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccination	INFLUENZA VACCINE	21OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	07SEP2020 (1)	07SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07SEP2020 (1)	07SEP2020 (1)	SERUM	NEGATIVE
Visit 2	29SEP2020 (23)	29SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06OCT2020 (30)/ 06OCT2020 (30)/ 16OCT2020 (40)	YES	DIARRHEA	
	NO		Headache
	NO		Nasal congestion
	NO		Throat irritation
COVID Illness Visit 2 / 27OCT2020 (51)/ 23OCT2020 (47)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Rhinorrhoea
	NO		Sputum increased

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 2	27OCT2020 (51)	COVID 19	28OCT2020 (52)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	06OCT2020 (30)	06OCT2020 (30)	NASAL_SWAB_SELF	NEGATIVE
2	COVID Illness Visit 2	27OCT2020 (51)	27OCT2020 (51)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	06OCT2020 (30)	06OCT2020 (30)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	27OCT2020 (51)	23OCT2020 (47)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 2	27OCT2020 (51)	28OCT2020 (52)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		OTHER	NALT unknown CLIA certified lab
2	NEGATIVE		OTHER	NALT unknown, CLIA certified lab
3	POSITIVE		OTHER	NALT unknown. CLIA certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06OCT2020 (30)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	27OCT2020 (51)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1028 10281138, a 38-year-old white female with a height of 163.83 cm, a weight of 73.27 kg, and a BMI of 27.2 kg/m2, received Dose 1 on 07 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 23). The subject had a reported medical history of adenoidectomy and tonsillectomy (both in 1992); foot deformity and bunion operation (both in 1995); nicotine dependence (in 1998); endometriosis (in 2005); female sterilization (on 26 Jan 2009); laparoscopy and salpingectomy (both on 15 Dec 2016); hysterectomy and salpingectomy (both on 10 Feb 2017); and fractured coccyx (on 01 Jan 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 28 Oct 2020 (Day 52), the subject was diagnosed with COVID-19 and reported chills, diarrhea, fever, new or increased sore throat, nasal congestion, rhinorrhea, and sputum increased, with the first symptom starting on 23 Oct 2020, 24 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 51) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Oct 2020 (Day 52) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	83.5 kg	27.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	1968	Present
ALLERGY TO PENACILLIN	Drug hypersensitivity	1975	Present
DIABETES MELLITUS TYPE TWO	Type 2 diabetes mellitus	31OCT1990	Present
ARTHRITIS	Arthritis	2007	Present
LOWER BACK PAIN	Back pain	03DEC2010	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2014	Present
HYPERLIPIDEMIA	Hyperlipidaemia	JUN2015	Present
HYPERTENSION	Hypertension	JUN2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	14:39
2	Placebo	10SEP2020 (22)	13:20

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (22)	10SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04NOV2020 (77)/ 31OCT2020 (73)/ ONGOING	YES	CHILLS	
	NO		Decreased appetite
	YES	FEVER	
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04NOV2020 (77)	COVID 19	05NOV2020 (78)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	04NOV2020 (77)	05NOV2020 (78)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	04NOV2020 (77)	05NOV2020 (78)	RESPIRATORY SECRETIONS	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	04NOV2020 (77)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1037 10371036, a 62-year-old black or African American male with a height of 175.3 cm, a weight of 83.5 kg, and a BMI of 27.2 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 1968), drug hypersensitivity (allergy to penicillin, since 1975), type 2 diabetes mellitus (since 31 Oct 1990), arthritis (since 2007), back pain (lower back pain, since 03 Dec 2010), gastroesophageal reflux disease (since 2014), and hyperlipidemia and hypertension (both since Jun 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 05 Nov 2020 (Day 78), the subject was diagnosed with COVID-19 and reported chills, decreased appetite, fever, fatigue, new or increased cough, and nasal congestion, with the first symptom starting on 31 Oct 2020, 51 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 78) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 78) was positive. The subject had a telephone consultation (once) and went to his primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	124.1 kg	39.2 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GOUT	Gout	JAN1995	Present
OBESITY	Obesity	2000	Present
CERVICAL DISC RUPTURE	Intervertebral disc protrusion	MAY2008	Past
C4-C5CERVICAL FUSION	Spinal fusion surgery	MAY2008	Past
HYPERTENSION	Hypertension	JAN2010	Present
DIABETES MELLITUS TYPE 2	Type 2 diabetes mellitus	JAN2010	Present
SULFA ALLERGY	Drug hypersensitivity	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	10:50
2	Placebo	14OCT2020 (22)	11:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	23SEP2020 (1)	23SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23SEP2020 (1)	23SEP2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (22)	14OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (50)/ 10NOV2020 (49)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (50)	Covid 19	11NOV2020 (50)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	11NOV2020 (50)	11NOV2020 (50)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	11NOV2020 (50)	11NOV2020 (50)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE	Records pending, verbal report	OTHER	NATL UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11NOV2020 (50)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA
		OTHER	YES	1	CNS Healthcare

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	11NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1037 10371280, a 58-year-old white male with a height of 178 cm, a weight of 124.1 kg, and a BMI of 39.2 kg/m2, received Dose 1 on 23 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 22). The subject had a reported medical history of gout (since Jan 1995), obesity (since 2000), intervertebral disc protrusion and spinal fusion surgery (both in May 2008), hypertension and type 2 diabetes mellitus (both since Jan 2010), and drug hypersensitivity (sulfa allergy, since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 11 Nov 2020 (Day 50), the subject was diagnosed with COVID-19 and reported chills, fever, fatigue, headache, new or increased cough, and new or increased muscle pain, with the first symptom starting on 10 Nov 2020, 27 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 50) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 50) was positive. The subject had a telephone consultation (once) and an urgent care visit (once) and went to CNS Healthcare (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	111.73 kg	36.3 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Pain Syndrome	Pain	1992	Present
Lumbar Vertebral Fusion	Spinal fusion surgery	1995	Past
Facet Arthroplasty, cervical	Facet joint syndrome	1996	Past
Lumbar Radiculopathy	Lumbar radiculopathy	1996	Present
Severe Obesity	Obesity	2000	Present
Type 2 Diabetes Mellitus	Type 2 diabetes mellitus	2001	Present
Hyperlipidemia	Hyperlipidaemia	2002	Present
Diabetic Neuropathy	Diabetic neuropathy	2010	Present
Hypertension	Hypertension	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	2010	Present
Osteoarthritis,multiple sites	Osteoarthritis	2014	Present
Right Knee Replacement	Knee arthroplasty	2018	Past
Left Knee Replacemnent	Knee arthroplasty	DEC2019	Past
Left Hand Trigger Finger	Trigger finger	FEB2020	Present
Right Hand Trigger Finger	Trigger finger	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	16:49
2	Placebo	18SEP2020 (23)	14:36

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	18SEP2020 (23)	18SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 09NOV2020 (75)/ 07NOV2020 (73)/ ONGOING	NO		Chest discomfort
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	09NOV2020 (75)	COVID-19	09NOV2020 (75)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	09NOV2020 (75)	09NOV2020 (75)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (75)	10NOV2020 (76)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Aptima, Hologic

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	09NOV2020 (75)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1038 10381051, a 69-year-old white male with a height of 175.26 cm, a weight of 111.73 kg, and a BMI of 36.3 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 18 Sep 2020 (Day 23). The subject had a reported medical history of pain (since 1992); spinal fusion surgery (in 1995); facet joint syndrome (in 1996); lumbar radiculopathy (since 1996); obesity (since 2000); type 2 diabetes mellitus (since 2001); hyperlipidemia (since 2002); diabetic neuropathy, hypertension, and insomnia (all since 2010); osteoarthritis (since 2014); knee arthroplasty (right knee replacement in 2018, left knee replacement in Dec 2019); and trigger finger (left and right hand trigger finger, since Feb 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 09 Nov 2020 (Day 75), the subject was diagnosed with COVID-19 and reported chest discomfort, new or increased cough, and new or increased sore throat, with the first symptom starting on 07 Nov 2020, 50 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 75) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 76) was positive. The subject had a telephone consultation (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.3 cm	66.4 kg	21.9 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
wisdom tooth extraction	Wisdom teeth removal	1985	Past
tubal ligation	Female sterilisation	2004	Past
augmentin allergy	Drug hypersensitivity	2010	Present
Eczema	Eczema	2018	Present
onychomycosis	Onychomycosis	25AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	13:07
2	Placebo	16SEP2020 (23)	12:37

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (23)	16SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28OCT2020 (65)/ 25OCT2020 (62)/ 03NOV2020 (71)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28OCT2020 (65)	COVID-19	27OCT2020 (64)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28OCT2020 (65)	28OCT2020 (65)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	28OCT2020 (65)	27OCT2020 (64)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		QUIDEL CORPORATION LYRA SARS-COV-2 ASSAY	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	28OCT2020 (65)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1039 10391025, a 55-year-old white female with a height of 174.3 cm, a weight of 66.4 kg, and a BMI of 21.9 kg/m2, received Dose 1 on 25 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 23). The subject had a reported medical history of wisdom teeth removal (in 1985); female sterilization (in 2004); drug hypersensitivity (Augmentin allergy since 2010); eczema (since 2018); and onychomycosis (since 25 Aug 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 27 Oct 2020 (Day 64), the subject was diagnosed with COVID-19 and reported new loss of taste or smell and new or increased sore throat starting on 25 Oct 2020, 39 days after receiving Dose 2, that resolved on 03 Nov 2020 (Day 71). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Oct 2020 (Day 65) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (64) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	77.27 kg	30.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Wellbutrin	Drug hypersensitivity	2001	Present
Breast Augmentation	Mammoplasty	2009	Past
ADD	Attention deficit hyperactivity disorder	2010	Present
Depression	Depression	2010	Present
Tubal Ligation	Female sterilisation	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	14:37
2	Placebo	09SEP2020 (22)	14:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09SEP2020 (22)	09SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (83)/ 09NOV2020 (83)/ ONGOING	NO		Fatigue
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (83)	09NOV2020 (83)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (83)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1046 10461058, a 44-year-old white female with a height of 160.02 cm, a weight of 77.27 kg, and a BMI of 30.1 kg/m2, received Dose 1 on 19 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 22). The subject had a reported medical history of drug hypersensitivity (allergy to Wellbutrin since 2001), mammoplasty (in 2009), female sterilization (in 2010), and attention deficit hyperactivity disorder and depression (both since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fatigue, new or increased muscle pain, and nasal congestion, with the first symptom starting on 09 Nov 2020, 61 days after receiving Dose 2 and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of COVID-19 illness on 09 Nov 2020 (Day 83) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject had a telephone consultation (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	110.91 kg	38.2 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	1960	Present
asthma	Asthma	1980	Present
tape allergy	Dermatitis contact	1983	Present
hysterectomy	Hysterectomy	1983	Past
irregular vaginal bleeding	Vaginal haemorrhage	1983	Present
carpal tunnel surgery (left)	Carpal tunnel decompression	1990	Past
wrist carpal tunnel surgery (right)	Carpal tunnel decompression	1990	Past
bilateral carpal tunnel syndrome wrists	Carpal tunnel syndrome	1990	Present
IVP dye (allergy)	Contrast media allergy	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
fluid retention	Fluid retention	1990	Present
lower extremity edema	Oedema peripheral	1990	Present
heel bone spur surgery (left)	Bone lesion excision	2000	Past
heel bone spur surgery(right)	Bone lesion excision	2000	Past
bilateral bone spurs in feet	Exostosis	2000	Past
constipation	Constipation	2005	Present
Hypercholesteralemia	Hypercholesterolaemia	2010	Present
cervical spine fractures (accident)	Cervical vertebral fracture	2014	Past
left knee torn meniscus	Meniscus injury	2014	Past
neck fusion implant	Spinal fusion surgery	21AUG2014	Past
left knee meniscus surgery	Meniscus operation	2015	Past
cervical spine fractures (accident)	Cervical vertebral fracture	2016	Past
osteoarthritis	Osteoarthritis	2016	Present
left knee replacement	Knee arthroplasty	15JUN2016	Past
neck fusion implant	Spinal fusion surgery	15JUN2016	Past
allergy to savella	Drug hypersensitivity	2018	Present
vitamin D deficiency	Vitamin D deficiency	SEP2019	Present
Dilaudid allergy	Drug hypersensitivity	MAR2020	Present
low potassium	Blood potassium decreased	JUN2020	Present
B12 deficiency	Vitamin B12 deficiency	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	15:33
2	BNT162b2	10SEP2020 (21)	14:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (21)	10SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22OCT2020 (63)/ 16OCT2020 (57)/ 18OCT2020 (59)	YES	DIARRHEA	
	YES	FEVER	
	NO		Nausea
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	22OCT2020 (63)	17OCT2020 (58)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	22OCT2020 (63)	17OCT2020 (58)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		OTHER	Hologic Aptima SARS-CoV-2 assay

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	22OCT2020 (63)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1047 10471024, a 63-year-old white female with a height of 170.18 cm, a weight of 110.91 kg, and a BMI of 38.2 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 21). The subject had a reported medical history of depression (since 1960); asthma (since 1980); dermatitis contact and vaginal hemorrhage (both since 1983); hysterectomy (in 1983); carpal tunnel syndrome (bilateral since 1990); carpal tunnel decompression (right and left, both in 1990); contrast media allergy, fluid retention, and edema peripheral (all since 1990); exostosis (in 2000); bone lesion excision (heel bone spur surgery [left and right], both in 2000); constipation (since 2005); hypercholesterolemia (since 2010); cervical vertebral fracture (in 2014 and 2016); meniscus injury (in 2014); spinal fusion surgery (on 21 Aug 2014); meniscus operation (in 2015); osteoarthritis (since 2016); knee arthroplasty and spinal fusion surgery (both in 15 Jun 2016); drug hypersensitivity (allergy to savella since 2018, Dilaudid allergy since Mar 2020); vitamin D deficiency (since Sep 2019); and blood potassium decreased and vitamin B12 deficiency (both since Jun 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported diarrhea, fever, nausea, and vomiting, with the first symptom starting on 16 Oct 2020, 36 days after receiving Dose 2, and the last symptom resolved on 18 Oct 2020 (Day 59). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 17 Oct 2020 (Day 58) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 17 Oct 2020 (Day 58) was negative. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	111.36 kg	32.3 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral broken ankles	Ankle fracture	2010	Past
bilateral fused ankles	Arthrodesis	2010	Past
cholecystectomy	Cholecystectomy	2010	Past
gallstones	Cholelithiasis	2010	Past
rotator cuff repair (right)	Rotator cuff repair	2010	Past
torn rotator cuff (right)	Rotator cuff syndrome	2010	Past
diabetes type II	Type 2 diabetes mellitus	2010	Present
atrial fibrillation	Atrial fibrillation	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ace inhibitor allergy	Drug hypersensitivity	2015	Present
left knee replacement	Knee arthroplasty	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	14:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 14OCT2020 (24)/ 12OCT2020 (22)/ ONGOING	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	14OCT2020 (24)	Covid-19	14OCT2020 (24)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	14OCT2020 (24)	14OCT2020 (24)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	14OCT2020 (24)	SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		OTHER	YES	1	Covid Test Center/Regional hospital

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	14OCT2020 (24)	HOSPITALIZATION STATUS	HOSPITAL	16OCT2020 (26)	ONGOING

Respiratory Treatment						
Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	14OCT2020 (24)	1	YES	HIGH FLOW OXYGEN THERAPY	16OCT2020 (26)	ONGOING

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	Creatinine	114.9	umol/L	61.9	106.1
			Urea Nitrogen	10	mmol/L	2.86	8.21
		17OCT2020 (27)	Alkaline Phosphatase	1.22	ukat/L	0.65	2.84
			Alanine Aminotransferase	0.5001	ukat/L	0.65013	0.65013
			Aspartate Aminotransferase	0.86684	ukat/L	0.70014	0.70014
			Bilirubin	6.8	umol/L	17.1	17.1
			Creatinine	114.9	umol/L	61.9	106.1
			C Reactive Protein	1.1	mg/L	0.5	0.5
			Urea Nitrogen	10.71	mmol/L	2.86	8.21
		18OCT2020 (28)	Alkaline Phosphatase	1.2	ukat/L	0.65	1.95
			Alanine Aminotransferase	0.63346	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.3334	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1
			Creatinine	88.4	umol/L	61.9	106.1
			Urea Nitrogen	8.57	mmol/L	2.86	8.21
		19OCT2020 (29)	Alkaline Phosphatase	1.12	ukat/L	0.48	1.95
			Alanine Aminotransferase	0.51677	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.28339	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1
			Creatinine	70.7	umol/L	61.9	106.1
			Urea Nitrogen	10.36	mmol/L	1.79	10
		23OCT2020 (33)	Alkaline Phosphatase	1.08	ukat/L	0.65	1.95
			Alanine Aminotransferase	0.55011	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.35007	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1

Laboratory Results - Clinical Chemistry							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
			Creatinine	79.6	umol/L	61.9	106.1
			Urea Nitrogen	8.93	mmol/L	7.86	10.36

Laboratory Results - Hematology							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	Basophils	0	10^9/L	0	0.01
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.44	L/L	0.38	0.49
			Hemoglobin	154	g/L	122	167
			Lymphocytes	1.21	10^9/L	1.1	3.4
			Monocytes	0.48	10^9/L	0.3	1.1
			Neutrophils	2.94	10^9/L	1.5	7.9
			Platelets	160	10^9/L	137	352
			Erythrocytes	5.27	10^12/L	4.4	5.5
			Leukocytes	4.63	10^9/L	4.1	12.2
		18OCT2020 (28)	Basophils	0.01	10^9/L	0	0.3
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.37	L/L	0.38	0.49
			Hemoglobin	129	g/L	122	167
			Lymphocytes	1.58	10^9/L	1.1	3.4
			Monocytes	0.45	10^9/L	0.3	1.1
			Neutrophils	2.39	10^9/L	1.5	7.9
			Platelets	165	10^9/L	137	352
			Erythrocytes	4.34	10^12/L	4.4	5.5
			Leukocytes	4450	10^9/L	4100	12200
		19OCT2020 (29)	Basophils	0	10^9/L	0	0.3
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.37	L/L	0.38	0.49
			Hemoglobin	131	g/L	122	167
			Lymphocytes	2.94	10^9/L	1.5	7.9

Laboratory Results - Hematology							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
			Monocytes	0.48	10^9/L	0.3	1.1
			Neutrophils	12.5	10^9/L	1.5	7.9
			Platelets	160	10^9/L	137	352
			Erythrocytes	4.31	10^12/L	4.4	5.5
			Leukocytes	4.63	10^9/L	4.1	12.2
		20OCT2020 (30)	Basophils	0.02	10^9/L	0	0.5
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	37.1	10^6/cu mm	38.2	49.2
			Hemoglobin	131	g/L	122	167
			Lymphocytes	1.86	10^9/L	1.1	3.4
			Monocytes	0.44	10^9/L	0.3	1.1
			Neutrophils	3.35	10^9/L	1.5	7.9
			Platelets	172	10^9/L	137	352
			Erythrocytes	4.36	10^12/L	4.4	5.5
			Leukocytes	5.8	10^9/L	4.1	12.2

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	1					80 %
		18OCT2020 (28)	2	130 mmHg	72 mmHg		47 beats/min	
		19OCT2020 (29)	3					95 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	14OCT2020 (24)	16OCT2020	CHEST		CT SCAN	NA	ABNORMAL

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	Lungs: Multifocal ground glass opacities scattered throughout the lungs bilaterally. No Pleura effusions. Extensive coronary atherosclerotic classifications. Normal thickness of the Pericardium.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Withdrawn	VACCINATION	12OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1047 10471252, a 63-year-old white male with a height of 185.42 cm, a weight of 111.36 kg, and a BMI of 32.3 kg/m2, received Dose 1 on 21 Sep 2020. The subject had a reported medical history of ankle fracture, arthrodesis, cholecystectomy, cholelithiasis, rotator cuff repair, and rotator cuff syndrome (all in 2010); type 2 diabetes mellitus (since 2010); atrial fibrillation (since 2012); knee arthroplasty (in 2015); and drug hypersensitivity (ACE inhibitor allergy, since 2015). The central laboratory SARS-CoV-2 NAAT result was negative at Visit 1. The central laboratory N-binding antibody result was negative at Visit 1. On 14 Oct 2020 (Day 24), the subject was diagnosed with severe COVID-19 and reported diarrhea, fever, headache, new or increased cough, new or increased muscle pain, and new or increased shortness of breath, with the first symptom starting on 12 Oct 2020, 21 days after receiving Dose 1, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Oct 2020 (Day 24) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Oct 2020 (Day 24) was positive. The subject went to the emergency room (once), went to his primary care physician (once), and visited a COVID test center/regional hospital (once). The subject was hospitalized on 16 Oct 2020 (Day 26) and remained hospitalized as of the last available report. On 16 Oct 2020 (Day 26), the subject had an oxygen saturation of 80% and required high-flow oxygen therapy. On 18 Oct 2020 (Day 28), the subject had a heart rate of 47 beats per minute and blood pressure of 130/72 mmHg. On 19 Oct 2020 (Day 29), the subject had an oxygen saturation of 95%. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, oxygen saturation ⩽93%, and requirement for high-flow oxygen therapy). On 16 Oct 2020 (Day 26), the creatinine was 114.9 µmol/L (normal range [NR]: 61.9 - 106.1 µmol/L) and blood urea nitrogen (BUN) was 10 mmol/L (NR: 2.86 - 8.21 mmol/L). On 17 Oct 2020 (Day 27), alanine aminotransferase (ALT) was 0.5001 µkat/L (NR: <0.65013 µkat/L), aspartate aminotransferase (AST) was 0.86684 µkat/L (NR: <0.70014 µkat/L), bilirubin was 6.8 µmol/L (NR: <17.1 µmol/L), BUN was 10.71 mmol/L (NR: 2.86 - 8.21 mmol/L), creatinine was 114.9 µmol/L (NR: 61.9 - 106.1 µmol/L), and C-reactive protein was 1.1 mg/L (NR: <0.5 mg/L). On 18 Oct 2020 (Day 28), the ALT was 0.63346 µkat/L (NR: <0.65013 µkat/L), AST was 0.3334 µkat/L (NR: <0.70014 µkat/L), bilirubin was 5.1 µmol/L (NR: <17.1 µmol/L), and BUN was 8.57 mmol/L (NR: 2.86 - 8.21 mmol/L). On 19 Oct 2020 (Day 29), the ALT was 0.51677 µkat/L (NR: <0.65013 µkat/L), AST was 0.28339 µkat/L (NR: <0.70014 µkat/L), bilirubin was 5.1 µmol/L (NR: <17.1 µmol/L), and BUN was 10.36 mmol/L (NR: 1.79 - 10 mmol/L). On 16 Oct 2020 (Day 26), a computed tomographic scan of the chest showed multifocal ground glass opacities scattered throughout the lungs bilaterally. No pleural effusions were observed. Extensive coronary atherosclerotic calcifications with normal thickness of the pericardium were observed. The subject was discontinued from the study intervention on 14 Oct 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.2 cm	95.7 kg	28.2 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ADD (attention deficit disorder)	Attention deficit hyperactivity disorder	2010	Present
Primary insomnia	Insomnia	12APR2017	Present
Gallstone pancreatitis	Obstructive pancreatitis	19OCT2017	Past
Erectile dysfunction	Erectile dysfunction	31OCT2017	Present
Prediabetes	Glucose tolerance impaired	31OCT2017	Present
Chronic right shoulder pain	Arthralgia	18SEP2019	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	APR2020	Past
Anxiety	Anxiety	30APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	18:48
2	Placebo	21SEP2020 (22)	09:16

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	Left shoulder pain	01SEP2020 (2)	07:00	01SEP2020 (2)	07:00	1
2	GENRL	Fatigue	Fatigue	31AUG2020 (1)	23:00	01SEP2020 (2)	07:00	2
3	MUSC	Neck pain	Left neck pain	01SEP2020 (2)	07:00	07SEP2020 (8)	07:00	7
4	NERV	Headache	Head Ache	31AUG2020 (1)	19:00	01SEP2020 (2)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC/TCN	N	Resolved (01SEP2020)	NOT RELATED/OTHER: Slept wrong	1	2	N
2	1	N	N	Resolved (01SEP2020)	Study Treatment	1	1	N
3	1	TC/TCN	N	Resolved (07SEP2020)	NOT RELATED/OTHER: Slept wrong on it	1	2	N
4	1	TC/TCN	N	Resolved (01SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31AUG2020 (1)	31AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31AUG2020 (1)	31AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (22)	21SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02NOV2020 (64)/ 01NOV2020 (63)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Sputum increased

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02NOV2020 (64)	covid-19	02NOV2020 (64)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	02NOV2020 (64)	02NOV2020 (64)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	02NOV2020 (64)	02NOV2020 (64)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		HOLOGIC PANTHER FUSION SARS-COV-2	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	02NOV2020 (64)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1068 10681082, a 58-year-old white male with a height of 184.2 cm, a weight of 95.7 kg, and a BMI of 28.2 kg/m2, received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject had a reported medical history of attention deficit hyperactivity disorder (since 2010), insomnia (since 12 Apr 2017), obstructive pancreatitis (on 19 Oct 2017), erectile dysfunction and glucose tolerance impaired (both since 31 Oct 2017), arthralgia (since 18 Sep 2019), gastroesophageal reflux disease (in Apr 2020), and anxiety (since 30 Apr 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 02 Nov 2020 (Day 64), the subject was diagnosed with COVID-19 and reported fever, new or increased cough, new or increased shortness of breath, new or increased sore throat, and sputum increased, with the first symptom starting on 01 Nov 2020, 41 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Nov 2020 (Day 64) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Nov 2020 (Day 64) was positive. The subject went to his primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.7 cm	105.2 kg	35.3 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fatigue	Fatigue	25JUL2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	12:28
2	Placebo	25SEP2020 (22)	09:19

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1			Left forearm hives	04SEP2020 (1)	17:00	07SEP2020 (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	N	N	Resolved (07SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04SEP2020 (1)	04SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04SEP2020 (1)	04SEP2020 (1)	SERUM	NEGATIVE
Visit 2	25SEP2020 (22)	25SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 18OCT2020 (45)/ 16OCT2020 (43)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	18OCT2020 (45)	Covid-19	18OCT2020 (45)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	18OCT2020 (45)	21OCT2020 (48)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	18OCT2020 (45)	18OCT2020 (45)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	Will upload exact trade name once confirmed with clinic where swab was collected, done my LabCorp in Seattle	OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	18OCT2020 (45)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1068 10681110, a 30-year-old white female with a height of 172.7 cm, a weight of 105.2 kg, and a BMI of 35.3 kg/m2, received Dose 1 on 04 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 22). The subject had a reported medical history of fatigue (on 25 Jul 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 18 Oct 2020 (Day 45), the subject was diagnosed with COVID-19 and reported new loss of taste or smell, new or increased cough, and nasal congestion, with the first symptom starting on 16 Oct 2020, 21 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 21 Oct 2020 (Day 48) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 18 Oct 2020 (Day 45) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.6 cm	120.7 kg	43 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ACID REFLUX	Gastrooesophageal reflux disease	1990	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	1996	Present
SLEEP APNEA	Sleep apnoea syndrome	2004	Present
MIGRAINES	Migraine	2006	Present
BILATERAL OSTEOARTHRITIS OF KNEES	Osteoarthritis	2010	Present
VASECTOMY	Vasectomy	2014	Past
OBESITY	Obesity	2015	Present
HYPERTENSION	Hypertension	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	11:20
2	Placebo	31AUG2020 (20)	10:55

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	31AUG2020 (20)	31AUG2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (63)/ 13OCT2020 (63)/ 14OCT2020 (64)	NO		Headache
	YES	NEW OR INCREASED SORE THROAT	

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 2 / 11NOV2020 (92)/ 10NOV2020 (91)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	13OCT2020 (63)	14OCT2020 (64)	NASAL_SWAB_SELF	NEGATIVE
2	COVID Illness Visit 2	11NOV2020 (92)	11NOV2020 (92)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	13OCT2020 (63)	14OCT2020 (64)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13OCT2020 (63)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 2	11NOV2020 (92)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1071 10711022, a 47-year-old multiracial male with a height of 167.6 cm, a weight of 120.7 kg, and a BMI of 43 kg/m2, received Dose 1 on 12 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 20). The subject had a reported medical history of gastroesophageal reflux disease (since 1990), hypercholesterolemia (since 1996), sleep apnea syndrome (since 2004), migraine (since 2006), osteoarthritis (since 2010), vasectomy (in 2014), obesity (since 2015), and hypertension (since Feb 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, headache, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 10 Nov 2020, 71 days after receiving Dose 2 and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of COVID-19 illness on 11 Nov 2020 (Day 92) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.5 cm	97.1 kg	35.9 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY TO PENICILLIN	Drug hypersensitivity	1949	Present
ALLERGY TO SULFAMIDIES	Drug hypersensitivity	1949	Present
HYPOTHYROIDISM	Hypothyroidism	1968	Present
HYPERTENSION	Hypertension	1980	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	1981	Present
OBESITY	Obesity	1994	Present
POSTMENOPAUSAL	Postmenopause	2000	Present
DIABETES TYPE II	Type 2 diabetes mellitus	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	13:05
2	Placebo	08SEP2020 (22)	17:05

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	18AUG2020 (1)	18AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18AUG2020 (1)	18AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (22)	08SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07NOV2020 (82)/ 06NOV2020 (81)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	07NOV2020 (82)	COVID-19	04NOV2020 (79)	1	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	07NOV2020 (82)	07NOV2020 (82)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	07NOV2020 (82)	04NOV2020 (79)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	07NOV2020 (82)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1071 10711058, a 72-year-old white female with a height of 164.5 cm, a weight of 97.1 kg, and a BMI of 35.9 kg/m2, received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject had a reported medical history of drug hypersensitivity (allergy to penicillin and sulfamides, both since 1949), hypothyroidism (since 1968), hypertension (since 1980), hypercholesterolemia (since 1981), obesity (since 1994), and postmenopause and type 2 diabetes mellitus (both since 2000). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody was negative at Visit 1. On 04 Nov 2020 (Day 79), the subject was diagnosed with COVID-19 and reported new or increased cough and new or increased sore throat, with the first symptom starting on 06 Nov 2020, 59 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 82) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 79) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	89.09 kg	31.6 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Appendectomy	Appendicectomy	1973	Past
Erectile Dysfunction	Erectile dysfunction	1979	Present
Osteoarthritis of bilateral knees	Osteoarthritis	1984	Past
Gateroeshophageal Reflux	Gastrooesophageal reflux disease	2005	Present
Hypercholesterolemia	Hypercholesterolaemia	2009	Present
Hypertension	Hypertension	2009	Present
Double Knee Replacement	Knee arthroplasty	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	15:32
2	Placebo	16SEP2020 (21)	09:17

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (21)	16SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details

Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 05NOV2020 (71)/ 26OCT2020 (61)/ ONGOING	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	05NOV2020 (71)	COVID19	04NOV2020 (70)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05NOV2020 (71)	05NOV2020 (71)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	05NOV2020 (71)	04NOV2020 (70)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	05NOV2020 (71)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1072 10721057, a 70-year-old white male with a height of 167.64 cm, a weight of 89.09 kg, and a BMI of 31.6 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 21). The subject had a reported medical history of appendectomy (in 1973), erectile dysfunction (since 1979), osteoarthritis (in 1984), gastroesophageal reflux disease (since 2005), hypercholesterolemia and hypertension (both since 2009), and knee arthroplasty (double knee replacement in 2014). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 04 Nov 2020 (Day 70), the subject was diagnosed with COVID-19 and reported new or increased cough starting on 26 Oct 2020, 40 days after receiving Dose 2, that was ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 71) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 70) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	62.9 kg	24.6 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERLIPIDEMIA	Hyperlipidaemia	2000	Present
HEMORRHOIDS	Haemorrhoids	2005	Present
HYSTERECTOMY	Hysterectomy	2006	Past
OSTEOARTHRITIS	Osteoarthritis	2009	Present
CECLOR (Cefaclor) ALLERGY	Drug hypersensitivity	2010	Present
SULFA ALLERGY	Drug hypersensitivity	2010	Present
IRRITABLE BOWEL SYNDROME	Irritable bowel syndrome	2010	Present
SUPRAVENTRICULAR TACHYCARDIA	Supraventricular tachycardia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	09:55
2	Placebo	23SEP2020 (20)	08:46

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04SEP2020 (1)	04SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04SEP2020 (1)	04SEP2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (20)	23SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (63)/ 01NOV2020 (59)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	05NOV2020 (63)	COVID-19	02NOV2020 (60)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05NOV2020 (63)	07NOV2020 (65)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	05NOV2020 (63)	02NOV2020 (60)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (63)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1077 10771195, a 73-year-old white female with a height of 160 cm, a weight of 62.9 kg, and a BMI of 24.6 kg/m2, received Dose 1 on 04 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 20). The subject had a reported medical history of hyperlipidemia (since 2000), hemorrhoids (since 2005), hysterectomy (in 2006), osteoarthritis (since 2009), drug hypersensitivity (allergy to Cefaclor and sulfa) and irritable bowel syndrome (both since 2010), and supraventricular tachycardia (since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 02 Nov 2020 (Day 60), the subject was diagnosed with COVID-19 and reported fever, new or increased cough, new or increased muscle pain, and nasal congestion, with the first symptom starting on 01 Nov 2020, 39 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 65) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Nov 2020 (Day 60) was positive. The subject went to her primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	98 kg	35.6 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2008	Present
hysterectomy	Hysterectomy	2008	Past
Hypothyroidism	Hypothyroidism	2013	Present
Type II Diabetes	Type 2 diabetes mellitus	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	13:05
2	Placebo	26AUG2020 (23)	10:21

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04AUG2020 (1)	04AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04AUG2020 (1)	04AUG2020 (1)	SERUM	NEGATIVE
Visit 2	26AUG2020 (23)	26AUG2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (88)/ 26OCT2020 (84)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30OCT2020 (88)	COVID 19	29OCT2020 (87)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (88)	30OCT2020 (88)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30OCT2020 (88)	29OCT2020 (87)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	30OCT2020 (88)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1079 10791046, a 55-year-old white female with a height of 166 cm, a weight of 98 kg, and a BMI of 35.6 kg/m2, received Dose 1 on 04 Aug 2020 and Dose 2 on 26 Aug 2020 (Day 23). The subject had a reported medical history of hypertension (since 2008), hysterectomy (in 2008), hypothyroidism (since 2013), and type 2 diabetes mellitus (since Jan 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 29 Oct 2020 (Day 87), the subject was diagnosed with COVID-19 and reported a new loss of taste or smell starting on 26 Oct 2020, 61 days after receiving Dose 2. The symptom was ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 88) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 87) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	83.18 kg	33.5 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GERD	Gastrooesophageal reflux disease	2015	Present
Hernia	Hernia	2015	Present
Anxiety	Anxiety	2018	Present
Attention Deficit Disorder	Attention deficit hyperactivity disorder	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	11:58
2	Placebo	28AUG2020 (24)	12:17

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	05AUG2020 (1)	05AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	05AUG2020 (1)	05AUG2020 (1)	SERUM	NEGATIVE
Visit 2	28AUG2020 (24)	28AUG2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (87)/ 29OCT2020 (86)/ ONGOING	NO		Fatigue
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30OCT2020 (87)	COVID 19	06NOV2020 (94)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (87)	30OCT2020 (87)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30OCT2020 (87)	29OCT2020 (86)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	30OCT2020 (87)	06NOV2020 (94)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		OTHER	NALT Unknown
2	POSITIVE		OTHER	Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	30OCT2020 (87)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1079 10791054, a 28-year-old white female with a height of 157.48 cm, a weight of 83.18 kg, and a BMI of 33.5 kg/m2, received Dose 1 on 05 Aug 2020 and Dose 2 on 28 Aug 2020 (Day 24). The subject had a reported medical history of gastroesophageal reflux disease and hernia (both since 2015) and anxiety and attention deficit hyperactivity disorder (both since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Nov 2020 (Day 94), the subject was diagnosed with COVID-19, and reported fatigue and new or increased cough, with the first symptom starting on 29 Oct 2020, 62 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 87) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 86) was negative. The local laboratory SARS-CoV-2-NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 94) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	95.91 kg	37.4 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dyslipidemia	Dyslipidaemia	01JAN2000	Present
Hypothyroidism	Hypothyroidism	01JAN2000	Present
Hypertension	Hypertension	01JAN2005	Present
Abdominal infection	Abdominal infection	01JAN2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	13:22
2	Placebo	21SEP2020 (21)	14:30

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Vaccination	INFLUENZA VACCINE	30OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	01SEP2020 (1)	01SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	01SEP2020 (1)	01SEP2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (21)	21SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details

Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 14OCT2020 (44)/ 30SEP2020 (30)/ 14OCT2020 (44)	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	14OCT2020 (44)	14OCT2020 (44)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	14OCT2020 (44)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	14OCT2020 (44)	14OCT2020 (44)	1	168 mmHg	102 mmHg	12 breaths/min	92 beats/min	

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1081 10811151, a 79-year-old white female with a height of 160.02 cm, a weight of 95.91 kg, and a BMI of 37.4 kg/m2, received Dose 1 on 01 Sep 2020 and Dose 2 on 21 Sep 2020 (Day 21). The subject had a reported medical history of dyslipidemia and hypothyroidism (both since 01 Jan 2000), hypertension (since 01 Jan 2005), and abdominal infection (on 01 Jan 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported new or increased cough starting on 30 Sep 2020, 9 days after receiving Dose 2, that resolved on 14 Oct 2020 (Day 44). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Oct 2020 (Day 44) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel. On 14 Oct 2020 (Day 44), the subject had a heart rate of 92 beats per minute, blood pressure of 168/102 mmHg, and respiratory rate of 12 breaths per minute.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	71 kg	29.2 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
myopia	Myopia	1983	Present
presbyopia	Presbyopia	1983	Present
premenstrual syndrome	Premenstrual syndrome	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	13:12
2	Placebo	24AUG2020 (22)	11:03

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	03AUG2020 (1)	03AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	03AUG2020 (1)	03AUG2020 (1)	SERUM	NEGATIVE
Visit 2	24AUG2020 (22)	24AUG2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 07OCT2020 (66)/ 06OCT2020 (65)/ 27OCT2020 (86)	YES	CHILLS	
	NO		Dizziness
	YES	FEVER	
	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	07OCT2020 (66)	COVID 19	07OCT2020 (66)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	07OCT2020 (66)	07OCT2020 (66)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	07OCT2020 (66)	07OCT2020 (66)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07OCT2020 (66)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	07OCT2020 (66)	07OCT2020 (66)	Alkaline Phosphatase	1.25	ukat/L	0.65	1.95
			Alanine Aminotransferase	0.28339	ukat/L	0	0.53344
			Aspartate Aminotransferase	0.38341	ukat/L	0	0.6668
			Creatinine	67.2	umol/L	50.4	88.4
			C Reactive Protein	5	mg/L	0	3
			Urea Nitrogen	3.57	mmol/L	2.14	8.57

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	07OCT2020 (66)	07OCT2020 (66)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.4
			Hematocrit	0.38	L/L	0.34	0.47
			Hemoglobin	126	g/L	111	159
			Lymphocytes	0.4	10^9/L	0.7	3.1
			Monocytes	0.5	10^9/L	0.1	0.9
			Neutrophils	2.5	10^9/L	1.4	7
			Platelets	277	10^9/L	150	450
			Erythrocytes	4.35	10^12/L	3.77	5.28

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	07OCT2020 (66)	07OCT2020 (66)	1	107 mmHg	75 mmHg	18 breaths/min	98 beats/min	98 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	21SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1082 10821016, a 46-year-old white female with a height of 156 cm, a weight of 71 kg, and a BMI of 29.2 kg/m2, received Dose 1 on 03 Aug 2020 and Dose 2 on 24 Aug 2020 (Day 22). The subject had a reported medical history of myopia and presbyopia (both since 1983), and premenstrual syndrome (since 2012). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Oct 2020 (Day 66), the subject was diagnosed with COVID-19, and reported chills, dizziness, fever, fatigue, new loss of taste or smell, new or increased cough, and new or increased muscle pain, with the first symptom starting on 06 Oct 2020, 43 days after receiving Dose 2, and the last symptom resolved on 27 Oct 2020 (Day 86). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Oct 2020 (Day 66) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Oct 2020 (Day 66) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 07 Oct 2020 (Day 66), the subject had a heart rate of 98 beats per minute, blood pressure of 107/75 mmHg, respiratory rate of 18 breaths per minute, and oxygen saturation of 98% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	63.64 kg	27.3 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eczema	Eczema	1990	Present
hypercholesterolemia	Hypercholesterolaemia	2010	Present
post menopausal	Postmenopause	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	17:02
2	Placebo	02OCT2020 (24)	16:24

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Pain	body aches	05OCT2020 (27)	08:00	06OCT2020 (28)	23:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	TC	N	Resolved (06OCT2020)	Study Treatment	2	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	09SEP2020 (1)	09SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09SEP2020 (1)	09SEP2020 (1)	SERUM	NEGATIVE
Visit 2	02OCT2020 (24)	02OCT2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10NOV2020 (63)/ 07NOV2020 (60)/ ONGOING	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10NOV2020 (63)	10NOV2020 (63)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10NOV2020 (63)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	03NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1085 10851293, a 63-year-old Asian female with a height of 152.4 cm, a weight of 63.64 kg, and a BMI of 27.3 kg/m2, received Dose 1 on 09 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 24). The subject had a reported medical history of eczema (since 1990), hypercholesterolemia (since 2010), and postmenopause (since 2012). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fever, new loss of taste or smell, and new or increased cough, with the first symptom starting on 07 Nov 2020, 36 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 63) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188.1 cm	99.2 kg	28 kg/m2	18SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	09:56
2	Placebo	09OCT2020 (22)	13:45

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	18SEP2020 (1)	18SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18SEP2020 (1)	18SEP2020 (1)	SERUM	NEGATIVE
Visit 2	09OCT2020 (22)	09OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (39)/ 25OCT2020 (38)/ ONGOING	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (39)	COVID-19	25OCT2020 (38)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (39)	26OCT2020 (39)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26OCT2020 (39)	25OCT2020 (38)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Quidel Sofia SARS Antigen Flourescent Immnoassay

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (39)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1088 10881219, a 63-year-old white male with a height of 188.1 cm, a weight of 99.2 kg, and a BMI of 28 kg/m2, received Dose 1 on 18 Sep 2020 and Dose 2 on 09 Oct 2020 (Day 22). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 25 Oct 2020 (Day 38), the subject was diagnosed with COVID-19 and reported fever, headache, new or increased cough, and new or increased muscle pain, with the first symptom starting on 25 Oct 2020, 16 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 39) was positive. The local laboratory SARS-CoV-2 Quidel Sofia SARS Antigen Fluorescent Immunoassay result at the time of the COVID-19 illness on 25 Oct 2020 (Day 38) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	Native Hawaiian or Other Pacific Islander	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.5 cm	90.2 kg	26.5 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	2015	Present
low testosterone	Blood testosterone decreased	2017	Present
hypercholesterolemia	Hypercholesterolaemia	2017	Present
attention deficit disorder	Attention deficit hyperactivity disorder	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	11:47
2	Placebo	19OCT2020 (25)	12:47

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	25SEP2020 (1)	25SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25SEP2020 (1)	25SEP2020 (1)	SERUM	NEGATIVE
Visit 2	19OCT2020 (25)	19OCT2020 (25)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 04NOV2020 (41)/ 02NOV2020 (39)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Pain

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	04NOV2020 (41)	04NOV2020 (41)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	04NOV2020 (41)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1088 10881233, a 47-year-old Native Hawaiian or Other Pacific Islander male with a height of 184.5 cm, a weight of 90.2 kg, and a BMI of 26.5 kg/m2, received Dose 1 on 25 Sep 2020 and Dose 2 on 19 Oct 2020 (Day 25). The subject had a reported medical history of insomnia (since 2015), blood testosterone decreased and hypercholesterolemia (both since 2017), and attention deficit hyperactivity disorder (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, new or increased cough, new or increased sore throat, and pain, with the first symptom starting on 02 Nov 2020, 14 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 41) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	86.82 kg	33.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cesarean section	Caesarean section	2008	Past
depression	Depression	2010	Present
insomnia	Insomnia	2010	Present
chemical dependence	Substance dependence	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	16:21
2	Placebo	23SEP2020 (22)	14:49

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	02SEP2020 (1)	02SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	02SEP2020 (1)	02SEP2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (22)	23SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12NOV2020 (72)/ 08NOV2020 (68)/ ONGOING	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	12NOV2020 (72)	COVID-19	12NOV2020 (72)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	12NOV2020 (72)	12NOV2020 (72)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	12NOV2020 (72)	12NOV2020 (72)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	Patient called and reported positive test.The patient is going to bring test results by the office once she recovers from COVID-19.		

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	12NOV2020 (72)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1089 10891235, a 29-year-old black or African American female with a height of 161.29 cm, a weight of 86.82 kg, and a BMI of 33.3 kg/m2, received Dose 1 on 02 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 22). The subject had a reported medical history of cesarean section (in 2008), depression and insomnia (both since 2010), and substance dependence (in 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 12 Nov 2020 (Day 72), the subject was diagnosed with COVID-19 and reported headache, new or increased cough, and new or increased sore throat, with the first symptom starting on 08 Nov 2020, 46 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Nov 2020 (Day 72) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Nov 2020 (Day 72) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	76.3 kg	30.6 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1968	Past
Eczema	Eczema	1983	Present
Tubal Ligation	Female sterilisation	1986	Past
Post Menopausal	Postmenopause	1986	Past
Basal Cell carcinoma- Right Knee	Basal cell carcinoma	2008	Past
Basal cell Right Shoulder	Basal cell carcinoma	2008	Past
Allergic Rhinitis	Rhinitis allergic	2010	Present
Hot Flashes	Hot flush	2012	Present
Squamous Cell carcinoma - Chest	Squamous cell carcinoma	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Blepharoplasty - Left	Blepharoplasty	JAN2020	Past
Cataract surgery - Both Eyes	Cataract operation	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	12:36
2	Placebo	31AUG2020 (22)	09:53

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	10AUG2020 (1)	10AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	10AUG2020 (1)	10AUG2020 (1)	SERUM	NEGATIVE
Visit 2	31AUG2020 (22)	31AUG2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 19OCT2020 (71)/ 18OCT2020 (70)/ 22OCT2020 (74)	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	19OCT2020 (71)	COVID-19	20OCT2020 (72)	1	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	19OCT2020 (71)	20OCT2020 (72)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	19OCT2020 (71)	20OCT2020 (72)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	19OCT2020 (71)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	28SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901121, a 58-year-old white female with a height of 158 cm, a weight of 76.3 kg, and a BMI of 30.6 kg/m2, received Dose 1 on 10 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 22). The subject had a reported medical history of tonsillectomy (in 1968), eczema (since 1983), female sterilization (in 1986), postmenopause (since 1986), basal cell carcinoma (right knee and shoulder in 2008), rhinitis allergic (since 2010), hot flush (since 2012), squamous cell carcinoma (in 2017), blepharoplasty (in Jan 2020), and cataract operation (in Jul 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 20 Oct 2020 (Day 72), the subject was diagnosed with COVID-19 and reported fever, new loss of taste or smell, and nasal congestion, with the first symptom starting on 18 Oct 2020, 48 days after receiving Dose 2, and the last symptom resolved on 22 Oct 2020 (Day 74). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 20 Oct 2020 (Day 72) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 20 Oct 2020 (Day 72) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195 cm	109 kg	28.7 kg/m2	09SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	09:40
2	Placebo	30SEP2020 (22)	09:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	09SEP2020 (1)	09SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09SEP2020 (1)	09SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (22)	30SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (62)/ 08NOV2020 (61)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (62)	Covid 19	11NOV2020 (64)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (62)	09NOV2020 (62)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (62)	09NOV2020 (62)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (62)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1090 10901353, a 63-year-old white male with a height of 195 cm, a weight of 109 kg, and a BMI of 28.7 kg/m2, received Dose 1 on 09 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 22).
The subject had no reported medical history.
The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.
On 11 Nov 2020 (Day 64), the subject was diagnosed with COVID-19 and reported fever and new or increased cough, with the first symptom starting on 08 Nov 2020, 39 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report.
The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 62) was positive.
The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 62) was positive.
The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	113.5 kg	33.9 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
meningioma (benign)	Meningioma benign	2005	Present
meningioma resection	Meningioma surgery	2005	Past
slipped disc	Intervertebral disc protrusion	2011	Present
meningioma resection	Meningioma surgery	2012	Past
Bilateral carpel tunnel syndrome	Carpal tunnel syndrome	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	11:48
2	Placebo	23SEP2020 (24)	16:56

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	31AUG2020 (1)	31AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31AUG2020 (1)	31AUG2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (24)	23SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (71)/ 05NOV2020 (67)/ ONGOING	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Respiratory tract congestion
	NO		Sneezing

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (71)	Covid 19	06NOV2020 (68)	2	COVID-19

SARS-COV-2 Test - Central Laboratory
No SARS-COV-2 Test - Central Laboratory

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (71)	05NOV2020 (67)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	09NOV2020 (71)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1091 10911203, a 43-year-old white male with a height of 183 cm, a weight of 113.5 kg, and a BMI of 33.9 kg/m2, received Dose 1 on 31 Aug 2020 and Dose 2 on 23 Sep 2020 (Day 24). The subject had a reported medical history of meningioma benign (since 2005), meningioma surgery (in 2005 and 2012), intervertebral disc protrusion (since 2011), and carpal tunnel syndrome (since Feb 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Nov 2020 (Day 68), the subject was diagnosed with COVID-19 and reported fatigue, new or increased cough, new or increased muscle pain, respiratory tract congestion, and sneezing, with the first symptom starting on 05 Nov 2020, 43 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness is pending. The local laboratory SARS-CoV-2 NAAT (Roche molecular systems cobas SARS-COV-2) result at the time of the COVID-19 illness on 05 Nov 2020 (Day 67) was positive. The subject went to his primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	69.45 kg	26.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dyslipidemia	Dyslipidaemia	2000	Present
dry eye syndrome	Dry eye	2005	Present
thyroid goiter	Goitre	2005	Present
hypertension	Hypertension	AUG2008	Present
postmenopausal	Postmenopause	2010	Present
seasonal allergies	Seasonal allergy	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	09:30
2	Placebo	10SEP2020 (22)	08:48

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (22)	10SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29OCT2020 (71)/ 27OCT2020 (69)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	29OCT2020 (71)	29OCT2020 (71)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29OCT2020 (71)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1092 10921021, a 60-year-old white female with a height of 162.56 cm, a weight of 69.45 kg, and a BMI of 26.2 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had a reported medical history of dyslipidemia (since 2000), dry eye and goiter (both since 2005), hypertension (since Aug 2008), postmenopause (since 2010), and seasonal allergy (since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, new or increased cough, and new or increased muscle pain, with the first symptom starting on 27 Oct 2020, 47 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 71) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
193.04 cm	116.82 kg	31.3 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	1995	Present
insomnia	Insomnia	1995	Present
post traumatic stress disorder	Post-traumatic stress disorder	1995	Present
vasectomy	Vasectomy	2002	Past
dyslipidemia	Dyslipidaemia	2008	Present
seasonal allergies	Seasonal allergy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	14:34
2	Placebo	22SEP2020 (22)	13:24

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Epistaxis	intermittent bilateral nose bleed	12OCT2020 (42)		09NOV2020 (70)		29

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (09NOV2020)	NOT RELATED/OTHER: unknown	2	21	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	01SEP2020 (1)	01SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	01SEP2020 (1)	01SEP2020 (1)	SERUM	NEGATIVE
Visit 2	22SEP2020 (22)	22SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12OCT2020 (42)/ 09OCT2020 (39)/ ONGOING	NO		Arthralgia
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Respiratory tract congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	12OCT2020 (42)	covid 19	12OCT2020 (42)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	12OCT2020 (42)	12OCT2020 (42)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	12OCT2020 (42)	12OCT2020 (42)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	12OCT2020 (42)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Withdrawn	VACCINATION	12OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1092 10921130, a 53-year-old white male with a height of 193.04 cm, a weight of 116.82 kg, and a BMI of 31.3 kg/m2, received Dose 1 on 01 Sep 2020 and Dose 2 on 22 Sep 2020 (Day 22). The subject had a reported medical history of depression, insomnia, and post-traumatic stress disorder (all since 1995); vasectomy (in 2002); dyslipidemia (since 2008); and seasonal allergy (since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 12 Oct 2020 (Day 42), the subject was diagnosed with COVID-19 and reported arthralgia, diarrhea, fever, headache, new loss of taste or smell, new or increased cough, new or increased shortness of breath, new or increased sore throat, and respiratory tract congestion, with the first symptom starting on 09 Oct 2020, 17 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Oct 2020 (Day 42) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Oct 2020 (Day 42) was positive. The subject had a telephone consultation (once) and went to his primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	64 kg	25.7 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
POST MENOPAUSAL	Postmenopause	2005	Present
LEFT HIP REPLACEMENT	Hip arthroplasty	2009	Past
INSOMNIA	Insomnia	2010	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
GENERALIZED OSTEOARTHRITIS	Osteoarthritis	2019	Present
ACID REFLUX	Gastrooesophageal reflux disease	FEB2020	Present
LEFT LEG PAIN	Pain in extremity	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	17:53
2	Placebo	17SEP2020 (22)	17:11

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINATION	INFLUENZA VACCINE	26OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	17SEP2020 (22)	17SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06OCT2020 (41)/ 05OCT2020 (40)/ 19OCT2020 (54)	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06OCT2020 (41)	06OCT2020 (41)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06OCT2020 (41)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1093 10931081, a 67-year-old white female with a height of 157.48 cm, a weight of 64 kg, and a BMI of 25.7 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 22). The subject had a reported medical history of postmenopause (since 2005), hip arthroplasty (in 2009), insomnia (since 2010), hypercholesterolemia (since 2015), osteoarthritis (since 2019), and gastroesophageal reflux disease and pain in extremity (both since Feb 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fatigue, headache, new or increased sore throat, nasal congestion, and rhinorrhea, with the first symptom starting on 05 Oct 2020, 18 days after receiving Dose 2, and the last symptom resolved on 19 Oct 2020 (Day 54). . The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Oct 2020 (Day 41) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	79.9 kg	29 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lower back pain	Back pain	1977	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	1995	Present
Post Menopausal	Postmenopause	2005	Present
seasonal allergies	Seasonal allergy	2005	Present
Hypertension	Hypertension	AUG2019	Present
Hypothyroidism	Hypothyroidism	20MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	15:43
2	Placebo	15OCT2020 (21)	14:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Nausea	nausea	25SEP2020 (1)	18:00	25SEP2020 (1)	19:00
2	GASTR	Vomiting	Vomiting	25SEP2020 (1)	18:00	25SEP2020 (1)	19:00

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (25SEP2020)	Study Treatment	1	1	N
2	1	1	N	N	Resolved (25SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25SEP2020 (1)	25SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25SEP2020 (1)	25SEP2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (21)	15OCT2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (46)/ 02NOV2020 (39)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (46)	COVID 19 viral infection	07NOV2020 (44)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (46)	09NOV2020 (46)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (46)	07NOV2020 (44)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (46)	EMERGENCY ROOM	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		OTHER	YES	1	CVS

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1095 10951238, a 63-year-old white female with a height of 166 cm, a weight of 79.9 kg, and a BMI of 29 kg/m2, received Dose 1 on 25 Sep 2020 and Dose 2 on 15 Oct 2020 (Day 21). The subject had a reported medical history of back pain (since 1977), gastroesophageal reflux disease (since 1995), postmenopause and seasonal allergy (both since 2005), hypertension (since Aug 2019), and hypothyroidism (since 20 May 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Nov 2020 (Day 44), the subject was diagnosed with COVID-19 and reported chills, diarrhea, new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 02 Nov 2020, 18 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 46) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 44) was positive. The subject went to her primary care physician (once) and CVS Pharmacy (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	89.5 kg	27.9 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07OCT2020 (1)	09:42
2	Placebo	28OCT2020 (22)	09:03

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	07OCT2020 (1)	07OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07OCT2020 (1)	07OCT2020 (1)	SERUM	NEGATIVE
Visit 2	28OCT2020 (22)	28OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (34)/ 05NOV2020 (30)/ ONGOING	YES	CHILLS	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (34)	COVID 19 viral infection	06NOV2020 (31)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (34)	09NOV2020 (34)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (34)	06NOV2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (34)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	CareNow

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1095 10951260, a 25-year-old white male with a height of 179 cm, a weight of 89.5 kg, and a BMI of 27.9 kg/m2, received Dose 1 on 07 Oct 2020 and Dose 2 on 28 Oct 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 2000). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Nov 2020 (Day 31), the subject was diagnosed with COVID-19 and reported chills, headache, new or increased cough, new or increased muscle pain, new or increased sore throat, and nasal congestion, with the first symptom starting on 05 Nov 2020, 8 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 34) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 31) was positive. The subject visited another practitioner (Care Now; once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	86.36 kg	23.7 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Male pattern baldness	Androgenetic alopecia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29AUG2020 (1)	10:49
2	Placebo	19SEP2020 (22)	09:18

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	29AUG2020 (1)	29AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29AUG2020 (1)	29AUG2020 (1)	SERUM	NEGATIVE
Visit 2	19SEP2020 (22)	19SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (73)/ 06NOV2020 (70)/ 08NOV2020 (72)	YES	FEVER	
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (73)	SARS-COV-2 positive	06NOV2020 (70)	1	SARS-CoV-2 test positive

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (73)	10NOV2020 (74)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (73)	06NOV2020 (70)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	bd veritor system rapid detection

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (73)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1096 10961172, a 51-year-old white male with a height of 190.5 cm, a weight of 86.36 kg, and a BMI of 23.7 kg/m2, received Dose 1 on 29 Aug 2020 and Dose 2 on 19 Sep 2020 (Day 22). The subject had a reported medical history of androgenetic alopecia (since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Nov 2020 (Day 70), the subject had a positive SARS-CoV-2 test and reported fever, fatigue, and new or increased cough, with the first symptom starting on 06 Nov 2020, 48 days after receiving Dose 2, and the last symptom resolved on 08 Nov 2020 (Day 72). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 74) was positive. The local laboratory SARS-CoV-2 chromatographic immunoassay result at the time of the COVID-19 illness on 06 Nov 2020 (Day 70) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	55.91 kg	21.8 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post menopausal	Postmenopause	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	16:04
2	Placebo	28SEP2020 (25)	11:31

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	04SEP2020 (1)	04SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04SEP2020 (1)	04SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (25)	28SEP2020 (25)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (53)/ 22OCT2020 (49)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (53)	COVID-19	22OCT2020 (49)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (53)	26OCT2020 (53)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26OCT2020 (53)	22OCT2020 (49)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (53)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1096 10961258, a 55-year-old white female with a height of 160.02 cm, a weight of 55.91 kg, and a BMI of 21.8 kg/m2, received Dose 1 on 04 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 25). The subject had a reported medical history of postmenopause (since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 22 Oct 2020 (Day 49), the subject was diagnosed with COVID-19 and reported fatigue, headache, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 22 Oct 2020, 24 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The local laboratory SARS-CoV-2 NAAT result at the time of COVID-19 illness on 22 Oct 2020 (Day 49) was positive. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 53) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	77.27 kg	29.2 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1994	Past
Hyperlipidemia	Hyperlipidaemia	25JAN2018	Present
Hypertension	Hypertension	25JAN2018	Present
Type 2 Diabetes	Type 2 diabetes mellitus	25AUG2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	15:28
2	Placebo	16SEP2020 (20)	14:55

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (20)	16SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 21OCT2020 (55)/ 17OCT2020 (51)/ 20OCT2020 (54)	NO		Body temperature increased
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	21OCT2020 (55)	19OCT2020 (53)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	21OCT2020 (55)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1098 10981062, a 63-year-old black or African American female with a height of 162.56 cm, a weight of 77.27 kg, and a BMI of 29.2 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject had a reported medical history of hysterectomy (in 1994) and hyperlipidemia, hypertension (both since 25 Jan 2018), and type 2 diabetes mellitus (since 25 Aug 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported body temperature increased and new or increased muscle pain, with the first symptom starting on 17 Oct 2020, 31 days after receiving Dose 2, and the last symptom resolved on 20 Oct 2020 (Day 54). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Oct 2020 (Day 53) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186.5 cm	95.5 kg	27.5 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2000	Present
asthma	Asthma	2005	Present
GERD	Gastrooesophageal reflux disease	2010	Present
carotid artery disease	Carotid artery disease	2016	Present
myocardial infarction	Myocardial infarction	2016	Past
coronary artery stent placement	Coronary arterial stent insertion	SEP2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	14:23
2	Placebo	14OCT2020 (21)	15:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	24SEP2020 (1)	24SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24SEP2020 (1)	24SEP2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (21)	14OCT2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04NOV2020 (42)/ 02NOV2020 (40)/ ONGOING	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion
	NO		Rhinorrhoea
	NO		Throat irritation

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04NOV2020 (42)	COVID-19	05NOV2020 (43)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	04NOV2020 (42)	04NOV2020 (42)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	04NOV2020 (42)	05NOV2020 (43)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Quidel Sofia 2 SARS Antigen FIA Test

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	04NOV2020 (42)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1101 11011095, a 60-year-old white male with a height of 186.5 cm, a weight of 95.5 kg, and a BMI of 27.5 kg/m2, received Dose 1 on 24 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 21). The subject had a reported medical history of allergic rhinitis (since 2000), asthma (since 2005), gastroesophageal reflux disease (since 2010), carotid artery disease (since 2016), myocardial infarction (in 2016), and coronary arterial stent insertion (in Sep 2016). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 05 Nov 2020 (Day 43), the subject was diagnosed with COVID-19 and reported new or increased cough, nasal congestion, rhinorrhea, and throat irritation, with the first symptom starting on 02 Nov 2020, 19 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 42) was positive. The local laboratory SARS-CoV-2 Quidel Sofia 2 SARS antigen fluorescent immunoassay result at the time of the COVID-19 illness on 05 Nov 2020 (Day 43) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195.58 cm	139.09 kg	36.3 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ENVIRONMENTAL ALLERGIES	Hypersensitivity	2000	Present
OVERWEIGHT	Overweight	2010	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2011	Present
ERECTILE DYSFUNCTION	Erectile dysfunction	2013	Present
ANXIETY	Anxiety	2014	Present
HYPOGONADISM	Hypogonadism	2014	Present
GOUT	Gout	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	12:10
2	Placebo	14SEP2020 (21)	13:53

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	REPRO	Prostatitis	ACUTE PROSTATITIS	11SEP2020 (18)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: UNKNOWN	1	18	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (21)	14SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (79)/ 10NOV2020 (78)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Respiratory tract congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (79)	COVID-19	11NOV2020 (79)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11NOV2020 (79)	11NOV2020 (79)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11NOV2020 (79)	11NOV2020 (79)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Quidel Sofia SARS Antigen FIA

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	11NOV2020 (79)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	12OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1107 11071171, a 39-year-old white male with a height of 195.58 cm, a weight of 139.09 kg, and a BMI of 36.3 kg/m2, received Dose 1 on 25 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 21). The subject had a reported medical history of hypersensitivity (since 2000), overweight (since 2010), gastroesophageal reflux disease (since 2011), erectile dysfunction (since 2013), anxiety and hypogonadism (both since 2014), and gout (since 2016). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 11 Nov 2020 (Day 79), the subject was diagnosed with COVID-19 and reported chills, fever, and respiratory tract congestion, with the first symptom starting on 10 Nov 2020, 57 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 79) was positive. The local laboratory SARS-CoV-2 Quidel Sofia 2 SARS antigen fluorescent immunoassay result at the time of the COVID-19 illness on 11 Nov 2020 (Day 79) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	88.64 kg	28.8 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	15:26
2	Placebo	20AUG2020 (21)	15:29

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31JUL2020 (1)	31JUL2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31JUL2020 (1)	31JUL2020 (1)	SERUM	NEGATIVE
Visit 2	20AUG2020 (21)	20AUG2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (104)/ 11NOV2020 (104)/ ONGOING	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11NOV2020 (104)	11NOV2020 (104)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	11NOV2020 (104)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	18SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091067, a 42-year-old white male with a height of 175.26 cm, a weight of 88.64 kg, and a BMI of 28.8 kg/m2, received Dose 1 on 31 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 21). The subject had a reported medical history of hypertension (since Jan 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported new or increased shortness of breath and new or increased sore throat, with the first symptom starting on 11 Nov 2020, 83 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 104) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2002	18	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	62.27 kg	19.1 kg/m2	01AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	2012	Present
ACNE	Acne	01JAN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01AUG2020 (1)	11:47
2	Placebo	23AUG2020 (23)	14:34

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	01AUG2020 (1)	01AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	01AUG2020 (1)	01AUG2020 (1)	SERUM	NEGATIVE
Visit 2	23AUG2020 (23)	23AUG2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (101)/ 31OCT2020 (92)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (101)	COVID-19	04NOV2020 (96)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (101)	10NOV2020 (102)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (101)	04NOV2020 (96)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (101)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01AUG2020	
Completed	VACCINATION	26SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091092, an 18-year-old white male with a height of 180.34 cm, a weight of 62.27 kg, and a BMI of 19.1 kg/m2, received Dose 1 on 01 Aug 2020 and Dose 2 on 23 Aug 2020 (Day 23). The subject had a reported medical history of asthma (since 2012) and acne (since 01 Jan 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 04 Nov 2020 (Day 96), the subject was diagnosed with COVID-19 and reported fever, new or increased cough, and new or increased sore throat, with the first symptom starting on 31 Oct 2020, 69 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 102) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 96) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	95.45 kg	28.5 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2018	Present
DIABETES MELLITUS TYPEII	Type 2 diabetes mellitus	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	09:24
2	Placebo	15SEP2020 (22)	10:06

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (22)	15SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (71)/ 31OCT2020 (68)/ 02NOV2020 (70)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03NOV2020 (71)	03NOV2020 (71)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03NOV2020 (71)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091323, a 64-year-old white male with a height of 182.88 cm, a weight of 95.45 kg, and a BMI of 28.5 kg/m2, received Dose 1 on 25 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 22). The subject had a reported medical history of hypercholesterolemia and type 2 diabetes mellitus (both since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, new or increased cough, and new or increased muscle pain, with the first symptom starting on 31 Oct 2020, 46 days after receiving Dose 2, and the last symptom resolved on 02 Nov 2020 (Day 70). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Nov 2020 (Day 71) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	106.82 kg	36.8 kg/m2	05SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY TO PENICILLIN	Drug hypersensitivity	1974	Present
Asthma	Asthma	1994	Present
Hysterectomy	Hysterectomy	2015	Past
Postmenopausal	Postmenopause	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05SEP2020 (1)	14:32
2	Placebo	24SEP2020 (20)	12:23

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	05SEP2020 (1)	05SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	05SEP2020 (1)	05SEP2020 (1)	SERUM	NEGATIVE
Visit 2	24SEP2020 (20)	24SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (66)/ 03NOV2020 (60)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (66)	11NOV2020 (68)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (66)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05SEP2020	
Completed	VACCINATION	23OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091416, a 46-year-old white female with a height of 170.18 cm, a weight of 106.82 kg, and a BMI of 36.8 kg/m2, received Dose 1 on 05 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 20). The subject had a reported medical history of drug hypersensitivity (penicillin allergy since 1974), asthma (since 1994), hysterectomy (in 2015), and postmenopause (since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fever, new or increased cough, and new or increased sore throat, with the first symptom starting on 03 Nov 2020, 40 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 68) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	82.73 kg	29.4 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FIBROMYALGIA	Fibromyalgia	1990	Present
ALLERGY TO AUGMENTIN	Drug hypersensitivity	1995	Present
ALLERGY TO KEFLEX	Drug hypersensitivity	1995	Present
ALLERGY TO BIAXIN	Drug hypersensitivity	2005	Present
ALLERGY TO LATEX	Rubber sensitivity	2005	Present
HYSTERECTOMY	Hysterectomy	2006	Past
POSTMENOPAUSAL	Postmenopause	2006	Present
ALLERGY TO SEPTRA	Drug hypersensitivity	2008	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	2010	Present
Hemiplegic Migraine	Hemiplegic migraine	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	15:07
2	Placebo	28SEP2020 (21)	08:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Hemiplegic migraine	Hemiplegic Migraine	20OCT2020 (43)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Related to subjects history of headaches	2	23	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (21)	28SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09OCT2020 (32)/ 06OCT2020 (29)/ 28OCT2020 (51)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09OCT2020 (32)	COVID-19 Infection	21OCT2020 (44)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09OCT2020 (32)	09OCT2020 (32)	NASAL_SWAB_SELF	POSITIVE
2	COVID Illness Visit 1 - Repeat Swab	23OCT2020 (46)	23OCT2020 (46)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09OCT2020 (32)	21OCT2020 (44)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09OCT2020 (32)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091448, a 46-year-old white female with a height of 167.64 cm, a weight of 82.73 kg, and a BMI of 29.4 kg/m2, received Dose 1 on 08 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 21). The subject had a reported medical history of fibromyalgia (since 1990), drug hypersensitivity (allergy to Augmentin and Keflex, both since 1995; Biaxin, since 2005; and Septra, since 2008), rubber sensitivity (latex allergy, since 2005), hysterectomy (in 2006), postmenopause (since 2006), and headache and hemiplegic migraine (both since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 20 Oct 2020 (Day 43), the subject experienced hemiplegic migraine and visited emergency room requiring hospitalization on the same day. During hospitalization, a magnetic resonance imaging of head (date not reported) did not show any abnormalities. A computed tomogram of the brain was unremarkable and a computed tomography angiogram was negative. Complete blood count and coagulation tests were unremarkable. Perfusion brain scan showed no mismatch. Metabolic panel showed potassium of 3.1 and troponin <0.02 (units and normal ranges not provided). Urine analysis showed leukocytes. The final diagnosis was a flare-up of hemiplegic migraine, which was not a worsening event but only a flare-up. The subject stated that she had a history of hemiplegic migraines and she visited the hospital when they flared-up to break the cycle, which then resolved until the next flare-up. The subject was recovering from the hemiplegic migraine. On 22 Oct 2020 (Day 45), the subject was discharged from the hospital. The investigator considered the hemiplegic migraine was not related to the study intervention, but related to the subject's history of headaches. Pfizer concurred with the investigator's causality assessment. On 21 Oct 2020 (Day 44), the subject was diagnosed with COVID-19 and reported fever, new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 06 Oct 2020, 8 days after receiving Dose 2, and the last symptom resolved on 28 Oct 2020 (Day 51). The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 09 Oct 2020 (Day 32) and 23 Oct 2020 (Day 46) were positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 21 Oct 2020 (Day 44) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	86.36 kg	25.8 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	01JAN2018	Present
CHRONIC OBSTRUCETIVE PULOMNARY DISEASE	Chronic obstructive pulmonary disease	01JAN2019	Present
ATRIAL FIBRILLATION	Atrial fibrillation	01JUN2019	Present
CARDIAC ABLATION	Cardiac ablation	15SEP2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	13:14
2	Placebo	02OCT2020 (23)	14:09

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza	INFLUENZA VACCINE	16SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	10SEP2020 (1)	10SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	10SEP2020 (1)	10SEP2020 (1)	SERUM	NEGATIVE
Visit 2	02OCT2020 (23)	02OCT2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (55)/ 29OCT2020 (50)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	03NOV2020 (55)	03NOV2020 (55)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	03NOV2020 (55)	29OCT2020 (50)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03NOV2020 (55)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	03NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091482, a 63-year-old white male with a height of 182.88 cm, a weight of 86.36 kg, and a BMI of 25.8 kg/m2, received Dose 1 on 10 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 23). The subject had a reported medical history of hypertension (since 01 Jan 2018), chronic obstructive pulmonary disease (since 01 Jan 2019), atrial fibrillation (since 01 Jun 2019), and cardiac ablation (on 15 Sep 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported new loss of taste or smell and new or increased cough, with the first symptom starting on 29 Oct 2020, 27 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Nov 2020 (Day 55) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 50) was negative. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.8 cm	81.6 kg	24.4 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
attention deficit disorder	Attention deficit hyperactivity disorder	(b) (6) 1973	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	11:52
2	BNT162b2	27AUG2020 (21)	09:12

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1			Hypertension	12NOV2020 (98)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC	N	Yes	NOT RELATED/OTHER: Unknown	2	78	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	07AUG2020 (1)	07AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07AUG2020 (1)	07AUG2020 (1)	SERUM	NEGATIVE
Visit 2	27AUG2020 (21)	27AUG2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12NOV2020 (98)/ 10NOV2020 (96)/ ONGOING	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	12NOV2020 (98)	COVID19	12NOV2020 (98)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	12NOV2020 (98)	12NOV2020 (98)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	12NOV2020 (98)	12NOV2020 (98)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Nalt unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	12NOV2020 (98)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	24SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1110 11101050, a 47-year-old white male with a height of 182.8 cm, a weight of 81.6 kg, and a BMI of 24.4 kg/m2, received Dose 1 on 07 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 21). The subject had a reported medical history of attention deficit hyperactivity disorder (since (b) (6) 1973). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 12 Nov 2020 (Day 98), the subject was diagnosed with COVID-19 and reported chills, new or increased cough, and new or increased sore throat, with the first symptom starting on 10 Nov 2020, 75 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Nov 2020 (Day 98) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Nov 2020 (Day 98) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	123.36 kg	37.8 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	DEC2017	Present
Osteoarthritis Right Knee	Osteoarthritis	OCT2018	Past
Right Knee Arthroplasty	Knee arthroplasty	05AUG2019	Past
Sleep Disturbance Disorder	Sleep disorder	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	13:11
2	Placebo	14SEP2020 (21)	11:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	VASC	Hypertension	hypertension	07SEP2020 (14)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: unknown	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (21)	14SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06NOV2020 (74)/ 04NOV2020 (72)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	NO		Respiratory tract congestion
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06NOV2020 (74)	Covid-19	05NOV2020 (73)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	06NOV2020 (74)	06NOV2020 (74)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location	Test Result
1	COVID Illness Visit 1	06NOV2020 (74)	05NOV2020 (73)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	subject tested a nasal swab at marlins stadium and received phone call he was covis-19 positive on 06nov2020.	OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06NOV2020 (74)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1110 11101136, a 62-year-old white male with a height of 180.34 cm, a weight of 123.36 kg, and a BMI of 37.8 kg/m2, received Dose 1 on 25 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 21). The subject had a reported medical history of gastroesophageal reflux disease (since Dec 2017), osteoarthritis (in Oct 2018), knee arthroplasty (right knee, on 05 Aug 2019), and sleep disorder (since Jun 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 05 Nov 2020 (Day 73), the subject was diagnosed with COVID-19 and reported chills, diarrhea, fatigue, headache, new or increased cough, respiratory tract congestion, and rhinorrhea, with the first symptom starting on 04 Nov 2020, 51 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 74) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 73) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.51 cm	124.27 kg	40.3 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	FEB2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	12:03
2	BNT162b2	21SEP2020 (24)	09:13

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	29AUG2020 (1)	29AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29AUG2020 (1)	29AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (24)	21SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (59)/ 24OCT2020 (57)/ ONGOING	NO		Arthralgia
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (59)	Covid-19	24OCT2020 (57)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (59)	26OCT2020 (59)	NASAL_SWAB_SELF	POSITIVE
2	COVID Illness Visit 1	26OCT2020 (59)	03NOV2020 (67)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26OCT2020 (59)	24OCT2020 (57)	SWABBED MATERIAL	THROAT
2	COVID Illness Visit 1	26OCT2020 (59)	30OCT2020 (63)	SWABBED MATERIAL	THROAT

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Curative-Korva SARS-Cov-2 Assay
2	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	26OCT2020 (59)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1110 11101162, a 51-year-old white male with a height of 175.51 cm, a weight of 124.27 kg, and a BMI of 40.3 kg/m2, received Dose 1 on 29 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 24). The subject had a reported medical history of type 2 diabetes mellitus (since Feb 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 24 Oct 2020 (Day 57), the subject was diagnosed with COVID-19 and reported arthralgia, headache, new loss of taste or smell, new or increased cough, with the first symptom starting on 24 Oct 2020, 33 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 26 Oct 2020 (Day 59) and 03 Nov 2020 (Day 67) were positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 24 Oct 2020 (Day 57) and 30 Oct 2020 (Day 63) were positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	103.73 kg	29.3 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hernia repair	Hernia repair	1982	Past
Erectile dysfunction	Erectile dysfunction	2000	Present
Low libido	Libido decreased	2000	Present
nearsighted	Myopia	2000	Present
Type II Diabetes Mellitus	Type 2 diabetes mellitus	2000	Present
diabetic neuropathy	Diabetic neuropathy	2005	Present
Left knee torn meiniscus	Meniscus injury	2014	Past
osteoarthritis Right knee and shoulder	Osteoarthritis	2014	Present
depression	Depression	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2017	Present
replaced mitral valve	Mitral valve replacement	2017	Past
transient ischemic attack	Transient ischaemic attack	2017	Past
hernia repair	Hernia repair	2018	Past
Colon polyps-benign	Large intestine polyp	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	15:36
2	Placebo	21AUG2020 (22)	11:12

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLUAD Quadrivalent	INFLUENZA VACCINE INACT SAG 4V	22SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	31JUL2020 (1)	31JUL2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31JUL2020 (1)	31JUL2020 (1)	SERUM	NEGATIVE
Visit 2	21AUG2020 (22)	21AUG2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05OCT2020 (67)/ 04OCT2020 (66)/ 05OCT2020 (67)	YES	CHILLS	
	YES	FEVER	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05OCT2020 (67)	06OCT2020 (68)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05OCT2020 (67)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	18SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1111 11111010, a 75-year-old white male with a height of 187.96 cm, a weight of 103.73 kg, and a BMI of 29.3 kg/m2, received Dose 1 on 31 Jul 2020 and Dose 2 on 21 Aug 2020 (Day 22). The subject had a reported medical history of hernia repair (in 1982); erectile dysfunction, libido decreased, myopia, and type 2 diabetes mellitus (all since 2000); diabetic neuropathy (since 2005); meniscus injury (in 2014); osteoarthritis (since 2014); mitral valve replacement and transient ischemic attack (both in 2017); depression and hypertension (both since 2017); hernia repair (in 2018); and large intestine polyp (in 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills and fever, with the first symptom starting on 04 Oct 2020, 44 days after receiving Dose 2, and the last symptom resolved on 05 Oct 2020 (Day 67). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Oct 2020 (Day 68) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject had a telephone consultation (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186.69 cm	108.91 kg	31.2 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High Cholesterol	Blood cholesterol increased	2018	Present
Heart Stent placement	Coronary arterial stent insertion	2018	Present
Parkinson disease	Parkinson's disease	FEB2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	10:29
2	Placebo	22SEP2020 (22)	08:39

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	SURG	Meniscus operation	Repair torn meniscus	13OCT2020 (43)	00:00	13OCT2020 (43)	00:00	1
2	EAR	Tinnitus	tinnitus	04OCT2020 (34)	00:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: Injury	2	22	N
2	1	N	N	Yes	NOT RELATED/OTHER: natural occurance	2	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	01SEP2020 (1)	01SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	01SEP2020 (1)	01SEP2020 (1)	SERUM	NEGATIVE
Visit 2	22SEP2020 (22)	22SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (66)/ 03NOV2020 (64)/ ONGOING	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05NOV2020 (66)	05NOV2020 (66)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (66)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	05NOV2020 (66)	05NOV2020 (66)	1	132 mmHg	70 mmHg	21 breaths/min	58 beats/min	97 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1116 11161075, a 73-year-old white male with a height of 186.69 cm, a weight of 108.91 kg, and a BMI of 31.2 kg/m2, received Dose 1 on 01 Sep 2020 and Dose 2 on 22 Sep 2020 (Day 22). The subject had a reported medical history of blood cholesterol increased and coronary arterial stent insertion (both since 2018) and Parkinson's disease (since Feb 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, new or increased cough, and new or increased shortness of breath, with the first symptom starting on 03 Nov 2020, 42 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 66) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel. On 05 Nov 2020 (Day 66), the subject had a heart rate of 58 beats per minute, blood pressure of 132/70 mmHg, respiratory rate of 21 breaths per minute, and oxygen saturation of 97% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.79 cm	115.05 kg	33.6 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral Eye Radial Keratotomy	Keratotomy	1981	Past
Prostate Cancer	Prostate cancer	2005	Past
Prostatectomy	Prostatectomy	2005	Past
ERECTILE DYSFUNCTION	Erectile dysfunction	2010	Present
Hypertension	Hypertension	2015	Present
Asymptomatic Tachycardia	Tachycardia	18SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	17:37

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	18SEP2020 (1)	18SEP2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	18SEP2020 (1)	18SEP2020 (1)	SERUM	NEGATIVE
Visit 2	08OCT2020 (21)	08OCT2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28SEP2020 (11)/ 25SEP2020 (8)/ 06OCT2020 (19)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 2 / 27OCT2020 (40)/ 25OCT2020 (38)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	NO		Pain
	NO		Primary cough headache

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28SEP2020 (11)	Covid-19	26SEP2020 (9)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28SEP2020 (11)	28SEP2020 (11)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	27OCT2020 (40)	27OCT2020 (40)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	28SEP2020 (11)	26SEP2020 (9)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	The trade name of swab was not in the medical report. CRC called and was given name below.	OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28SEP2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA
COVID Illness Visit 2	27OCT2020 (40)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	28SEP2020 (11)	28SEP2020 (11)	1	118 mmHg	84 mmHg	28 breaths/min	137 beats/min	96 %
COVID Illness Visit 2	27OCT2020 (40)	27OCT2020 (40)	2	125 mmHg	91 mmHg	22 breaths/min	108 beats/min	98 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Withdrawn	VACCINATION	28SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1116 11161253, a 61-year-old white male with a height of 184.79 cm, a weight of 115.05 kg, and a BMI of 33.6 kg/m2, received Dose 1 on 18 Sep 2020. The subject had a reported medical history of keratotomy (in 1981), prostate cancer and prostatectomy (both in 2005), erectile dysfunction (since 2010), hypertension (since 2015), and tachycardia (since 18 Sep 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 (18 Sep 2020 [Day 1]) and positive at Visit 2 (08 Oct 2020 [Day 21]). The central laboratory N-binding antibody result was negative at Visit 1 (18 Sep 2020 [Day 1]). On 26 Sep 2020 (Day 9), the subject was diagnosed with severe COVID-19 and reported chills, fever, new or increased cough, and new or increased muscle pain, with the first symptom starting on 25 Sep 2020, 7 days after receiving Dose 1 and the last symptom resolved on 06 Oct 2020 (Day 19). The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Sep 2020 (Day 9) was positive. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Sep 2020 (Day 11) was positive. On 28 Sep 2020 (Day 11), the subject had a heart rate of 137 beats per minute (bpm), blood pressure of 118/84 mmHg, respiratory rate of 28 breaths per minute, and oxygen saturation of 96% on room air. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and heart rate more than 125 bpm). The subject had an urgent care visit (once). The subject was discontinued from the study intervention on 28 Sep 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.5 cm	74.73 kg	29.7 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MYOPIA BILATERAL	Myopia	1954	Past
VARICOSE VEINS	Varicose vein	1978	Present
KERATOTOMY BILATERAL	Keratotomy	1998	Past
CATARACT LEFT EYE	Cataract	2010	Past
CATARACT RIGHT EYE	Cataract	2010	Past
GERD	Gastrooesophageal reflux disease	2013	Present
OSTEOPENIA	Osteopenia	03SEP2014	Present
URGE TYPE URINARY INCONTINENCE	Urinary incontinence	02MAY2017	Present
UTERINE PROLAPSE	Uterine prolapse	02MAY2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HIGH CHOLESTEROL	Blood cholesterol increased	FEB2018	Present
LEFT KNEE INJURY	Joint injury	MAR2018	Past
LOW VITAMIN D	Vitamin D decreased	24OCT2018	Present
HYSTERECTOMY	Hysterectomy	12DEC2018	Past
CATARACT SURGERY	Cataract operation	23JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	17:51
2	Placebo	08SEP2020 (23)	16:02

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
FLU VACCINE	INFLUENZA VACCINE	25SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	17AUG2020 (1)	17AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17AUG2020 (1)	17AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (23)	08SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12OCT2020 (57)/ 11OCT2020 (56)/ 19OCT2020 (64)	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	12OCT2020 (57)	11OCT2020 (56)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	12OCT2020 (57)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1117 11171010, a 72-year-old white female with a height of 158.5 cm, a weight of 74.73 kg, and a BMI of 29.7 kg/m2, received Dose 1 on 17 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 23). The subject had a reported medical history of myopia (in 1954); varicose vein (since 1978); keratotomy (in 1998); cataract (left and right eyes, in 2010); gastroesophageal reflux disease (since 2013); osteopenia (since 03 Sep 2014); uterine prolapse (on 02 May 2017); urinary incontinence (since 02 May 2017); blood cholesterol increased (since Feb 2018); joint injury (left knee; in Mar 2018); vitamin D decreased (since 24 Oct 2018); hysterectomy (on 12 Dec 2018); and cataract operation (on 23 Jun 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fever, headache, and new or increased cough, with the first symptom starting on 11 Oct 2020, 33 days after receiving Dose 2, and the last symptom resolved on 19 Oct 2020 (Day 64).. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Oct 2020 (Day 56) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject had a telephone consultation (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.1 cm	90 kg	28.4 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
vasectomy	Vasectomy	1976	Past
varicose veins - right leg	Varicose vein	2000	Present
INSERT HEART STENT (3)	Coronary arterial stent insertion	2011	Present
hypercholesterolemia	Hypercholesterolaemia	2011	Present
heart attack	Myocardial infarction	2011	Past
triple bypass surgery	Coronary artery bypass	DEC2011	Past
gout	Gout	2013	Present
diabetes type 2	Type 2 diabetes mellitus	2014	Present
insert leg stent - right leg	Vascular stent insertion	2014	Present

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	08:18
2	Placebo	15SEP2020 (20)	14:44

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluzone Quadrivalent Influenza Vaccine	INFLUENZA VACCINE INACT SPLIT 4V	20OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (20)	15SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (65)/ 20OCT2020 (55)/ ONGOING	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Rhinorrhoea
	NO		Sputum increased

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30OCT2020 (65)	COVID-19	28OCT2020 (63)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (65)	29OCT2020 (64)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (65)	28OCT2020 (63)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	confirmed test manufacturer and kit name with local health department through which test was performed	ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	30OCT2020 (65)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	health department nurse

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1118 11181088, a 73-year-old white male with a height of 178.1 cm, a weight of 90 kg, and a BMI of 28.4 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 20). The subject had a reported medical history of vasectomy (in 1976), varicose vein (since 2000), myocardial infarction (in 2011), coronary arterial stent insertion and hypercholesterolemia (both since 2011), coronary artery bypass (in Dec 2011), gout (since 2013), type 2 diabetes mellitus and vascular stent insertion (both since 2014). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 28 Oct 2020 (Day 63), the subject was diagnosed with COVID-19 and reported headache, new or increased cough, new or increased muscle pain, rhinorrhea, and sputum increased, with the first symptom starting on 20 Oct 2020, 35 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 64) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Oct 2020 (Day 63) was positive. The subject visited a health department nurse (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2001	19	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.6 cm	119.9 kg	40.7 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Exercise induced Bronchospasms	Bronchospasm	2012	Present
Anxiety	Anxiety	2014	Present
Depression	Depression	2015	Present
Hypothyriodism	Hypothyroidism	2016	Present
Idiopathic Hypersomnia	Hypersomnia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	16:34
2	Placebo	26AUG2020 (20)	16:25

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	07AUG2020 (1)	07AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07AUG2020 (1)	07AUG2020 (1)	SERUM	NEGATIVE
Visit 2	26AUG2020 (20)	26AUG2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (95)/ 06NOV2020 (92)/ ONGOING	YES	DIARRHEA	
	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (95)	09NOV2020 (95)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	09NOV2020 (95)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	25SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1120 11201115, a 19-year-old white female with a height of 171.6 cm, a weight of 119.9 kg, and a BMI of 40.7 kg/m2, received Dose 1 on 07 Aug 2020 and Dose 2 on 26 Aug 2020 (Day 20). The subject had a reported medical history of bronchospasm (exercise induced, since 2012), anxiety (since 2014), depression (since 2015), hypothyroidism (since 2016), and hypersomnia (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported diarrhea, fever, fatigue, headache, new or increased muscle pain, new or increased sore throat, and nasal congestion, with the first symptom starting on 06 Nov 2020, 72 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 95) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	90.14 kg	28.4 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cold sores	Oral herpes	1995	Present
schatzki ring	Acquired oesophageal web	2008	Past
hiatal hernia	Hiatus hernia	2008	Present
dilated esophagus procedure	Oesophageal dilation procedure	2008	Past
vasectomy	Vasectomy	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	16:40
2	Placebo	01OCT2020 (22)	10:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Oral herpes	worsening of cold sore	15SEP2020 (6)		18SEP2020 (9)		4	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (18SEP2020)	NOT RELATED/OTHER: pre-existing medical condition	1	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	10SEP2020 (1)	10SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	10SEP2020 (1)	10SEP2020 (1)	SERUM	NEGATIVE
Visit 2	01OCT2020 (22)	01OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (55)/ 01NOV2020 (53)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	NO		Insomnia
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03NOV2020 (55)	COVID-19	03NOV2020 (55)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03NOV2020 (55)	03NOV2020 (55)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	03NOV2020 (55)	03NOV2020 (55)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		THERMOFISHER SCIENTIFIC TAQPATH COVID-19 COMBO KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03NOV2020 (55)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA
		OTHER	YES	1	personnel health clinic

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1122 11221025, a 40-year-old white male with a height of 177.8 cm, a weight of 90.14 kg, and a BMI of 28.4 kg/m2, received Dose 1 on 10 Sep 2020 and Dose 2 on 01 Oct 2020 (Day 22). The subject had a reported medical history of oral herpes (since 1995), esophageal dilation procedure and acquired esophageal web (both in 2008), hiatus hernia (since 2008), and vasectomy (in 2016). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 03 Nov 2020 (Day 55), the subject was diagnosed with COVID-19 and reported chills, fever, headache, insomnia, new or increased cough, and new or increased muscle pain, with the first symptom starting on 01 Nov 2020, 31 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Nov 2020 (Day 55) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Nov 2020 (Day 55) was positive. The subject had a telephone consultation (once) and went to a personnel health clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	65.8 kg	23.9 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	2005	Present
Depression	Depression	2009	Past
Obesity	Obesity	2018	Past
Gastric sleeve	Gastrectomy	APR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	15:58
2	Placebo	01SEP2020 (22)	15:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	11AUG2020 (1)	11AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11AUG2020 (1)	11AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (22)	01SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11SEP2020 (32)/ 10SEP2020 (31)/ 06OCT2020 (57)	YES	CHILLS	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Sputum increased

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11SEP2020 (32)	COVID-19	11SEP2020 (32)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11SEP2020 (32)	11SEP2020 (32)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	11SEP2020 (32)	11SEP2020 (32)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	Nurse Called Back. Information updated	ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	11SEP2020 (32)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1123 11231073, a 25-year-old white female with a height of 166 cm, a weight of 65.8 kg, and a BMI of 23.9 kg/m2, received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 2005), depression (in 2009), obesity (in 2018), and gastrectomy (in Apr 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 11 Sep 2020 (Day 32), the subject was diagnosed with COVID-19 and reported chills, fatigue, headache, new or increased cough, new or increased muscle pain, new or increased sore throat, nasal congestion, and increased sputum, with the first symptom starting on 10 Sep 2020, 9 days after receiving Dose 2, and the last symptom resolved on 06 Oct 2020 (Day 57). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Sep 2020 (Day 32) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Sep 2020 (Day 32) was positive. The subject went to her primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	72.5 kg	22.4 kg/m2	13AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	14:16
2	Placebo	01SEP2020 (20)	11:20

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Fatigue	Fatigue	04SEP2020 (23)		09SEP2020 (28)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	6	1	N	N	Resolved (09SEP2020)	Study Treatment	2	4	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	13AUG2020 (1)	13AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13AUG2020 (1)	13AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (20)	01SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28OCT2020 (77)/ 27OCT2020 (76)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion
	NO		Productive cough
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28OCT2020 (77)	COVID-19	29OCT2020 (78)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	28OCT2020 (77)	28OCT2020 (77)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	28OCT2020 (77)	29OCT2020 (78)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28OCT2020 (77)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1123 11231086, a 35-year-old white female with a height of 180 cm, a weight of 72.5 kg, and a BMI of 22.4 kg/m2, received Dose 1 on 13 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 20). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 29 Oct 2020 (Day 78), the subject was diagnosed with COVID-19 and reported fatigue, headache, new or increased cough, new or increased muscle pain, nasal congestion, productive cough, and rhinorrhea, with the first symptom starting on 27 Oct 2020, 56 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Oct 2020 (Day 77) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 78) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	55	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	69.5 kg	24 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Menorrhagia	Menorrhagia	2000	Past
Thyroid nodules	Thyroid mass	2012	Past
Thyroidectomy	Thyroidectomy	2012	Past
Hysterectomy	Hysterectomy	2015	Past
R shoulder adhesive capsulitis	Periarthritis	2015	Present
Left Nephrectomy (kidney donation)	Organ donor	FEB2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	11:43
2	Placebo	08SEP2020 (22)	12:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Periarthritis	Worsening of right adhesive capsulitis shoulder	14SEP2020 (28)		06OCT2020 (50)		23

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (06OCT2020)	NOT RELATED/OTHER: med hx	2	7	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	18AUG2020 (1)	18AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18AUG2020 (1)	18AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (22)	08SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (86)/ 10NOV2020 (85)/ ONGOING	YES	CHILLS	
	NO		Fatigue
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11NOV2020 (86)	11NOV2020 (86)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11NOV2020 (86)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1123 11231117, a 55-year-old white female with a height of 170 cm, a weight of 69.5 kg, and a BMI of 24 kg/m2, received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject had a reported medical history of menorrhagia (in 2000), thyroid mass and thyroidectomy (both in 2012), hysterectomy (in 2015), periarthritis (right shoulder, since 2015), and organ donor (kidney donation, in Feb 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fatigue, and new or increased muscle pain, with the first symptom starting on 10 Nov 2020, 63 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 86) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	62.3 kg	23.7 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2000	Present
Slipped L4 disc	Intervertebral disc protrusion	2005	Present
Hypothyroidism	Hypothyroidism	2014	Present
Nerve pain in right leg	Neuralgia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	14:18
2	Placebo	23SEP2020 (20)	11:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04SEP2020 (1)	04SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04SEP2020 (1)	04SEP2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (20)	23SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (63)/ 26OCT2020 (53)/ ONGOING	YES	CHILLS	
	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Productive cough
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	05NOV2020 (63)	COVID-19	29OCT2020 (56)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05NOV2020 (63)	05NOV2020 (63)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	05NOV2020 (63)	28OCT2020 (55)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (63)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1123 11231214, a 60-year-old white female with a height of 162 cm, a weight of 62.3 kg, and a BMI of 23.7 kg/m2, received Dose 1 on 04 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 20). The subject had a reported medical history of depression (since 2000), intervertebral disc protrusion (slipped L4 disc, since 2005), hypothyroidism (since 2014), and neuralgia (right leg, since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 29 Oct 2020 (Day 56), the subject was diagnosed with COVID-19 and reported chills, fatigue, headache, new loss of taste or smell, new or increased cough, new or increased shortness of breath, new or increased sore throat, nasal congestion, productive cough, and rhinorrhea, with the first symptom starting on 26 Oct 2020, 33 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 63) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Oct 2020 (Day 55) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	79.5 kg	24.3 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	2005	Present
Diabetes mellitus type 2	Type 2 diabetes mellitus	2010	Present
Retagliptin allergy	Drug hypersensitivity	2015	Present
Hyperlipidemia	Hyperlipidaemia	2015	Present
Hypertension	Hypertension	2015	Present
Hammer toe	Foot deformity	2019	Past
Toes 1-5 amputation (Right)	Toe amputation	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	12:24
2	Placebo	05OCT2020 (20)	10:58

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16SEP2020 (1)	16SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16SEP2020 (1)	16SEP2020 (1)	SERUM	NEGATIVE
Visit 2	05OCT2020 (20)	05OCT2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02NOV2020 (48)/ 24OCT2020 (39)/ ONGOING	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	02NOV2020 (48)	02NOV2020 (48)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	02NOV2020 (48)	30OCT2020 (45)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02NOV2020 (48)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1123 11231255, a 76-year-old white male with a height of 181 cm, a weight of 79.5 kg, and a BMI of 24.3 kg/m2, received Dose 1 on 16 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 20). The subject had a reported medical history of hypothyroidism (since 2005); type 2 diabetes mellitus (since 2010); drug hypersensitivity (retagliptin allergy), hyperlipidemia, and hypertension (all since 2015); and foot deformity and toe amputation (both in 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported new or increased cough starting on 24 Oct 2020, 19 days after receiving Dose 2, that was ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Nov 2020 (Day 48) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 45) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.7 cm	72.6 kg	25.2 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	2005	Present
Low progesterone	Progesterone decreased	2009	Present
Hypertension	Hypertension	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	12:18
2	Placebo	05OCT2020 (20)	10:48

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16SEP2020 (1)	16SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16SEP2020 (1)	16SEP2020 (1)	SERUM	NEGATIVE
Visit 2	05OCT2020 (20)	05OCT2020 (20)	NASAL_SWAB	NEGATIVE

Case Details

Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 02NOV2020 (48)/ 28OCT2020 (43)/ ONGOING	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	02NOV2020 (48)	02NOV2020 (48)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02NOV2020 (48)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1123 11231256, a 72-year-old white female with a height of 169.7 cm, a weight of 72.6 kg, and a BMI of 25.2 kg/m2, received Dose 1 on 16 Sep 2020 and Dose 2 on 05 Oct 2020 (Day 20). The subject had a reported medical history of hypothyroidism (since 2005), progesterone decreased (since 2009), and hypertension (since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fatigue, new or increased cough, nasal congestion, and rhinorrhea, with the first symptom starting on 28 Oct 2020, 23 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Nov 2020 (Day 48) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189.5 cm	86.5 kg	24.1 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	1958	Present
Hypertension	Hypertension	2008	Present
Hyperlipidemia	Hyperlipidaemia	2017	Present
Osteoarthritis bilateral knees	Osteoarthritis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	14:26
2	Placebo	13OCT2020 (22)	14:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22SEP2020 (1)	22SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22SEP2020 (1)	22SEP2020 (1)	SERUM	NEGATIVE
Visit 2	13OCT2020 (22)	13OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (35)/ 24OCT2020 (33)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (35)	COVID 19	26OCT2020 (35)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	26OCT2020 (35)	26OCT2020 (35)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	26OCT2020 (35)	26OCT2020 (35)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	26OCT2020 (35)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22SEP2020	
Completed	VACCINATION	10NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1123 11231284, a 67-year-old white male with a height of 189.5 cm, a weight of 86.5 kg, and a BMI of 24.1 kg/m2, received Dose 1 on 22 Sep 2020 and Dose 2 on 13 Oct 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 1958), hypertension (since 2008), hyperlipidemia (since 2017), and osteoarthritis (since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 26 Oct 2020 (Day 35), the subject was diagnosed with COVID-19 and reported chills, fever, fatigue, headache, new or increased cough, and new or increased muscle pain, with the first symptom starting on 24 Oct 2020, 11 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 35) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 35) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.15 cm	103.64 kg	30.5 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	MAR2020	Present
Acid reflux	Gastrooesophageal reflux disease	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	13:07
2	Placebo	31AUG2020 (20)	16:18

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	30SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	31AUG2020 (20)	31AUG2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12OCT2020 (62)/ 11OCT2020 (61)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	12OCT2020 (62)	11OCT2020 (61)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	12OCT2020 (62)	13OCT2020 (63)	SWABBED MATERIAL	THROAT

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Realtime PCR (molecular)

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	12OCT2020 (62)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1125 11251006, a 35-year-old white male with a height of 184.15 cm, a weight of 103.64 kg, and a BMI of 30.5 kg/m2, received Dose 1 on 12 Aug 2020 and Dose 2 on 31 Aug 2020 (Day 20).
The subject had a reported medical history of anxiety and gastroesophageal reflux disease (both since Mar 2020).
The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.
The subject reported chills, fever, and new or increased cough, with the first symptom starting on 11 Oct 2020, 41 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report.
The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Oct 2020 (Day 61) was positive.
The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 63) was positive.
The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	104.09 kg	38.1 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hyperthyroidism	Hyperthyroidism	1994	Past
Radioactive Iodine Treatment on thyroid	Radioactive iodine therapy	1994	Past
General discomfort	Discomfort	1995	Present
bilateral tubal ligation	Female sterilisation	19AUG2004	Past
Seasonal Allergies	Seasonal allergy	2005	Present
Anxiety	Anxiety	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	17:46
2	Placebo	02SEP2020 (22)	08:47

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	02SEP2020 (22)	02SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10NOV2020 (91)/ 30OCT2020 (80)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10NOV2020 (91)	10NOV2020 (91)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	10NOV2020 (91)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251014, a 45-year-old white female with a height of 165.1 cm, a weight of 104.09 kg, and a BMI of 38.1 kg/m2, received Dose 1 on 12 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 22). The subject had a reported medical history of hyperthyroidism and radioactive iodine therapy (both in 1994), general discomfort (since 1995), female sterilization (on 19 Aug 2004), seasonal allergy (since 2005), and anxiety (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, diarrhea, fever, fatigue, new or increased cough, new or increased muscle pain, and new or increased shortness of breath, with the first symptom starting on 30 Oct 2020, 58 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 91) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.4 cm	113.4 kg	33 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity-BMI of 33.0	Obesity	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	15:50
2	Placebo	02SEP2020 (21)	10:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	13AUG2020 (1)	13AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13AUG2020 (1)	13AUG2020 (1)	SERUM	NEGATIVE
Visit 2	02SEP2020 (21)	02SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06NOV2020 (86)/ 27OCT2020 (76)/ ONGOING	YES	CHILLS	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	06NOV2020 (86)	06NOV2020 (86)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06NOV2020 (86)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251023, a 49-year-old white male with a height of 185.4 cm, a weight of 113.4 kg, and a BMI of 33 kg/m2, received Dose 1 on 13 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 21). The subject had a reported medical history of obesity (since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fatigue, headache, new or increased cough, new or increased muscle pain, new or increased shortness of breath, and rhinorrhea, with the first symptom starting on 27 Oct 2020, 55 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 86) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.9 cm	75.2 kg	31.3 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1970	Present
Migraines	Migraine	2010	Present
Depression	Depression	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	18:10
2	Placebo	03SEP2020 (22)	12:14

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Sinusitis	Sinus Infection	26AUG2020 (14)		30AUG2020 (18)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (30AUG2020)	NOT RELATED/OTHER: unknown	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	13AUG2020 (1)	13AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13AUG2020 (1)	13AUG2020 (1)	SERUM	NEGATIVE
Visit 2	03SEP2020 (22)	03SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01OCT2020 (50)/ 29SEP2020 (48)/ 02OCT2020 (51)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	01OCT2020 (50)	01OCT2020 (50)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	01OCT2020 (50)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251028, a 39-year-old white female with a height of 154.9 cm, a weight of 75.2 kg, and a BMI of 31.3 kg/m2, received Dose 1 on 13 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 1970), migraines (since 2010), and depression (since May 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 29 Sep 2020, 26 days after receiving Dose 2, and the last symptom resolved on 02 Oct 2020 (Day 51). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Oct 2020 (Day 50) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	112.27 kg	32.6 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to codeine	Drug hypersensitivity	1997	Present
Vasectomy	Vasectomy	2001	Past
Anxiety	Anxiety	2015	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	13:58
2	Placebo	08SEP2020 (23)	13:23

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	17AUG2020 (1)	17AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17AUG2020 (1)	17AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (23)	08SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02NOV2020 (78)/ 27OCT2020 (72)/ ONGOING	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02NOV2020 (78)	02NOV2020 (78)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02NOV2020 (78)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251049, a 52-year-old white male with a height of 185.42 cm, a weight of 112.27 kg, and a BMI of 32.6 kg/m2, received Dose 1 on 17 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 23). The subject had a reported medical history of drug hypersensitivity (codeine allergy, since 1997), vasectomy (in 2001), anxiety (since 2015), and benign prostatic hyperplasia (since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fatigue, new loss of taste or smell, new or increased sore throat, and nasal congestion, with the first symptom starting on 27 Oct 2020, 49 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Nov 2020 (Day 78) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	148.64 kg	56.1 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2000	Present
Polycystic ovarian syndrome	Polycystic ovaries	2000	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Acid reflux	Gastrooesophageal reflux disease	2013	Present
Depression	Depression	2014	Present
hypertension	Hypertension	2014	Present
Seasonal allergies	Seasonal allergy	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	10:24
2	Placebo	15SEP2020 (20)	09:31

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	IMMUN	Seasonal allergy	Acute exacerbation of seasonal allergies	18SEP2020 (23)	08:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: unknown	2	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Triamcinolone, 40 mg, seasonal allergies		18SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (20)	15SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (71)/ 04NOV2020 (70)/ ONGOING	YES	DIARRHEA	
	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	NO		Nasal congestion
	NO		Rhinorrhoea
	NO		Sputum increased

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05NOV2020 (71)	05NOV2020 (71)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (71)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	Subject was tested +COVID-19 through employer.

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251109, a 46-year-old white female with a height of 162.56 cm, a weight of 148.64 kg, and a BMI of 56.1 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 20). The subject had a reported medical history of obesity and polycystic ovaries (both since 2000), hypercholesterolemia (since 2010), gastroesophageal reflux disease (since 2013), depression and hypertension (both since 2014), and seasonal allergy (since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported diarrhea, fever, fatigue, headache, new or increased muscle pain, new or increased shortness of breath, nasal congestion, rhinorrhea, and sputum increased, with the first symptom starting on 04 Nov 2020, 50 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 71) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject tested positive for COVID-19 through their employer (no date provided).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	102.73 kg	31.5 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hyperlipidemia	Hyperlipidaemia	2017	Present
Hypertension	Hypertension	2017	Present
Hypothyroidism	Hypothyroidism	2017	Present
Diabetes mellitus type 2	Type 2 diabetes mellitus	2017	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	27AUG2020 (1)	16:28
2	Placebo	15SEP2020 (20)	16:04

Adverse Events

No Adverse Events

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (20)	15SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details

Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 28OCT2020 (63)/ 22OCT2020 (57)/ ONGOING	YES	FEVER	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28OCT2020 (63)	28OCT2020 (63)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	28OCT2020 (63)	22OCT2020 (57)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28OCT2020 (63)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251114, a 59-year-old white male with a height of 180.34 cm, a weight of 102.73 kg, and a BMI of 31.5 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 20). The subject had a reported medical history of hyperlipidemia, hypertension, hypothyroidism, and type 2 diabetes mellitus (all since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fever starting on 22 Oct 2020, 37 days after receiving Dose 2, that was ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Oct 2020 (Day 63) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Oct 2020 (Day 57) was positive. The subject went to his primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	79.55 kg	23.7 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	2015	Past
Seasonal allergies	Seasonal allergy	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	14:26
2	Placebo	17SEP2020 (21)	08:35

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	17SEP2020 (21)	17SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10NOV2020 (75)/ 08NOV2020 (73)/ 10NOV2020 (75)	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10NOV2020 (75)	10NOV2020 (75)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10NOV2020 (75)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251124, a 39-year-old white male with a height of 182.88 cm, a weight of 79.55 kg, and a BMI of 23.7 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 21). The subject had a reported medical history of vasectomy (in 2015) and seasonal allergy (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, headache, and new or increased muscle pain, with the first symptom starting on 08 Nov 2020, 52 days after receiving Dose 2, and the last symptom resolved on 10 Nov 2020 (Day 75). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 75) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	112.9 kg	35.7 kg/m2	22SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2000	Present
diabetic type 2	Type 2 diabetes mellitus	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	09:59
2	Placebo	13OCT2020 (22)	08:49

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22SEP2020 (1)	22SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22SEP2020 (1)	22SEP2020 (1)	SERUM	NEGATIVE
Visit 2	13OCT2020 (22)	13OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (51)/ 06NOV2020 (46)/ ONGOING	NO		Headache
	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion
	NO		Sputum increased

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	11NOV2020 (51)	11NOV2020 (51)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11NOV2020 (51)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1125 11251215, a 43-year-old white male with a height of 177.8 cm, a weight of 112.9 kg, and a BMI of 35.7 kg/m2, received Dose 1 on 22 Sep 2020 and Dose 2 on 13 Oct 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 2000) and type 2 diabetes mellitus (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported headache, new or increased cough, nasal congestion, and sputum increased, with the first symptom starting on 06 Nov 2020, 24 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 51) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	59.1 kg	22.5 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Major Depression, in full remission	Major depression	21MAR2014	Present
Allergy to Bee Venom	Allergy to arthropod sting	13MAR2015	Present
Insect Venom Allergic Reaction	Allergy to arthropod sting	13MAR2015	Past
Intermittent Asthma	Asthma	31MAR2015	Past
Hypertension	Hypertension	18JUN2015	Past
Iron Deficiency without Anemia	Iron deficiency	01OCT2015	Present
Migraine with Aura	Migraine with aura	15JUL2018	Present
Coagulopathy, Unspecified Type	Coagulopathy	01MAR2019	Present
Cervical High Risk HPV test positive	Human papilloma virus test positive	05APR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	12:09
2	Placebo	01SEP2020 (20)	12:32

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Acute sinusitis	Acute sinusitis	15AUG2020 (3)	04:00	20AUG2020 (8)	12:00	6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (20AUG2020)	NOT RELATED/OTHER: UNKNOWN	1	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine (Fluarix quadrivalent)	INFLUENZA VACCINE INACT SPLIT 4V	21SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	13AUG2020 (1)	13AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13AUG2020 (1)	13AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (20)	01SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 21OCT2020 (70)/ 20OCT2020 (69)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	21OCT2020 (70)	21OCT2020 (70)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	21OCT2020 (70)	20OCT2020 (69)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		OTHER	CORONAVIR PAN-2019 NCOV, NAA, QL (KAISER CLIA LAB)

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	21OCT2020 (70)	OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	21OCT2020 (70)	20OCT2020 (69)	1	141 mmHg	92 mmHg	18 breaths/min	99 beats/min	100 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1126 11261017, a 34-year-old white female with a height of 162 cm, a weight of 59.1 kg, and a BMI of 22.5 kg/m2, received Dose 1 on 13 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 20). The subject had a reported medical history of major depression (since 21 Mar 2014), allergy to arthropod sting (since 13 Mar 2015), asthma (from 31 Mar 2015 to 01 Mar 2018), hypertension (from 18 Jun 2015 to 01 Jun 2016), iron deficiency (since 01 Oct 2015), migraine with aura (since 15 Jul 2018), coagulopathy (since 01 Mar 2019), and human papilloma virus test positive (on 05 Apr 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fever and new or increased muscle pain, with the first symptom starting on 20 Oct 2020, 49 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 21 Oct 2020 (Day 70) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 20 Oct 2020 (Day 69) was negative. The subject had a telephone consultation (once), went to her primary care physician (once) and went to the emergency room (once). On 20 Oct 2020 (Day 69), the subject had a heart rate of 99 beats per minute, blood pressure of 141/92 mmHg, respiratory rate of 18 breaths per minute, and oxygen saturation of 100% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	26	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	63.09 kg	21.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MIGRAINES	Migraine	2009	Present
ANXIETY	Anxiety	2010	Present
Wisdom teeth impaction	Tooth impacted	2011	Past
WISDOM TOOTH EXTRACTION	Wisdom teeth removal	2011	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	01:27
2	Placebo	14SEP2020 (22)	12:06

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	29SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (22)	14SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02NOV2020 (71)/ 29OCT2020 (67)/ ONGOING	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02NOV2020 (71)	COVID-19	31OCT2020 (69)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02NOV2020 (71)	02NOV2020 (71)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02NOV2020 (71)	31OCT2020 (69)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	02NOV2020 (71)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1128 11281165, a 26-year-old white female with a height of 172.72 cm, a weight of 63.09 kg, and a BMI of 21.1 kg/m2, received Dose 1 on 24 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 22). The subject had a reported medical history of migraines (since 2009), anxiety (since 2010), and impacted tooth (wisdom tooth) and wisdom teeth removal (both in 2011). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 31 Oct 2020 (Day 69), the subject was diagnosed with COVID-19 and reported headache, new or increased cough, and new or increased sore throat, with the first symptom starting on 29 Oct 2020, 45 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Nov 2020 (Day 71) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 31 Oct 2020 (Day 69) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	111 kg	32.1 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	1965	Past
eye glass wearer	Corrective lens user	1965	Present
myopia	Myopia	1965	Present
recurrent back pain	Back pain	1980	Past
allergic rhinitis, seasonal	Seasonal allergy	1990	Present
type II diabetes, with no history of ketoacidosis	Type 2 diabetes mellitus	1995	Present
high blood pressure	Hypertension	2000	Present
evidence of past cardiac infarction	Myocardial infarction	2000	Past
kidney stones	Nephrolithiasis	2000	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis in lumbar spine	Spinal osteoarthritis	2000	Present
osteoarthritis in neck	Spinal osteoarthritis	2000	Present
1st degree atrioventricular block	Atrioventricular block first degree	2003	Present
right bundle branch block	Bundle branch block right	2003	Present
chest pain	Chest pain	2003	Past
triple by-pass heart surgery	Coronary artery bypass	2003	Past
hyperlipidemia	Hyperlipidaemia	2005	Present
diabetic neuropathy in both feet	Diabetic neuropathy	2010	Present
inguinal hernia	Inguinal hernia	2011	Past
inguinal hernia surgical repair	Inguinal hernia repair	2011	Past
chronic kidney disease, stage 2	Chronic kidney disease	2013	Present
L4-L5-S1 spinal fusion surgery	Spinal fusion surgery	2013	Past
C-PAP wearer	Continuous positive airway pressure	2015	Present
hypothyroidism	Hypothyroidism	2015	Present
polycythemia	Polycythaemia	2015	Present
sleep apnea	Sleep apnoea syndrome	2015	Present
gallstones	Cholelithiasis	2018	Present
recurrent neck pain	Neck pain	2018	Present
motor vehicle accident	Road traffic accident	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	11:28
2	Placebo	16SEP2020 (20)	16:56

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (20)	16SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13NOV2020 (78)/ 12NOV2020 (77)/ ONGOING	NO		Blood glucose increased
	YES	CHILLS	
	NO		Chest pain
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	13NOV2020 (78)	13NOV2020 (78)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	13NOV2020 (78)	14NOV2020 (79)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	INDETERM	Awaiting results	OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13NOV2020 (78)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1131 11311100, a 64-year-old white male with a height of 186 cm, a weight of 111 kg, and a BMI of 32.1 kg/m2, received Dose 1 on 28 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 20). The subject had a reported medical history of appendectomy (in 1965); corrective lens user and myopia (both since 1965); back pain (in 1980); seasonal allergy (since 1990); type 2 diabetes mellitus (since 1995); myocardial infarction and nephrolithiasis (both in 2000); hypertension and spinal osteoarthritis (neck and lumbar spine) (both since 2000); chest pain and coronary artery bypass (both in 2003); atrioventricular block first degree and bundle branch block right (both since 2003); hyperlipidemia (since 2005); diabetic neuropathy (since 2010); inguinal hernia and inguinal hernia repair (both in 2011); spinal fusion surgery (in 2013); chronic kidney disease (since 2013); continuous positive airway pressure, hypothyroidism, polycythemia, and sleep apnea syndrome (all since 2015); road traffic accident (in 2018); and cholelithiasis and neck pain (both since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported blood glucose increased, chills, chest pain, fever, new loss of taste or smell, new or increased muscle pain, and nasal congestion, with the first symptom starting on 12 Nov 2020, 57 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Nov 2020 (Day 78) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Nov 2020 (Day 79) was indeterminate (awaiting results). The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	61 kg	22.4 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1980	Present
mitral valve proplapse	Mitral valve prolapse	1991	Present
hyperopia	Hypermetropia	1993	Present
allergic rhinitis, seasonal	Seasonal allergy	2000	Present
recurrent back pain, etiology unknown	Back pain	2002	Present
asthma, induced with exercise	Asthma exercise induced	2005	Present
bunionectomy in left foot	Bunion operation	2006	Present
osteoarthritis in both knees	Osteoarthritis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	10:02
2	Placebo	24SEP2020 (21)	11:24

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04SEP2020 (1)	04SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04SEP2020 (1)	04SEP2020 (1)	SERUM	NEGATIVE
Visit 2	24SEP2020 (21)	24SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10NOV2020 (68)/ 07NOV2020 (65)/ ONGOING	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10NOV2020 (68)	10NOV2020 (68)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10NOV2020 (68)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1131 11311138, a 45-year-old white female with a height of 165 cm, a weight of 61 kg, and a BMI of 22.4 kg/m2, received Dose 1 on 04 Sep 2020 and Dose 2 on 24 Sep 2020 (Day 21). The subject had a reported medical history of tonsillectomy (in 1980), mitral valve prolapse (since 1991), hypermetropia (since 1993), seasonal allergy (since 2000), back pain (since 2002), asthma exercise induced (since 2005), bunion operation (left foot, in 2006), and osteoarthritis (both knees, since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported headache, new or increased cough, new or increased shortness of breath, and nasal congestion, with the first symptom starting on 07 Nov 2020, 44 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 68) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	Black or African American	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	73.4 kg	25.4 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT EAR HEARING LOSS	Deafness unilateral	1966	Present
FOREIGN BODY INSIDE RIGHT EAR	Foreign body in ear	1992	Past
RIGHT TYMPANIC RUPTURE	Tympanic membrane perforation	1992	Past
SURGERY - TYMPANOPLASTY	Tympanoplasty	1996	Past
CONSTIPATION	Constipation	1997	Present
BACK PAIN	Back pain	05AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	17:15
2	Placebo	09SEP2020 (22)	11:17

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09SEP2020 (22)	09SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (56)/ 10OCT2020 (53)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Pain
	NO		Sputum increased

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	13OCT2020 (56)	Upper Respiratory Infection	13OCT2020 (56)	1	Upper respiratory tract infection

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	13OCT2020 (56)	13OCT2020 (56)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13OCT2020 (56)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1133 11331209, a 30-year-old Black or African American male with a height of 170 cm, a weight of 73.4 kg, and a BMI of 25.4 kg/m2, received Dose 1 on 19 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 22). The subject had a reported medical history of deafness unilateral (since 1966), foreign body in ear and tympanic membrane perforation (in 1992), tympanoplasty (in 1996), constipation (since 1997), and back pain (on 05 Aug 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 13 Oct 2020 (Day 56), the subject was diagnosed with upper respiratory tract infection, and reported fatigue, headache, new or increased cough, new or increase sore throat, nasal congestion, pain, and increased sputum, with the first symptom starting on 10 Oct 2020, 31 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 56) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
196.85 cm	121.36 kg	31.3 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	1999	Present
Depression	Depression	1999	Present
Type 2 Diabetes	Type 2 diabetes mellitus	2015	Present
Hypercholesterolemia	Hypercholesterolaemia	2017	Present
Hypertension	Hypertension	2018	Present
Benign Prostatic Hyperplasia	Benign prostatic hyperplasia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	12:52
2	Placebo	01SEP2020 (23)	10:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	10AUG2020 (1)	10AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	10AUG2020 (1)	10AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (23)	01SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30SEP2020 (52)/ 29SEP2020 (51)/ 03OCT2020 (55)	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30SEP2020 (52)	30SEP2020 (52)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	30SEP2020 (52)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341022, a 66-year-old white male with a height of 196.85 cm, a weight of 121.36 kg, and a BMI of 31.3 kg/m2, received Dose 1 on 10 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 23). The subject had a reported medical history of anxiety and depression (both since 1999), type 2 diabetes mellitus (since 2015), hypercholesterolemia (since 2017), hypertension (since 2018), and benign prostatic hyperplasia (since 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported new or increased muscle pain and new or increased sore throat, with the first symptom starting on 29 Sep 2020, 28 days after receiving Dose 2, and the last symptom resolved 03 Oct 2020 (Day 55). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Sep 2020 (Day 52) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	33	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	59.1 kg	24.6 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin drug allergy	Drug hypersensitivity	1988	Present
myopia	Myopia	2004	Present
nearsighted	Myopia	2004	Present
sulfa drug allergy	Drug hypersensitivity	2007	Present
lipoma	Lipoma	2017	Past
lipoma removal	Lipoma excision	2017	Past
seasonal allergies	Seasonal allergy	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	13:11
2	Placebo	14SEP2020 (21)	11:06

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (21)	14SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19OCT2020 (56)/ 13OCT2020 (50)/ ONGOING	YES	DIARRHEA	
	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	19OCT2020 (56)	19OCT2020 (56)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19OCT2020 (56)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1135 11351207, a 33-year-old white female with a height of 155 cm, a weight of 59.1 kg, and a BMI of 24.6 kg/m2, received Dose 1 on 25 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 21). The subject had a reported medical history of drug hypersensitivity (penicillin drug allergy since 1988 and sulfa drug allergy since 2007), myopia (since 2004), lipoma and lipoma excision (both in 2017), and seasonal allergy (since 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported diarrhea, fatigue, headache, new loss of taste or smell, new or increased muscle pain, and nasal congestion, with the first symptom starting on 13 Oct 2020, 29 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Oct 2020 (Day 56) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.5 cm	81.4 kg	23.7 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
fracture of clavicular fracture	Clavicle fracture	2012	Past
open reduction of fracture clavicle	Open reduction of fracture	2012	Past
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	11:59
2	Placebo	09SEP2020 (24)	15:53

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	23OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	17AUG2020 (1)	17AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17AUG2020 (1)	17AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09SEP2020 (24)	09SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 08OCT2020 (53)/ 07OCT2020 (52)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	08OCT2020 (53)	COVID-19	08OCT2020 (53)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	08OCT2020 (53)	08OCT2020 (53)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	08OCT2020 (53)	08OCT2020 (53)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	08OCT2020 (53)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	2	NA
		OTHER	YES	1	Influenza like Illness clinic

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1141 11411088, a 52-year-old white male with a height of 185.5 cm, a weight of 81.4 kg, and a BMI of 23.7 kg/m2, received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24). The subject had a reported medical history of clavicle fracture and open reduction of fracture (both in 2012) and gastroesophageal reflux disease (since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 08 Oct 2020 (Day 53), the subject was diagnosed with COVID-19 and reported chills, fever, headache, new or increased sore throat, and rhinorrhea, with the first symptom starting on 07 Oct 2020, 28 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Oct 2020 (Day 53) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Oct 2020 (Day 53) was positive. The subject had a telephone consultation (twice) and went to an influenza-like illness clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	76.6 kg	28.5 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
back pain	Back pain	2006	Present
anxiety	Anxiety	2019	Present
depression	Depression	2019	Present
breast reduction surgery	Mammoplasty	14JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	10:06
2	Placebo	23SEP2020 (22)	15:34

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Dyspnoea exertional	shortness of breathe while exercising	21SEP2020 (20)		07OCT2020 (36)		17	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (07OCT2020)	NOT RELATED/OTHER: deconditioned physical state	1	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
hepatitis B vaccination	HEPATITIS B VACCINE	20OCT2020
influenza vaccination	INFLUENZA VACCINE	20OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	02SEP2020 (1)	02SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	02SEP2020 (1)	02SEP2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (22)	23SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 09NOV2020 (69)/ 08NOV2020 (68)/ ONGOING	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nausea
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	09NOV2020 (69)	Covid-19	10NOV2020 (70)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (69)	10NOV2020 (70)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (69)	10NOV2020 (70)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (69)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	2	NA
		OTHER	YES	1	Influenza like Illness Clinic

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1141 11411161, a 25-year-old white female with a height of 164 cm, a weight of 76.6 kg, and a BMI of 28.5 kg/m2, received Dose 1 on 02 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 22). The subject had a reported medical history of back pain (since 2006), anxiety and depression (both since 2019), and mammoplasty (on 14 Jun 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 10 Nov 2020 (Day 70), the subject was diagnosed with COVID-19 and reported diarrhea, fever, headache, new or increased cough, new or increased muscle pain, nausea, and vomiting, with the first symptom starting on 08 Nov 2020, 46 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 70) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 70) was positive. The subject had a telephone consultation (twice) and went to an influenza-like illness clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	20	Not Reported	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.8 cm	57.8 kg	22.4 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2010	Present
benign tumor removal right knee	Knee operation	2014	Past
tumor right knee	Neoplasm	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	10:16
2	Placebo	23SEP2020 (22)	09:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Dizziness	Lightheadedness	24SEP2020 (23)		25SEP2020 (24)		2
2	MUSC	Myalgia	muscle aches	16OCT2020 (45)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (25SEP2020)	Study Treatment	2	2	N
2	2	N	N	Yes	NOT RELATED/OTHER: exercise	2	24	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	02SEP2020 (1)	02SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	02SEP2020 (1)	02SEP2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (22)	23SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 08NOV2020 (68)/ 05NOV2020 (65)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	08NOV2020 (68)	Covid-19	07NOV2020 (67)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	08NOV2020 (68)	08NOV2020 (68)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	08NOV2020 (68)	07NOV2020 (67)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	08NOV2020 (68)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA
		OTHER	YES	1	Influenza like Illness Clinic

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1141 11411162, a 20-year-old male with a height of 160.8 cm, a weight of 57.8 kg, and a BMI of 22.4 kg/m2, received Dose 1 on 02 Sep 2020 and Dose 2 on 23 Sep 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 2010) and benign tumor right knee and knee operation (both in 2014). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Nov 2020 (Day 67), the subject was diagnosed with COVID-19 and reported fatigue, headache, new or increased cough, and new or increased sore throat, with the first symptom starting on 05 Nov 2020, 43 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Nov 2020 (Day 68) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 67) was positive. The subject had a telephone consultation (once) and went to an influenza-like illness clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.1 cm	95.7 kg	28.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2010	Present
Bilateral Hearing Aids	Hearing aid user	2014	Present
Left Knee degeneration	Osteoarthritis	2016	Past
Left Knee Replacement	Knee arthroplasty	2018	Past
Prostate Cancer	Prostate cancer	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	12:56
2	BNT162b2	10SEP2020 (22)	11:21

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu Vaccine	INFLUENZA VACCINE	25SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (22)	10SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 26OCT2020 (68)/ 23OCT2020 (65)/ 24OCT2020 (66)	YES	CHILLS	
	YES	FEVER	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	26OCT2020 (68)	26OCT2020 (68)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (68)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1149 11491113, a 69-year-old white male with a height of 184.1 cm, a weight of 95.7 kg, and a BMI of 28.2 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had a reported medical history of hypertension (since 2010), hearing aid user (bilateral, since 2014), osteoarthritis (left knee, in 2016), and left knee arthroplasty and prostate cancer (both in 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, and vomiting, with the first symptom starting on 23 Oct 2020, 43 days after receiving Dose 2, and the last symptom resolved on 24 Oct 2020 (Day 66). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 68) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject had a telephone consultation (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	19	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	78.18 kg	23.3 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	09:25
2	Placebo	28SEP2020 (21)	12:28

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (21)	28SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07OCT2020 (30)/ 06OCT2020 (29)/ ONGOING	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	07OCT2020 (30)	07OCT2020 (30)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07OCT2020 (30)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521363, a 19-year-old white male with a height of 182.88 cm, a weight of 78.18 kg, and a BMI of 23.3 kg/m2, received Dose 1 on 08 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 21). The subject had a reported medical history of drug hypersensitivity (penicillin allergy, since 2005). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported a new or increased cough, starting on 06 Oct 2020, 8 days after receiving Dose 2, that was ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Oct 2020 (Day 30) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	28	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	62 kg	22 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
frequent ear infections	Ear infection	1991	Past
perennial allergies	Perennial allergy	1991	Present
tubes inserted in ears	Ear tube insertion	1996	Past
asthma u	Asthma	1997	Past
bilateral otoplasty	Otoplasty	2004	Past
wisdom teeth extracte	Wisdom teeth removal	2005	Past
mole removed from back	Mole excision	2006	Past
mole removed from forehead	Mole excision	2007	Past
mole removed from tailbone area	Mole excision	2008	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety	Anxiety	2010	Present
depression	Depression	2013	Present
human papilloma virus	Human papilloma virus test positive	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:01
2	Placebo	28SEP2020 (21)	09:13

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (21)	28SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (53)/ 29OCT2020 (52)/ ONGOING	YES	CHILLS	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (53)	31OCT2020 (54)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	30OCT2020 (53)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521372, a 28-year-old white female with a height of 167.64 cm, a weight of 62 kg, and a BMI of 22 kg/m2, received Dose 1 on 08 Sep 2020 and Dose 2 on 28 Sep 2020 (Day 21). The subject had a reported medical history of ear infection (in 1991), perennial allergy (since 1991), ear tube insertion (in 1996), asthma (in 1997), otoplasty (bilateral, in 2004), wisdom teeth removal (in 2005), mole excision (back in 2006; forehead in 2007; tailbone area in 2008), anxiety (since 2010), depression (since 2013), and human papilloma virus test positive (in 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, headache, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 29 Oct 2020, 31 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 31 Oct 2020 (Day 54) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	87.05 kg	31 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2002	Present
mild anxiety depression	Depression	2010	Present
chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2018	Present
fatty liver	Hepatic steatosis	2018	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	25FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	11:52

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09OCT2020 (44)	09OCT2020 (44)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02SEP2020 (7)/ 01SEP2020 (6)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02SEP2020 (7)	COVID-19 PNEUMONIA	05SEP2020 (10)	4	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	02SEP2020 (7)	08SEP2020 (13)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 1	02SEP2020 (7)	09SEP2020 (14)	SWABBED MATERIAL	NASOPHARYNX
4	COVID Illness Visit 1	02SEP2020 (7)	14SEP2020 (19)	SWABBED MATERIAL	NASOPHARYNX
5	COVID Illness Visit 1	02SEP2020 (7)	15SEP2020 (20)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		LABCORP COVID-19 RT-PCR TEST	
2	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	
3	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
4	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	
5	NEGATIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	02SEP2020 (7)	OTHER	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		SPECIALIST	YES	1	NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	5	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	02SEP2020 (7)	HOSPITALIZATION STATUS	HOSPITAL	05SEP2020 (10)	19SEP2020 (24)
COVID Illness Visit 1	02SEP2020 (7)	HOSPITALIZATION STATUS	ICU	05SEP2020 (10)	19SEP2020 (24)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	02SEP2020 (7)	1	YES	HIGH FLOW OXYGEN THERAPY	05SEP2020 (10)	09SEP2020 (14)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Visit	Visit Date (Study Day)	Subcategory of Clinical Event	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	End Date or Ongoing	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	02SEP2020 (7)	SIGNIFICANT ACUTE HEPATIC DYSFUNCTION	ACUTE LIVER DYSFUNCTION	03SEP2020 (8)	09SEP2020 (14)	2	Hepatic function abnormal
COVID Illness Visit 1	02SEP2020 (7)	SIGNIFICANT ACUTE RENAL DYSFUNCTION	ACUTE RENAL AZOTEMIA	03SEP2020 (8)	ONGOING	2	Azotaemia

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	Alkaline Phosphatase	1.2	ukat/L	0.65	1.95
			Alanine Aminotransferase	2.85057	ukat/L	0	0.73348
			Aspartate Aminotransferase	3.21731	ukat/L	0	0.6668
			Bilirubin	10.3	umol/L	0	20.5
			Creatinine	139.7	umol/L	67.2	112.3
			Urea Nitrogen	10.71	mmol/L	2.86	9.64
		05SEP2020 (10)	Alkaline Phosphatase	1.48	ukat/L	0.77	1.93
			Alanine Aminotransferase	2.60052	ukat/L	0.23338	1.05021
			Aspartate Aminotransferase	2.55051	ukat/L	0.25005	0.61679
			Bilirubin	5.1	umol/L	6.8	13.7
			Creatinine	123.8	umol/L	53	114.9
			C Reactive Protein	8	mg/L	0	9
			Urea Nitrogen	11.43	mmol/L	2.5	6.43

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	02SEP2020 (7)	05SEP2020 (10)	Basophils	0.3	%	0	3
			Eosinophils	0.1	%	0	6
			Hematocrit	0.46	L/L	0.42	0.52
			Hemoglobin	154	g/L	140	180
			Lymphocytes	14.7	%	18	46
			Monocytes	9	%	0	11
			Neutrophils	75.9	%	47	75
			Platelets	186	10^9/L	130	400
			Erythrocytes	5.14	10^12/L	4.7	6.1
			Leukocytes	6.3	10^9/L	4.8	10.8

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	02SEP2020 (7)	05SEP2020 (10)	1					88 %
		14SEP2020 (19)	2					84 %
		29SEP2020 (34)	3					89 %
		01OCT2020 (36)	4					92 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	02SEP2020 (7)	05SEP2020	CHEST		X-RAY	NA	ABNORMAL
2	COVID Illness Visit 1	02SEP2020 (7)	08SEP2020	CHEST		X-RAY	NA	ABNORMAL
3	COVID Illness Visit 1	02SEP2020 (7)	12SEP2020	CHEST		X-RAY	NA	ABNORMAL
4	COVID Illness Visit 1	02SEP2020 (7)	14SEP2020	CHEST		X-RAY	NA	ABNORMAL
5	COVID Illness Visit 1	02SEP2020 (7)	30SEP2020	CHEST		X-RAY	NA	ABNORMAL

Imaging	
Assessment Number	If Abnormal, Specify Findings
1	Bibasilar diffuse mixed infiltrates. No focal infiltrates, effusions or pneumothoraces. Mild overinflation, chronic appearing diffuse interstitial prominence.
2	Bibasilar mixed infiltrates, greater to the LEFT. Mild overinflation mild, chronic appearing diffuse interstitial prominence.
3	Scattered alveolar interstitial changes are seen in the perihilar region and at the lung bases. Findings are consistent with atypical infiltrates.

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
4	There are bilateral interstitial infiltrates within both lungs. Interval improvement is observed. No alveolar consolidation or pleural effusion is noted. No acute osseous abnormality is detected.
5	Chronic interstitial fibrosis in lungs, especially on right side with suggestion of patchy infiltrates in both lower lobes, especially on the left side. No evidence of pleural effusions.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Withdrawn	VACCINATION	08SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561044, a 63-year-old white male with a height of 167.5 cm, a weight of 87.05 kg, and a BMI of 31 kg/m2, received Dose 1 on 27 Aug 2020.
The subject had a reported medical history of hypertension (since 2002), depression (since 2010), chronic obstructive pulmonary disease and hepatic steatosis (both since 2018), and type 2 diabetes mellitus (since 25 Feb 2020).
The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.
On 05 Sep 2020 (Day 10), the subject was diagnosed with severe COVID-19 pneumonia and reported chills, diarrhea, fever, new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 01 Sep 2020, 5 days after receiving Dose 1, and at least 1 symptom ongoing as of the last available report.
The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Sep 2020 (Day 8) was positive.
The local laboratory SARS-CoV-2 NAAT result(s) at the time of the COVID-19 illness on 03 Sep 2020 (Day 8), 08 Sep 2020 (Day 13), 09 Sep 2020 (Day 14), and 14 Sep 2020 (Day 19) were positive and on 15 Sep 2020 (Day 20) was negative.
The subject went to his primary care physician (5 times), to the emergency room (once), and to a specialist (once).
The subject was hospitalized and was in the intensive care unit on 05 Sep 2020 (Day 10) for 15 days and discharged on 19 Sep 2020 (Day 24).
The subject experienced significant acute renal dysfunction (moderate azotemia) and significant acute hepatic dysfunction (moderate) on 03 Sep 2020 (Day 8).
On 03 Sep 2020 (Day 8), the alanine aminotransferase (ALT) was 2.85057 µkat/L (normal range [NR]: 0 - 0.73348 µkat/L), aspartate aminotransferase (AST) was 3.21731 µkat/L (NR: 0 - 0.6668 µkat/L), creatinine was 139.7 µmol/L (NR: 67.2 - 112.3 µmol/L), and blood urea nitrogen (BUN) was 10.71 mmol/L (NR: 2.86 – 9.64 mmol/L).
On 05 Sep 2020 (Day 10), the ALT was 2.60052 µkat/L (NR: 0.23338 - 1.05021 µkat/L), AST was 2.55051 µkat/L (NR: 0.25005 - 0.61679 µkat/L), bilirubin was 5.1 µmol/L (NR: 6.8 – 13.7 µmol/L), creatinine was 123.8 µmol/L (NR: 53 - 114.9 µmol/L), BUN was 11.43 mmol/L (NR: 2.5 – 6.43 mmol/L), lymphocytes were 14.7% (NR: 18% - 46%), and neutrophils were 75.9% (NR: 47% - 75%).
The subject had an oxygen saturation of 88% on 05 Sep 2020 (Day 10), 84% on 14 Sep 2020 (Day 19), 89% on room air on 29 Sep 2020 (Day 34), and 92% on room air on 01 Oct 2020 (Day 36).
The subject required high-flow oxygen therapy from 05 Sep 2020 (Day 10) to 09 Sep 2020 (Day 14).
The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an intensive care unit, significant acute renal dysfunction, significant acute hepatic dysfunction, oxygen saturation of ≤93%, and requirement for high-flow oxygen therapy).
Chest radiographs revealed: bibasilar diffuse mixed infiltrates, no focal infiltrates, effusions or pneumothoraxes, mild overinflation, chronic appearing diffuse interstitial prominence on 05 Sep 2020 (Day 10); bibasilar mixed infiltrates, greater to the left, mild overinflation, chronic appearing diffuse interstitial prominence on 08 Sep 2020 (Day 13); scattered alveolar interstitial changes were observed in the perihilar region and at the lung bases, findings were consistent with atypical infiltrates on 12 Sep 2020 (Day 17); bilateral interstitial infiltrates within both lungs, interval improvement was observed, no alveolar consolidation or pleural effusion was noted, and no acute osseous abnormality was detected on 14 Sep 2020 (Day 19), and chronic interstitial fibrosis on right side of the lungs, with patchy infiltrates in both lower lobes, especially on the left side; and no evidence of pleural effusions were observed on 30 Sep 2020 (Day 35).
The subject was discontinued from the study intervention on 08 Sep 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	52.4 kg	21.8 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraines	Migraine	2010	Present
Cesarean Section	Caesarean section	23FEB2014	Past
Acne	Acne	2017	Present
Cesarean Section	Caesarean section	04OCT2017	Past
Tubal ligation	Female sterilisation	04OCT2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	10:41
2	Placebo	01SEP2020 (22)	09:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	11AUG2020 (1)	11AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11AUG2020 (1)	11AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (22)	01SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (91)/ 06NOV2020 (88)/ ONGOING	NO		Fatigue
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nausea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (91)	COVID-19	07NOV2020 (89)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (91)	09NOV2020 (91)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (91)	07NOV2020 (89)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE	Test was done off-site	OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	09NOV2020 (91)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1162 11621075, a 40-year-old white female with a height of 155 cm, a weight of 52.4 kg, and a BMI of 21.8 kg/m2, received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject had a reported medical history of migraines (since 2010), cesarean section (on 23 Feb 2014 and 04 Oct 2017), acne (since 2017), and female sterilization (on 04 Oct 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Nov 2020 (Day 89), the subject was diagnosed with COVID-19 and reported fatigue, new or increased muscle pain, and nausea, with the first symptom starting on 06 Nov 2020, 66 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 91) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 89) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	111.91 kg	32.5 kg/m2	14AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	16:19
2	Placebo	02SEP2020 (20)	14:47

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	14AUG2020 (1)	14AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14AUG2020 (1)	14AUG2020 (1)	SERUM	NEGATIVE
Visit 2	02SEP2020 (20)	02SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19OCT2020 (67)/ 14OCT2020 (62)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	19OCT2020 (67)	19OCT2020 (67)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	19OCT2020 (67)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1163 11631113, a 25-year-old black or African American male with a height of 185.42 cm, a weight of 111.91 kg, and a BMI of 32.5 kg/m2, received Dose 1 on 14 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 20). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, new or increased cough, and new or increased sore throat, with the first symptom starting on 14 Oct 2020, 42 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Oct 2020 (Day 67) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	42	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
147.32 cm	75 kg	34.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	17:43
2	Placebo	10SEP2020 (22)	16:37

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (22)	10SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30SEP2020 (42)/ 30SEP2020 (42)/ 02OCT2020 (44)	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30SEP2020 (42)	30SEP2020 (42)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	30SEP2020 (42)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1163 11631135, a 42-year-old white male with a height of 147.32 cm, a weight of 75 kg, and a BMI of 34.5 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had a reported medical history of hypertension (since May 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported diarrhea, fever, and new or increased muscle pain, with the first symptom starting on 30 Sep 2020, 20 days after receiving Dose 2, and the last symptom resolved on 02 Oct 2020 (Day 44). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Sep 2020 (Day 42) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	122.73 kg	44.9 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
polycystic ovary syndrome	Polycystic ovaries	2005	Present
multiple sclerosis	Multiple sclerosis	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	14:54
2	Placebo	25SEP2020 (22)	09:27

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04SEP2020 (1)	04SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04SEP2020 (1)	04SEP2020 (1)	SERUM	NEGATIVE
Visit 2	25SEP2020 (22)	25SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (53)/ 20OCT2020 (47)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (53)	COVID 19	25OCT2020 (52)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (53)	26OCT2020 (53)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26OCT2020 (53)	25OCT2020 (52)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (53)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology

No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	26OCT2020 (53)	26OCT2020 (53)	1	118 mmHg	78 mmHg	16 breaths/min	88 beats/min	96 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	11NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1167 11671152, a 41-year-old white female with a height of 165.1 cm, a weight of 122.73 kg, and a BMI of 44.9 kg/m2, received Dose 1 on 04 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 22). The subject had a reported medical history of polycystic ovaries (since 2005) and multiple sclerosis (since 2013). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 25 Oct 2020 (Day 52), the subject was diagnosed with COVID 19 and reported chills, diarrhea, fever, headache, new loss of taste or smell, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 20 Oct 2020, 25 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 53) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 25 Oct 2020 (Day 52) was positive. The subject had an urgent care visit (once). On 26 Oct 2020 (Day 53), the subject had a heart rate of 88 beats per minute, blood pressure of 118/78 mmHg, respiratory rate of 16 breaths per minute, and oxygen saturation of 96% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	122.73 kg	34.7 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergies/allergic rhinitis	Rhinitis allergic	2000	Present
hyperlipidemia	Hyperlipidaemia	2005	Present
hypertension	Hypertension	2008	Present
anxiety	Anxiety	2010	Present
pulmonary embolism	Pulmonary embolism	SEP2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:11
2	Placebo	29SEP2020 (22)	10:30

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	29SEP2020 (22)	29SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 15OCT2020 (38)/ 14OCT2020 (37)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	15OCT2020 (38)	15OCT2020 (38)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	15OCT2020 (38)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1167 11671157, a 58-year-old white male with a height of 187.96 cm, a weight of 122.73 kg, and a BMI of 34.7 kg/m2, received Dose 1 on 08 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 22). The subject had a reported medical history of rhinitis allergic (since 2000), hyperlipidemia (since 2005), hypertension (since 2008), anxiety (since 2010) and pulmonary embolism (in Sep 2016). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, fever, new or increased cough, and new or increased muscle pain, with the first symptom starting on 14 Oct 2020, 15 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 15 Oct 2020 (Day 38) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject had a telephone consultation (once) and went to the emergency room (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	78.8 kg	26.6 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	2000	Present
CHLORHEXADINE DRUG ALLERGY	Drug hypersensitivity	2005	Present
ZITHROMAX DRUG ALLERGY	Drug hypersensitivity	2010	Present
PREMATURE EJACULATION	Premature ejaculation	2015	Present
FARSIGHTED	Hypermetropia	2018	Present
MENISCUS REPAIR/ DEBRIDEMENT	Meniscus operation	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	10:30
2	Placebo	02SEP2020 (22)	09:19

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	02SEP2020 (22)	02SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (92)/ 07NOV2020 (88)/ ONGOING	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (92)	COVID-19 infection	10NOV2020 (91)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	11NOV2020 (92)	11NOV2020 (92)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	11NOV2020 (92)	10NOV2020 (91)	SWABBED MATERIAL	THROAT

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	CFX384 Touch Real-Time PCR Detection System

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11NOV2020 (92)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1168 11681004, a 54-year-old white male with a height of 172 cm, a weight of 78.8 kg, and a BMI of 26.6 kg/m2, received Dose 1 on 12 Aug 2020 and Dose 2 on 02 Sep 2020 (Day 22). The subject had a reported medical history of seasonal allergy (since 2000), drug hypersensitivity (chlorhexidine allergy since 2005 and Zithromax allergy since 2010), premature ejaculation (since 2015), hypermetropia (since 2018), and meniscus operation (in 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 10 Nov 2020 (Day 91), the subject was diagnosed with COVID-19 and reported fever, headache, new or increased cough, and new or increased muscle pain, with the first symptom starting on 07 Nov 2020, 66 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 92) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 91) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	33	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.5 cm	82 kg	30.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
APPENDECTOMY	Appendicectomy	1989	Past
CECLOR ALLERGY	Drug hypersensitivity	1989	Present
HEARTBURN	Dyspepsia	2002	Present
HYPOTHYROIDISM	Hypothyroidism	2003	Present
DEPRESSION	Depression	2006	Present
THYROIDECTOMY	Thyroidectomy	2014	Past
TUBAL LIGATION BILATERAL	Female sterilisation	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	14:23
2	Placebo	01SEP2020 (21)	10:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (21)	01SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07OCT2020 (57)/ 06OCT2020 (56)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	07OCT2020 (57)	Covid-19	08OCT2020 (58)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	07OCT2020 (57)	08OCT2020 (58)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	07OCT2020 (57)	06OCT2020 (56)	SWABBED MATERIAL	NASOPHARYNX	NEGATIVE
2	COVID Illness Visit 1	07OCT2020 (57)	08OCT2020 (58)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1		OTHER	NALT Unknown
2	records have been requested to obtain all required information	OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07OCT2020 (57)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	2	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1168 11681007, a 33-year-old white female with a height of 164.5 cm, a weight of 82 kg, and a BMI of 30.3 kg/m2, received Dose 1 on 12 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 21). The subject had a reported medical history of appendectomy (in 1989), drug hypersensitivity (Ceclor allergy, since 1989), dyspepsia (since 2002), hypothyroidism (since 2003), depression (since 2006), thyroidectomy (in 2014), and female sterilization (in 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 08 Oct 2020 (Day 58), the subject was diagnosed with COVID-19 and reported fatigue, headache, new loss of taste or smell, new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 06 Oct 2020, 35 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Oct 2020 (Day 58) was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 06 Oct 2020 (Day 56) was negative and on 08 Oct 2020 (Day 58) was positive. The subject had an urgent care visit (twice).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181.5 cm	79.1 kg	24 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	2009	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	14:25
2	Placebo	01SEP2020 (21)	09:44

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (21)	01SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06OCT2020 (56)/ 05OCT2020 (55)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06OCT2020 (56)	Covid-19	06OCT2020 (56)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06OCT2020 (56)	06OCT2020 (56)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	06OCT2020 (56)	06OCT2020 (56)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	records have been requested for information on the test.	OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06OCT2020 (56)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1168 11681008, a 37-year-old white male with a height of 181.5 cm, a weight of 79.1 kg, and a BMI of 24 kg/m2, received Dose 1 on 12 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 21).
The subject had a reported medical history of seasonal allergy (since 2009).
The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.
On 06 Oct 2020 (Day 56), the subject was diagnosed with COVID-19 and reported fatigue, headache, new loss of taste or smell, and new or increased cough, with the first symptom starting on 05 Oct 2020, 34 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report.
The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Oct 2020 (Day 56) was positive.
The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Oct 2020 (Day 56) was positive.
The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	63.5 kg	24.8 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEADACHES	Headache	1979	Present
SEASONAL ALLERGIES	Seasonal allergy	1979	Present
ASTHMA	Asthma	1986	Present
NEARSIGHTED	Myopia	1996	Present
OVARIAN CYST	Ovarian cyst	2016	Past
ROSACEA	Rosacea	2016	Present
THYROID CANCER	Thyroid cancer	2016	Past
THYROIDECTOMY	Thyroidectomy	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	13:01
2	Placebo	21SEP2020 (22)	09:48

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	31AUG2020 (1)	31AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31AUG2020 (1)	31AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (22)	21SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (44)/ 13OCT2020 (44)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	13OCT2020 (44)	COVID-19	13OCT2020 (44)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	13OCT2020 (44)	13OCT2020 (44)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	13OCT2020 (44)	13OCT2020 (44)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13OCT2020 (44)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1168 11681114, a 46-year-old white female with a height of 160 cm, a weight of 63.5 kg, and a BMI of 24.8 kg/m2, received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject had a reported medical history of headache and seasonal allergy (both since 1979); asthma (since 1986); myopia (since 1996); ovarian cyst, thyroid cancer, and thyroidectomy (all in 2016); and rosacea (since 2016). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 13 Oct 2020 (Day 44), the subject was diagnosed with COVID-19 and reported chills, diarrhea, fever, headache, new loss of taste or smell, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 13 Oct 2020, 22 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 44) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 44) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	37	American Indian or Alaska Native	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	107.6 kg	35.5 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
STUTTER	Dysphemia	1983	Present
SEASONAL ALLERGIES	Seasonal allergy	1986	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2000	Present
HEARTBURN(ACID REFLUX)	Gastrooesophageal reflux disease	2005	Present
HIGH BLOOD PRESSURE	Hypertension	2005	Present
VASECTOMY	Vasectomy	2007	Past
CHIARI MALFORMATION TYPE 1(CORRECTIVE SURGERY)	Brain operation	2009	Past
NEUROPATHY	Neuropathy peripheral	2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TONSILLECTOMY	Tonsillectomy	2010	Past
DISK FUSION(CERVICAL SPINE)	Spinal fusion surgery	2014	Past
HYPOTHYROIDISM	Hypothyroidism	2015	Present
THYROID CANCER	Thyroid cancer	2015	Past
THYROIDECTOMY	Thyroidectomy	2015	Past
KIDNEY STONES	Nephrolithiasis	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	16:41
2	Placebo	21SEP2020 (22)	15:11

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31AUG2020 (1)	31AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31AUG2020 (1)	31AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (22)	21SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (67)/ 04NOV2020 (66)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Sinus congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	05NOV2020 (67)	Covid-19	05NOV2020 (67)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05NOV2020 (67)	05NOV2020 (67)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	05NOV2020 (67)	05NOV2020 (67)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	05NOV2020 (67)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1168 11681117, a 37-year-old American Indian or Alaska native male with a height of 174 cm, a weight of 107.6 kg, and a BMI of 35.5 kg/m2, received Dose 1 on 31 Aug 2020 and Dose 2 on 21 Sep 2020 (Day 22). The subject had a reported medical history of dysphemia (since 1983), seasonal allergy (since 1986), hypercholesterolemia (since 2000), gastroesophageal reflux disease and hypertension (both since 2005), vasectomy (in 2007), brain operation (Chiari malformation type 1 corrective surgery, in 2009), neuropathy peripheral (since 2009), tonsillectomy (in 2010), spinal fusion surgery (in 2014), hypothyroidism (since 2015), thyroid cancer and thyroidectomy (both in 2015), and nephrolithiasis (in 2016). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 05 Nov 2020 (Day 67), the subject was diagnosed with COVID-19 and reported fever, new or increased muscle pain, and sinus congestion, with the first symptom starting on 04 Nov 2020, 44 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 67) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 67) was positive. The subject went to his primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	25	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	47.2 kg	19 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	12:00
2	Placebo	16SEP2020 (22)	11:26

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Pyrexia	Fever	27AUG2020 (2)		29AUG2020 (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	N	N	Resolved (29AUG2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza Vaccine	INFLUENZA VACCINE	15OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	26AUG2020 (1)	26AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	26AUG2020 (1)	26AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (22)	16SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03OCT2020 (39)/ 01OCT2020 (37)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03OCT2020 (39)	Coronavirus COVID-19	02OCT2020 (38)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03OCT2020 (39)	03OCT2020 (39)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	03OCT2020 (39)	02OCT2020 (38)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03OCT2020 (39)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1170 11701089, a 25-year-old white female with a height of 157.48 cm, a weight of 47.2 kg, and a BMI of 19 kg/m2, received Dose 1 on 26 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 22). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 02 Oct 2020 (Day 38), the subject was diagnosed with COVID-19 and reported fever and new or increased sore throat, with the first symptom starting on 01 Oct 2020, 15 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Oct 2020 (Day 39) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Oct 2020 (Day 38) was positive. The subject had a telephone consultation (once) and went to her primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	125.91 kg	34.6 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1986	Present
hypertension	Hypertension	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	13:45
2	Placebo	21SEP2020 (21)	12:56

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	01SEP2020 (1)	01SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	01SEP2020 (1)	01SEP2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (21)	21SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 14OCT2020 (44)/ 13OCT2020 (43)/ 25OCT2020 (55)	YES	CHILLS	
	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Vision blurred

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	14OCT2020 (44)	COVID-19	13OCT2020 (43)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	14OCT2020 (44)	14OCT2020 (44)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	14OCT2020 (44)	13OCT2020 (43)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	CLIA certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	14OCT2020 (44)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	Lewis Co. Health Department

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781065, a 48-year-old white male with a height of 190.5 cm, a weight of 125.91 kg, and a BMI of 34.6 kg/m2, received Dose 1 on 01 Sep 2020 and Dose 2 on 21 Sep 2020 (Day 21). The subject had a reported medical history of drug hypersensitivity (penicillin allergy, since 1986) and hypertension (since 2000). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 13 Oct 2020 (Day 43), the subject was diagnosed with COVID-19 and reported chills, fever, fatigue, headache, new or increased cough, new or increased muscle pain, new or increased sore throat, and vision blurred, with the first symptom starting on 13 Oct 2020, 22 days after receiving Dose 2, and the last symptom resolved on 25 Oct 2020 (Day 55). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Oct 2020 (Day 44) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 13 Oct 2020 (Day 43) was positive. The subject went to the Lewis Co. health department (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	68.18 kg	26.6 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Benign heart murmur	Cardiac murmur	1965	Present
benign thyroid nodule	Benign neoplasm of thyroid gland	1979	Past
Partial thyroidectomy	Thyroidectomy	1980	Past
Seasonal allergies	Seasonal allergy	2005	Present
Backache	Back pain	2010	Present
Hysterectomy	Hysterectomy	2018	Past
Prolapsed uterus	Uterine prolapse	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	09:34
2	Placebo	14OCT2020 (22)	08:48

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	23SEP2020 (1)	23SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23SEP2020 (1)	23SEP2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (22)	14OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (38)/ 29OCT2020 (37)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Sinus congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30OCT2020 (38)	COVID-19	30OCT2020 (38)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	30OCT2020 (38)	30OCT2020 (38)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	30OCT2020 (38)	30OCT2020 (38)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	30OCT2020 (38)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	Vanderbilt Clinic

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	11NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781238, a 60-year-old white female with a height of 160.02 cm, a weight of 68.18 kg, and a BMI of 26.6 kg/m2, received Dose 1 on 23 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 22). The subject had a reported medical history of cardiac murmur (since 1965), benign neoplasm of thyroid gland (in 1979), thyroidectomy (in 1980), seasonal allergy (since 2005), back pain (since 2010), and hysterectomy and uterine prolapse (both in 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 30 Oct 2020 (Day 38), the subject was diagnosed with COVID-19, and reported chills, fever, headache, new or increased cough, new or increased muscle pain, new or increased sore throat, and sinus congestion, with the first symptom starting on 29 Oct 2020, 15 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 38) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 38) was positive. The subject went to the Vanderbilt clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	Not Reported	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	90.91 kg	29.5 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bee stings, allergy	Allergy to arthropod sting	1992	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05OCT2020 (1)	10:41
2	Placebo	26OCT2020 (22)	09:52

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	05OCT2020 (1)	05OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	05OCT2020 (1)	05OCT2020 (1)	SERUM	NEGATIVE
Visit 2	26OCT2020 (22)	26OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04NOV2020 (31)/ 03NOV2020 (30)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04NOV2020 (31)	COVID-19	04NOV2020 (31)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	04NOV2020 (31)	04NOV2020 (31)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	04NOV2020 (31)	04NOV2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	04NOV2020 (31)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	Vanderbilt Walk-in Cliniic

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781280, a 58-year-old male with a height of 175.26 cm, a weight of 90.91 kg, and a BMI of 29.5 kg/m2, received Dose 1 on 05 Oct 2020 and Dose 2 on 26 Oct 2020 (Day 22). The subject had a reported medical history of allergy to arthropod sting (since 1992). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 04 Nov 2020 (Day 31), the subject was diagnosed with COVID-19 and reported chills, fever, fatigue, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 03 Nov 2020, 8 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 31) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 31) was positive. The subject went to the Vanderbilt clinic (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	82.27 kg	25.2 kg/m2	17SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	13:26
2	Placebo	07OCT2020 (21)	11:35

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	17SEP2020 (1)	17SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17SEP2020 (1)	17SEP2020 (1)	SERUM	NEGATIVE
Visit 2	07OCT2020 (21)	07OCT2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (54)/ 09NOV2020 (54)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (54)	COVID-19	09NOV2020 (54)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	09NOV2020 (54)	10NOV2020 (55)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location	Test Result
1	COVID Illness Visit 1	09NOV2020 (54)	09NOV2020 (54)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	Pending Subject Lab Transmission, however per Subject Positive.	OTHER	NALT Unknown.

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (54)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1179 11791085, a 34-year-old Asian male with a height of 180.34 cm, a weight of 82.27 kg, and a BMI of 25.2 kg/m2, received Dose 1 on 17 Sep 2020 and Dose 2 on 07 Oct 2020 (Day 21). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 09 Nov 2020 (Day 54), the subject was diagnosed with COVID-19 and reported fever, new or increased cough, and new or increased muscle pain, with the first symptom starting on 09 Nov 2020, 33 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 55) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 09 Nov 2020 (Day 54) was positive. The subject had a telephone consultation (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	American Indian or Alaska Native	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	139.73 kg	40.6 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Type 2	Type 2 diabetes mellitus	2000	Present
Kidney Stones	Nephrolithiasis	2004	Past
BPH	Benign prostatic hyperplasia	2019	Present
Congesutive Heart Failure	Cardiac failure congestive	JUL2019	Present
Coronary Stent placement	Coronary arterial stent insertion	JUL2019	Past
Circumcision	Circumcision	OCT2019	Past
Coronary Artery Disease	Coronary artery disease	15JUL2020	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	15JUL2020	Present
Hypertension	Hypertension	15JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13OCT2020 (1)	11:44
2	Placebo	02NOV2020 (21)	09:52

Adverse Events
No Adverse Events

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Dexamethasone (Decadron)	DEXAMETHASONE	03NOV2020	06NOV2020	INTRAVENOUS
Remdesivir	REMDESIVIR	03NOV2020	03NOV2020	INTRAVENOUS
Remdesivir	REMDESIVIR	04NOV2020	06NOV2020	INTRAVENOUS
Dexamethasone	DEXAMETHASONE	07NOV2020	ONGOING	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	13OCT2020 (1)	13OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13OCT2020 (1)	13OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (22)/ 01NOV2020 (20)/ ONGOING	YES	CHILLS	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03NOV2020 (22)	Viral Pneumonia secondary to COVID-19	03NOV2020 (22)	3	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory
No SARS-COV-2 Test - Central Laboratory

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03NOV2020 (22)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details					
Visit	**Visit Date (Study Day)**	**Hospitalization Category**	**Hospitalization Term**	**Admission Date (Study Day)**	**Discharge Date or Ongoing (Study Day)**
COVID Illness Visit 1	03NOV2020 (22)	HOSPITALIZATION STATUS	HOSPITAL	03NOV2020 (22)	06NOV2020 (25)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	Alkaline Phosphatase	2.33	ukat/L	0.63	2.1
			Alanine Aminotransferase	0.8335	ukat/L	0	0.8335
			Aspartate Aminotransferase	0.90018	ukat/L	0.28339	0.98353
			Bilirubin	8.6	umol/L	3.4	22.2
			Creatinine	53	umol/L	61.9	114.9
			C Reactive Protein	<5	mg/L	0	5
			Urea Nitrogen	3.93	mmol/L	3.21	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	Basophils	0	10^9/L	0	500
			Eosinophils	0	10^9/L	0	1000
			Hematocrit	0.48	L/L	0.41	0.49
			Hemoglobin	161	g/L	140	180
			Lymphocytes	800	10^9/L	900	4400
			Monocytes	1000	10^9/L	0	1000
			Neutrophils	3800	10^9/L	1500	8000
			Platelets	198000	10^9/L	180000	430000
			Erythrocytes	5.41	10^12/L	4	5.6
			Leukocytes	5700	10^9/L	4500	11000

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	1	153 mmHg	97 mmHg	32 breaths/min	72 beats/min	95 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020	CHEST		CT SCAN	NA	ABNORMAL
2	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020	CHEST		X-RAY	NA	NORMAL

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	Small patchy density in R Upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental ateletasis; R coronary atherosclerosis vs. stent
2	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1221 12211002, a 43-year-old American Indian or Alaska Native male with a height of 185.42 cm, a weight of 139.73 kg, and a BMI of 40.6 kg/m2, received Dose 1 on 13 Oct 2020 and Dose 2 on 02 Nov 2020 (Day 21). The subject had a reported medical history of type 2 diabetes mellitus (since 2000); nephrolithiasis (in 2004); benign prostatic hyperplasia (since 2019); congestive cardiac failure (since Jul 2019); coronary arterial stent insertion (in Jul 2019); circumcision (in Oct 2019); and coronary artery disease, hypercholesterolemia, and hypertension (all since 15 Jul 2020). The central laboratory SARS-CoV-2 NAAT result(s) was negative at Visit 1 and positive at Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 03 Nov 2020 (Day 22), the subject was diagnosed with severe COVID-19 pneumonia and reported chills and vomiting, with the first symptom starting on 01 Nov 2020, 19 days after receiving Dose 1, and at least 1 symptom ongoing as of the last available report. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Nov 2020 (Day 22) was positive. The subject went to the emergency room (ER) (once). On 01 Nov 2020 (Day 20), the subject developed mild nasal congestion, which was reported to be resolved on 02 Nov 2020 (Day 21). However, during Visit 2, the subject denied having any symptoms when queried if he had been ill in the previous 2 days. The subject received Dose 2 on 02 Nov 2020 (Day 21), and he developed nausea and vomiting around noon and developed chills later in the evening. On 03 Nov 2020 (Day 22), the subject went to the ER for further evaluation, at which time, he was noted to have nausea, vomiting, loss of appetite, difficulty breathing, sore throat, muscle aches, and chest tightness. The subject's body temperature was 97.2 F°. The ER nurse noted that "breath sounds were within normal limits" (respiratory rate: 19 breaths per minute). The subject was treated with ondansetron 4 mg for nausea. On 03 Nov 2020 (Day 22), the subject had a heart rate of 72 beats per minute, blood pressure of 153/97 mmHg, respiratory rate of 32 breaths per minute, and oxygen saturation of 95%. A respiratory examination showed mild respiratory distress with tachypnea. The subject received dexamethasone (intravenous [IV] from 03 Nov 2020 to 06 Nov 2020 and oral from 07 Nov 2020) and remdesivir (IV from 03 Nov 2020 to 06 Nov 2020) at the time of the COVID-19 illness. The influenza A and B virus tests were negative. The subject was hospitalized on 03 Nov 2020 (Day 22) for 4 days and discharged on 06 Nov 2020 (Day 25). A chest radiograph on 03 Nov 2020 (Day 22) was normal. Computed tomographic pulmonary angiography of the chest on 03 Nov 2020 (Day 22) was abnormal with small patchy density in the right upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental atelectasis; right coronary atherosclerosis vs. stent. On 03 Nov 2020 (Day 22), the subject's glucose was 312 mg/dL (normal range [NR]: 74 – 106 mg/dL), white blood cell count was 5.7 × 103/mm3 (NR: 4.5 – 11.0 × 103/mm3), alkaline phosphatase was 2.33 µkat/L (NR: 0.63 – 2.1 µkat/L), and lymphocyte count was 800 × 109/L (NR: 900 – 4400 × 109/L). The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, mild respiratory distress [respiratory rate >30 breaths per minute] with tachypnea).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	20	Asian	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	57.9 kg	20.3 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	11:27
2	Placebo	17SEP2020 (22)	14:31

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza Vaccine	INFLUENZA VACCINE	11OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	17SEP2020 (22)	17SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07NOV2020 (73)/ 06NOV2020 (72)/ ONGOING	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	07NOV2020 (73)	COVID 19	07NOV2020 (73)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	07NOV2020 (73)	07NOV2020 (73)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	07NOV2020 (73)	07NOV2020 (73)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		THERMOFISHER SCIENTIFIC TAQPATH COVID-19 COMBO KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07NOV2020 (73)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231005, a 20-year-old Asian female with a height of 169 cm, a weight of 57.9 kg, and a BMI of 20.3 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 22). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Nov 2020 (Day 73), the subject was diagnosed with COVID-19 and reported chills, new or increased cough, and new or increased sore throat, with the first symptom starting on 06 Nov 2020, 50 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 73) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 73) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	77.11 kg	29 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gerd	Gastrooesophageal reflux disease	2000	Present
myocardial infarction	Myocardial infarction	2000	Past
depression	Depression	2003	Present
hypertension	Hypertension	2010	Present
hypothyroidism	Hypothyroidism	MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	19:22
2	Placebo	25SEP2020 (24)	16:16

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	14OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	02SEP2020 (1)	02SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	02SEP2020 (1)	02SEP2020 (1)	SERUM	NEGATIVE
Visit 2	25SEP2020 (24)	25SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details

Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 12NOV2020 (72)/ 11NOV2020 (71)/ 12NOV2020 (72)	YES	CHILLS	
	NO		Headache
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	12NOV2020 (72)	11NOV2020 (71)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	12NOV2020 (72)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231096, a 77-year-old black or African American female with a height of 163 cm, a weight of 77.11 kg, and a BMI of 29 kg/m2, received Dose 1 on 02 Sep 2020 and Dose 2 on 25 Sep 2020 (Day 24). The subject had a reported medical history of myocardial infarction (in 2000), gastroesophageal reflux disease (since 2000), depression (since 2003), hypertension (since 2010), and hypothyroidism (since May 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, headache, and new or increased cough, with the first symptom starting on 11 Nov 2020, 47 days after receiving Dose 2, and the last symptom resolved on 12 Nov 2020 (Day 72). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 71) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.8 cm	88.5 kg	27.4 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
vasectomy	Vasectomy	2000	Present
Hypercholesterolemia	Hypercholesterolaemia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	11:16
2	Placebo	11SEP2020 (23)	09:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (23)	11SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 27OCT2020 (69)/ 20OCT2020 (62)/ 26OCT2020 (68)	YES	NEW OR INCREASED COUGH	
	NO		Rhinitis

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	27OCT2020 (69)	COVID-19	30OCT2020 (72)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	27OCT2020 (69)	27OCT2020 (69)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	27OCT2020 (69)	28OCT2020 (70)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	27OCT2020 (69)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	27OCT2020 (69)	27OCT2020 (69)	1	139 mmHg	74 mmHg	16 breaths/min	84 beats/min	94 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261309, a 61-year-old white male with a height of 179.8 cm, a weight of 88.5 kg, and a BMI of 27.4 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 23). The subject had a reported medical history of vasectomy (since 2000) and hypercholesterolemia (since 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 30 Oct 2020 (Day 72), the subject was diagnosed with COVID-19 and reported new or increased cough and rhinitis, with the first symptom starting on 20 Oct 2020, 39 days after receiving Dose 2, and the last symptom resolved on 26 Oct 2020 (Day 68). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 69) was positive. On 27 Oct 2020 (Day 69), the subject had a heart rate of 84 beats per minute, blood pressure of 139/74 mmHg, respiratory rate of 16 breaths per minute, and oxygen saturation of 94% on room air. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Oct 2020 (Day 70) was positive. The subject went to the emergency room (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	73.2 kg	29.7 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
menopause	Menopause	2016	Present
hypothyroidism	Hypothyroidism	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	14:14
2	Placebo	11SEP2020 (22)	12:05

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (22)	11SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06OCT2020 (47)/ 03OCT2020 (44)/ ONGOING	YES	CHILLS	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06OCT2020 (47)	Sars-Cov2 (COVID-19)	06OCT2020 (47)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06OCT2020 (47)	06OCT2020 (47)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	06OCT2020 (47)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	06OCT2020 (47)	06OCT2020 (47)	1	110 mmHg	64 mmHg	16 breaths/min	79 beats/min	95 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261363, a 48-year-old white female with a height of 157 cm, a weight of 73.2 kg, and a BMI of 29.7 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 22). The subject had a reported medical history of menopause (since 2016) and hypothyroidism (since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Oct 2020 (Day 47), the subject was diagnosed with COVID-19 and reported chills, new loss of taste or smell, new or increased cough, new or increased muscle pain, new or increased sore throat, and vomiting, with the first symptom starting on 03 Oct 2020, 22 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Oct 2020 (Day 47) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject went to her primary care physician (once). On 06 Oct 2020 (Day 47), the subject had a heart rate of 79 beats per minute, blood pressure of 110/64 mmHg, respiratory rate of 16 breaths per minute, and oxygen saturation of 95% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.9 cm	71.3 kg	27.5 kg/m2	07SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headache	Headache	2010	Present
Albright's osteodystrophy	Congenital osteodystrophy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07SEP2020 (1)	13:18
2	BNT162b2	02OCT2020 (26)	13:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	fatigue	07SEP2020 (1)	20:00	10SEP2020 (4)		4	1
2	MUSC	Myalgia	myalgia	07SEP2020 (1)	20:00	10SEP2020 (4)		4	1
3	EYE	Ulcerative keratitis	corneal ulcer right eye	20SEP2020 (14)		27SEP2020 (21)		8	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (10SEP2020)	Study Treatment	1	1	N
2	TC	N	Resolved (10SEP2020)	Study Treatment	1	1	N
3	TC	N	Resolved (27SEP2020)	NOT RELATED/OTHER: prolonged use of contact lens	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	07SEP2020 (1)	07SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07SEP2020 (1)	07SEP2020 (1)	SERUM	NEGATIVE
Visit 2	02OCT2020 (26)	02OCT2020 (26)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07NOV2020 (62)/ 06NOV2020 (61)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinitis

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	07NOV2020 (62)	COVID-19	07NOV2020 (62)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 1	07NOV2020 (62)	11NOV2020 (66)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07NOV2020 (62)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	1	133 mmHg	92 mmHg	16 breaths/min	89 beats/min	93 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07SEP2020	
Completed	VACCINATION	03NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261599, a 41-year-old white female with a height of 160.9 cm, a weight of 71.3 kg, and a BMI of 27.5 kg/m2, received Dose 1 on 07 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 26). The subject had a reported medical history of headache (since 2010) and congenital osteodystrophy (since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Nov 2020 (Day 62), the subject was diagnosed with severe COVID-19 and reported new loss of taste or smell, new or increased cough, new or increased sore throat, and rhinitis, with the first symptom starting on 06 Nov 2020, 35 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 07 Nov 2020 (Day 62) and on 11 Nov 2020 (Day 66) were positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 62) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 07 Nov 2020 (Day 62), the subject had a heart rate of 89 beats per minute, blood pressure of 133/92 mm Hg, respiratory rate of 16 breaths per minute, and oxygen saturation of 93% on room air. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93%).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.3 cm	91.1 kg	26.8 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:46
2	Placebo	30SEP2020 (23)	13:30

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (23)	30SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (59)/ 02NOV2020 (56)/ ONGOING	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05NOV2020 (59)	05NOV2020 (59)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	05NOV2020 (59)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	05NOV2020 (59)	05NOV2020 (59)	1	132 mmHg	78 mmHg	16 breaths/min	83 beats/min	92 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261624, a 52-year-old white male with a height of 184.3 cm, a weight of 91.1 kg, and a BMI of 26.8 kg/m2, received Dose 1 on 08 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 23). The subject had a reported medical history of vasectomy (since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, new or increased cough, new or increased muscle pain, new or increased sore throat, and rhinorrhea, with the first symptom starting on 02 Nov 2020, 33 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 59) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel. On 05 Nov 2020 (Day 59), the subject had a heart rate of 83 beats per minute, blood pressure of 132/78 mm Hg, respiratory rate of 16 breaths per minute, and oxygen saturation of 92% on room air. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ⩽93%).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.5 cm	97 kg	31.5 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	10:54
2	Placebo	30SEP2020 (20)	09:21

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	11SEP2020 (1)	11SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11SEP2020 (1)	11SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (20)	30SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (50)/ 28OCT2020 (48)/ 01NOV2020 (52)	YES	NEW OR INCREASED SORE THROAT	
COVID Illness Visit 2 / 06NOV2020 (57)/ 05NOV2020 (56)/ ONGOING	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30OCT2020 (50)	COVID-19	06NOV2020 (57)	1	COVID-19
COVID Illness Visit 2	06NOV2020 (57)	COVID-19	06NOV2020 (57)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (50)	30OCT2020 (50)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	06NOV2020 (57)	06NOV2020 (57)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30OCT2020 (50)	06NOV2020 (57)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	06NOV2020 (57)	06NOV2020 (57)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown
2	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	30OCT2020 (50)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	06NOV2020 (57)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	30OCT2020 (50)	30OCT2020 (50)	1	123 mmHg	84 mmHg	16 breaths/min	98 beats/min	96 %
COVID Illness Visit 2	06NOV2020 (57)	06NOV2020 (57)	2	139 mmHg	96 mmHg	16 breaths/min	117 beats/min	96 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261660, a 27-year-old white female with a height of 175.5 cm, a weight of 97 kg, and a BMI of 31.5 kg/m2, received Dose 1 on 11 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 20). The subject had a reported medical history of obesity (since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Nov 2020 (Day 57), the subject was diagnosed with COVID-19 and reported fever, headache, and new or increased muscle pain, with the first symptom starting on 05 Nov 2020, 36 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 57) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 57) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 06 Nov 2020 (Day 57), the subject had a heart rate of 117 beats per minute, blood pressure of 139/96 mmHg, respiratory rate of 16 breaths per minute, and oxygen saturation of 96% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.7 cm	64.5 kg	23.8 kg/m2	30SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	14:00
2	Placebo	21OCT2020 (22)	09:51

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	fatigue	21OCT2020 (22)	21:00	22OCT2020 (23)	
2	NERV	Headache	headache	21OCT2020 (22)	21:00	22OCT2020 (23)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (22OCT2020)	Study Treatment	2	1	N
2	2	1	TC	N	Resolved (22OCT2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	30SEP2020 (1)	30SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	30SEP2020 (1)	30SEP2020 (1)	SERUM	NEGATIVE
Visit 2	21OCT2020 (22)	21OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04NOV2020 (36)/ 29OCT2020 (30)/ ONGOING	YES	CHILLS	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Rhinitis
	NO		Sneezing

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04NOV2020 (36)	COVID-19	01NOV2020 (33)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	04NOV2020 (36)	04NOV2020 (36)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	04NOV2020 (36)	01NOV2020 (33)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	04NOV2020 (36)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	04NOV2020 (36)	04NOV2020 (36)	1	98 mmHg	68 mmHg	18 breaths/min	82 beats/min	99 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261964, a 27-year-old white female with a height of 164.7 cm, a weight of 64.5 kg, and a BMI of 23.8 kg/m2, received Dose 1 on 30 Sep 2020 and Dose 2 on 21 Oct 2020 (Day 22). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 01 Nov 2020 (Day 33), the subject was diagnosed with COVID-19 and reported chills, new loss of taste or smell, new or increased cough, new or increased muscle pain, new or increased sore throat, nasal congestion, rhinitis, and sneezing, with the first symptom starting on 29 Oct 2020, 8 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 36) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Nov 2020 (Day 33) was positive. The subject went to the emergency room (once). On 04 Nov 2020 (Day 36), the subject had a heart rate of 82 beats per minute, blood pressure of 98/68 mmHg, respiratory rate of 18 breaths per minute, and oxygen saturation of 99% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.5 cm	96 kg	29.8 kg/m2	08OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08OCT2020 (1)	13:24
2	Placebo	30OCT2020 (23)	09:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08OCT2020 (1)	08OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08OCT2020 (1)	08OCT2020 (1)	SERUM	NEGATIVE
Visit 2	30OCT2020 (23)	30OCT2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12NOV2020 (36)/ 10NOV2020 (34)/ 12NOV2020 (36)	YES	FEVER	
	NO		Headache
	NO		Sneezing

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	12NOV2020 (36)	12NOV2020 (36)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	12NOV2020 (36)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	**Visit Date (Study Day)**	**Date Collected (Study Day)**	**Record Identifier**	**Systolic Blood Pressure**	**Diastolic Blood Pressure**	**Respiratory Rate**	**Heart Rate**	**Oxygen Saturation**
COVID Illness Visit 1	12NOV2020 (36)	12NOV2020 (36)	1	135 mmHg	79 mmHg	17 breaths/min	78 beats/min	96 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08OCT2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12262111, a 51-year-old white male with a height of 179.5 cm, a weight of 96 kg, and a BMI of 29.8 kg/m2, received Dose 1 on 08 Oct 2020 and Dose 2 on 30 Oct 2020 (Day 23). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported fever, headache, and sneezing, with the first symptom starting on 10 Nov 2020, 11 days after receiving Dose 2, and the last symptom resolved on 12 Nov 2020 (Day 36). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Nov 2020 (Day 36) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel. On 12 Nov 2020 (Day 36), the subject had a heart rate of 78 beats per minute, blood pressure of 135/79 mmHg, respiratory rate of 17 breaths per minute, and oxygen saturation of 96% on room air.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	96 kg	31 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	01JUN2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	11:30
2	Placebo	01SEP2020 (22)	10:07

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	PSYCH	Anxiety disorder	Anxiety Disorder	26SEP2020 (47)	02:00	26SEP2020 (47)	03:30	1	2
2	INJ&P	Heat stroke	insolation	01NOV2020 (83)	21:00	02NOV2020 (84)	08:00	2	1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (26SEP2020)	NOT RELATED/OTHER: unknown	2	26	N
2	TC	N	Resolved (02NOV2020)	NOT RELATED/OTHER: Sun exposure during working hours	2	62	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	11AUG2020 (1)	11AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11AUG2020 (1)	11AUG2020 (1)	SERUM	NEGATIVE
Visit 2	01SEP2020 (22)	01SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 21AUG2020 (11)/ 19AUG2020 (9)/ 25AUG2020 (15)	YES	CHILLS	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
COVID Illness Visit 2 / 11OCT2020 (62)/ 10OCT2020 (61)/ 11OCT2020 (62)	YES	CHILLS	
	NO		Headache
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 2	11OCT2020 (62)	COVID-19	11OCT2020 (62)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	21AUG2020 (11)	21AUG2020 (11)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	11OCT2020 (62)	11OCT2020 (62)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	21AUG2020 (11)	21AUG2020 (11)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	11OCT2020 (62)	11OCT2020 (62)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	21AUG2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	11OCT2020 (62)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311043, a 46-year-old white male with a height of 176 cm, a weight of 96 kg, and a BMI of 31 kg/m2, received Dose 1 on 11 Aug 2020 and Dose 2 on 01 Sep 2020 (Day 22). The subject had a reported medical history of vasectomy (on 01 Jun 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 11 Oct 2020 (Day 62), the subject was diagnosed with COVID-19 and reported chills, headache, and new or increased cough, with the first symptom starting on 10 Oct 2020, 39 days after receiving Dose 2, and the last symptom resolved on 11 Oct 2020 (Day 62). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Oct 2020 (Day 62) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Oct 2020 (Day 62) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	85 kg	30.1 kg/m2	14AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	18:14
2	Placebo	03SEP2020 (21)	12:36

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	14AUG2020 (1)	14AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14AUG2020 (1)	14AUG2020 (1)	SERUM	NEGATIVE
Visit 2	03SEP2020 (21)	03SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02OCT2020 (50)/ 26SEP2020 (44)/ 07OCT2020 (55)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02OCT2020 (50)	COVID 19 INFECTION	03OCT2020 (51)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02OCT2020 (50)	02OCT2020 (50)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02OCT2020 (50)	02OCT2020 (50)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02OCT2020 (50)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311267, a 67-year-old white male with a height of 168 cm, a weight of 85 kg, and a BMI of 30.1 kg/m2, received Dose 1 on 14 Aug 2020 and Dose 2 on 03 Sep 2020 (Day 21). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 03 Oct 2020 (Day 51), the subject was diagnosed COVID-19 and reported fever, new or increased cough, and new or increased sore throat, with the first symptom starting on 26 Sep 2020, 23 days after receiving Dose 2, and the last symptom resolved on 07 Oct 2020 (Day 55). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Oct 2020 (Day 50) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Oct 2020 (Day 50) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	78 kg	27 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	01JUN2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	16:50
2	Placebo	04SEP2020 (21)	10:39

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	15AUG2020 (1)	15AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15AUG2020 (1)	15AUG2020 (1)	SERUM	NEGATIVE
Visit 2	04SEP2020 (21)	04SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01OCT2020 (48)/ 27SEP2020 (44)/ 06OCT2020 (53)	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01OCT2020 (48)	COVID-19 illness	01OCT2020 (48)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	01OCT2020 (48)	01OCT2020 (48)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	01OCT2020 (48)	01OCT2020 (48)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	01OCT2020 (48)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311407, a 63-year-old white male with a height of 170 cm, a weight of 78 kg, and a BMI of 27 kg/m2, received Dose 1 on 15 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 21). The subject had a reported medical history of hypertension (since 01 Jun 2014). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 01 Oct 2020 (Day 48), the subject was diagnosed with COVID-19 and reported chills, diarrhea, fever, headache, and new or increased muscle pain, with the first symptom starting on 27 Sep 2020, 23 days after receiving Dose 2, and the last symptom resolved on 06 Oct 2020 (Day 53). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Oct 2020 (Day 48) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Oct 2020 (Day 48) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	85.15 kg	28.1 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	12:51
2	Placebo	08SEP2020 (24)	10:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (24)	08SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19SEP2020 (35)/ 16SEP2020 (32)/ 27SEP2020 (43)	NO		Arthralgia
	YES	FEVER	
	NO		Fatigue
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	19SEP2020 (35)	COVID-19 ILLNESS	19SEP2020 (35)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	19SEP2020 (35)	19SEP2020 (35)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	19SEP2020 (35)	19SEP2020 (35)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	19SEP2020 (35)	02OCT2020 (48)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 1	19SEP2020 (35)	27OCT2020 (73)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
2	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
3	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19SEP2020 (35)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	19SEP2020 (35)	HOSPITALIZATION STATUS	HOSPITAL	26SEP2020 (42)	29SEP2020 (45)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	19SEP2020 (35)	29SEP2020 (45)	Alkaline Phosphatase	1.38	ukat/L	.	.
			Alanine Aminotransferase	1.13356	ukat/L	.	.
			Aspartate Aminotransferase	0.45009	ukat/L	.	.
			Creatinine	0,98	mg/dL	.	.
			Urea Nitrogen	10.71	mmol/L	.	.

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	19SEP2020 (35)	29SEP2020 (45)	Hematocrit	0.45	L/L	.	.
			Hemoglobin	153	g/L	.	.
			Platelets	386	10^9/L	.	.
			Leukocytes	6.7	10^9/L	.	.

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	19SEP2020 (35)	19SEP2020 (35)	1	120 mmHg	70 mmHg	20 breaths/min	74 beats/min	99 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	**Visit**	**Visit Date (Study Day)**	**Date of Assessment**	**Location of Assessment**	**If Other, Specify**	**Type of Imaging Exam**	**If Other, Specify**	**Overall Assessment**
1	COVID Illness Visit 1	19SEP2020 (35)	26SEP2020	CHEST		CT SCAN	NA	ABNORMAL

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	multiple pseudonodular opacities in ground glass with a tendency to coalescence, predominantly diffuse distribution, multilobar and bilateral.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311531, a 35-year-old white male with a height of 174 cm, a weight of 85.15 kg, and a BMI of 28.1 kg/m2, received Dose 1 on 16 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 24). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 19 Sep 2020 (Day 35), the subject was diagnosed with COVID-19 and reported arthralgia, fever, fatigue, new or increased muscle pain, new or increased shortness of breath, and rhinorrhea, with the first symptom starting on 16 Sep 2020, 8 days after receiving Dose 2, and the last symptom resolved on 27 Sep 2020 (Day 43). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Sep 2020 (Day 35) was positive. The local laboratory SARS-CoV-2 NAAT result(s) at the time of the COVID-19 illness on 19 Sep 2020 (Day 35) and 02 Oct 2020 (Day 48) were positive and on 27 Oct 2020 (Day 73) was negative. The subject went to the emergency room (once). On 19 Sep 2020 (Day 35), the subject had a heart rate of 74 beats per minute, blood pressure of 120/70 mmHg, respiratory rate of 20 breaths per minute, and oxygen saturation of 99% on room air. The subject was hospitalized on 26 Sep 2020 (Day 42) for 4 days and discharged on 29 Sep 2020 (Day 45). On 26 Sep 2020 (Day 42), a computed tomographic scan of the chest showed multiple pseudonodular ground-glass opacities with a tendency to coalescence, predominantly diffuse distribution, multilobar, and bilateral. On 29 Sep 2020 (Day 45), the alkaline phosphatase was 1.38 µkat/L, alanine aminotransferase was 1.13356 µkat/L, aspartate aminotransferase was 0.45009 µkat/L, creatinine was 0.98 mg/dL, blood urea nitrogen was 10.71 mmol/L, hematocrit was 0.45 L/L, hemoglobin was 153 g/L, platelets was 386 × 109/L, and leukocytes was 6.7 × 109/L (normal ranges for all values were not reported).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	91.8 kg	26 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	13:23
2	Placebo	07SEP2020 (23)	10:40

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Asthenia	Asthenia	23SEP2020 (39)	08:00	23SEP2020 (39)	23:00	1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (23SEP2020)	NOT RELATED/OTHER: unknown	2	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	07SEP2020 (23)	07SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22OCT2020 (68)/ 21OCT2020 (67)/ 09NOV2020 (86)	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	22OCT2020 (68)	COVID-19 DISEASE	22OCT2020 (68)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	22OCT2020 (68)	22OCT2020 (68)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	22OCT2020 (68)	22OCT2020 (68)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	22OCT2020 (68)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311556, a 24-year-old white male with a height of 188 cm, a weight of 91.8 kg, and a BMI of 26 kg/m2, received Dose 1 on 16 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 23). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 22 Oct 2020 (Day 68), the subject was diagnosed with COVID-19 and reported headache, new loss of taste or smell, and nasal congestion, with the first symptom starting on 21 Oct 2020, 44 days after receiving Dose 2, and the last symptom resolved on 09 Nov 2020 (Day 86). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Oct 2020 (Day 68) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Oct 2020 (Day 68) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184 cm	102 kg	30.1 kg/m2	16AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arterial hypertension	Hypertension	01MAR2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	13:31
2	Placebo	04SEP2020 (20)	09:35

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	04SEP2020 (20)	04SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12NOV2020 (89)/ 12NOV2020 (89)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	12NOV2020 (89)	COVID-19 ILLNESS	12NOV2020 (89)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	12NOV2020 (89)	12NOV2020 (89)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	12NOV2020 (89)	12NOV2020 (89)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	12NOV2020 (89)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311560, a 44-year-old white male with a height of 184 cm, a weight of 102 kg, and a BMI of 30.1 kg/m2, received Dose 1 on 16 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 20). The subject had a reported medical history of hypertension (since 01 Mar 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 12 Nov 2020 (Day 89), the subject was diagnosed with COVID-19 and reported fever and new or increased cough, with the first symptom starting on 12 Nov 2020, 69 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Nov 2020 (Day 89) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 12 Nov 2020 (Day 89) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	75.2 kg	26.6 kg/m2	16AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	20DEC2016	Past
Adenocarcinoma in situ of the breast	Breast cancer	01AUG2017	Past
Bilateral mastectomy	Mastectomy	01SEP2017	Past
Bilateral breast prosthesis insertion	Mammoplasty	07JUL2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	17:50
2	Placebo	07SEP2020 (23)	12:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Dizziness	Lipothymia Dizziness	17AUG2020 (2)	10:00	19AUG2020 (4)	20:00	3	1	TC/TCN	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19AUG2020)	NOT RELATED/OTHER: Unknown factors. Volunteer links symptoms to a stress episode.	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	07SEP2020 (23)	07SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16SEP2020 (32)/ 14SEP2020 (30)/ 01OCT2020 (47)	NO		Asthenia
	YES	CHILLS	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	16SEP2020 (32)	covid 19	16SEP2020 (32)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	16SEP2020 (32)	20SEP2020 (36)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	16SEP2020 (32)	16SEP2020 (32)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	16SEP2020 (32)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311651, a 52-year-old white female with a height of 168 cm, a weight of 75.2 kg, and a BMI of 26.6 kg/m2, received Dose 1 on 16 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 23). The subject had a reported medical history of hysterectomy (on 20 Dec 2016), breast cancer (on 01 Aug 2017), mastectomy (on 01 Sep 2017), and mammoplasty (on 07 Jul 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 16 Sep 2020 (Day 32), the subject was diagnosed with COVID-19 and reported asthenia, chills, headache, new or increased cough, new or increased muscle pain, new or increased sore throat, and vomiting, with the first symptom starting on 14 Sep 2020, 7 days after receiving Dose 2, and the last symptom resolved on 01 Oct 2020 (Day 47). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 20 Sep 2020 (Day 36) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Sep 2020 (Day 32) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	67.85 kg	23.5 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	18:45
2	Placebo	07SEP2020 (23)	20:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	07SEP2020 (23)	07SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 17SEP2020 (33)/ 15SEP2020 (31)/ 03OCT2020 (49)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	17SEP2020 (33)	COVID-19	17SEP2020 (33)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	17SEP2020 (33)	17SEP2020 (33)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	17SEP2020 (33)	17SEP2020 (33)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	17SEP2020 (33)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311664, a 34-year-old white female with a height of 170 cm, a weight of 67.85 kg, and a BMI of 23.5 kg/m2, received Dose 1 on 16 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 23). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 17 Sep 2020 (Day 33), the subject was diagnosed with COVID-19 and reported symptoms of fever and new or increased cough, with the first symptom starting on 15 Sep 2020, 8 days after receiving Dose 2, and the last symptom resolved on 03 Oct 2020 (Day 49). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 17 Sep 2020 (Day 33) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 17 Sep 2020 (Day 33) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	97.91 kg	29.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypercholesterolemia	Hypercholesterolaemia	07SEP2005	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	13:28
2	Placebo	07SEP2020 (22)	12:48

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	17AUG2020 (1)	17AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17AUG2020 (1)	17AUG2020 (1)	SERUM	NEGATIVE
Visit 2	07SEP2020 (22)	07SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16OCT2020 (61)/ 14OCT2020 (59)/ 25OCT2020 (70)	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	16OCT2020 (61)	covid-19 illness	16OCT2020 (61)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	16OCT2020 (61)	16OCT2020 (61)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	16OCT2020 (61)	16OCT2020 (61)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	16OCT2020 (61)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311754, a 54-year-old white male with a height of 181 cm, a weight of 97.91 kg, and a BMI of 29.9 kg/m2, received Dose 1 on 17 Aug 2020 and Dose 2 on 07 Sep 2020 (Day 22). The subject had a reported medical history of hypercholesterolemia (on 07 Sep 2005). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 16 Oct 2020 (Day 61), the subject was diagnosed with COVID-19 and reported fever, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 14 Oct 2020, 37 days after receiving Dose 2, and the last symptom resolved on 25 Oct 2020 (Day 70). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 61) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 61) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184 cm	84.8 kg	25 kg/m2	17AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	13:25
2	Placebo	08SEP2020 (23)	09:06

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	17AUG2020 (1)	17AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17AUG2020 (1)	17AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (23)	08SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10NOV2020 (86)/ 09NOV2020 (85)/ 09NOV2020 (85)	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	10NOV2020 (86)	COVID-19 illness	10NOV2020 (86)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10NOV2020 (86)	10NOV2020 (86)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	10NOV2020 (86)	10NOV2020 (86)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10NOV2020 (86)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311764, a 34-year-old white male with a height of 184 cm, a weight of 84.8 kg, and a BMI of 25 kg/m2, received Dose 1 on 17 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 23). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 10 Nov 2020 (Day 86), the subject was diagnosed with COVID-19 and reported new loss of taste or smell and nasal congestion, with the first symptom starting on 09 Nov 2020, 62 days after receiving Dose 2, and the last symptom resolved on 09 Nov 2020 (Day 85). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 86) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 86) was positive. The subject had an urgent care visit (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	50.4 kg	19 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	10OCT1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	13:00
2	Placebo	08SEP2020 (22)	12:06

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	18AUG2020 (1)	18AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18AUG2020 (1)	18AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (22)	08SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 20OCT2020 (64)/ 14OCT2020 (58)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	20OCT2020 (64)	Covid-19	15OCT2020 (59)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	20OCT2020 (64)	20OCT2020 (64)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	20OCT2020 (64)	15OCT2020 (59)	RESPIRATORY SECRETIONS	NASOPHARYNX
2	COVID Illness Visit 1	20OCT2020 (64)	20OCT2020 (64)	RESPIRATORY SECRETIONS	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Unknown
2	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	20OCT2020 (64)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12311982, a 41-year-old white female with a height of 163 cm, a weight of 50.4 kg, and a BMI of 19 kg/m2, received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject had a reported medical history of hypercholesterolemia (since 10 Oct 1995). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 15 Oct 2020 (Day 59), the subject was diagnosed with COVID-19 and reported new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 14 Oct 2020, 36 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 20 Oct 2020 (Day 64) was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 15 Oct 2020 (Day 59) and 20 Oct 2020 (Day 64) were positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	138 kg	39.9 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	12APR2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	10:19
2	Placebo	10SEP2020 (22)	18:38

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (22)	10SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11OCT2020 (53)/ 09OCT2020 (51)/ ONGOING	YES	CHILLS	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11OCT2020 (53)	Upper airway infection	11OCT2020 (53)	1	Upper respiratory tract infection

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11OCT2020 (53)	11OCT2020 (53)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11OCT2020 (53)	11OCT2020 (53)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11OCT2020 (53)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312479, a 43-year-old white male with a height of 186 cm, a weight of 138 kg, and a BMI of 39.9 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had a reported medical history of hypothyroidism (since 12 Apr 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 11 Oct 2020 (Day 53), the subject was diagnosed with upper respiratory tract infection and reported chills, new loss of taste or smell, new or increased cough, new or increased muscle pain, and nasal congestion, with the first symptom starting on 09 Oct 2020, 29 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Oct 2020 (Day 53) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Oct 2020 (Day 53) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	75 kg	27.5 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	11:36
2	Placebo	08SEP2020 (20)	14:30

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (20)	08SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19SEP2020 (31)/ 17SEP2020 (29)/ 28SEP2020 (40)	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	19SEP2020 (31)	Covid-19	19SEP2020 (31)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	19SEP2020 (31)	19SEP2020 (31)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	19SEP2020 (31)	19SEP2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19SEP2020 (31)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312507, a 47-year-old white female with a height of 165 cm, a weight of 75 kg, and a BMI of 27.5 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 20). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 19 Sep 2020 (Day 31), the subject was diagnosed with COVID-19 and reported new or increased muscle pain, new or increased sore throat, and rhinorrhea, with the first symptom starting on 17 Sep 2020, 9 days after receiving Dose 2, and the last symptom resolved on 28 Sep 2020 (Day 40). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Sep 2020 (Day 31) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 19 Sep 2020 (Day 31) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	106.9 kg	39.7 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	06AUG1983	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	16:59
2	Placebo	10SEP2020 (22)	11:12

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (22)	10SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (68)/ 23OCT2020 (65)/ ONGOING	NO		Asthenia
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (68)	COVID-19 ILLNESS	26OCT2020 (68)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (68)	26OCT2020 (68)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26OCT2020 (68)	24OCT2020 (66)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	26OCT2020 (68)	26OCT2020 (68)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE	RT-PCR	OTHER	Atila Biosystems IAMP Covid-19 Detection Kit.
2	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	26OCT2020 (68)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312630, a 39-year-old white female with a height of 164 cm, a weight of 106.9 kg, and a BMI of 39.7 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 22). The subject had a reported medical history of asthma (since 06 Aug 1983). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 26 Oct 2020 (Day 68), the subject was diagnosed with COVID-19, and reported asthenia, fever, new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 23 Oct 2020, 43 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 68) was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 24 Oct 2020 (Day 66) and 26 Oct 2020 (Day 68) were positive. The subject had a telephone consultation (once) and went to her primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185 cm	80.45 kg	23.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial Hypertension	Hypertension	01JAN1990	Present
COPD	Chronic obstructive pulmonary disease	01SEP2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	16:24
2	Placebo	08SEP2020 (20)	17:11

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (20)	08SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06OCT2020 (48)/ 04OCT2020 (46)/ ONGOING	NO		Asthenia
	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06OCT2020 (48)	covid 19 lung disease	06OCT2020 (48)	3	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	06OCT2020 (48)	06OCT2020 (48)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	06OCT2020 (48)	06OCT2020 (48)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	06OCT2020 (48)	27OCT2020 (69)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06OCT2020 (48)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		URGENT CARE	YES	1	NA
		TELEPHONE CONSULTATION	YES	5	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	06OCT2020 (48)	HOSPITALIZATION STATUS	HOSPITAL	17OCT2020 (59)	20OCT2020 (62)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	06OCT2020 (48)	19OCT2020 (61)	Alkaline Phosphatase	2.32	ukat/L	0.5	2.33
			Alanine Aminotransferase	0.65013	ukat/L	0	0.8335
			Aspartate Aminotransferase	0.43342	ukat/L	0	0.6668
			Bilirubin	7	umol/L	0	20.5
			Creatinine	82.2	umol/L	17.7	106.1
			Urea Nitrogen	12.86	mmol/L	5.36	17.86

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	06OCT2020 (48)	19OCT2020 (61)	Basophils	0.062	10^9/L	.	.
			Eosinophils	0.062	10^9/L	.	.
			Hematocrit	0.4	L/L	.	.
			Hemoglobin	136	g/L	.	.
			Lymphocytes	0.1	10^9/L	.	.
			Monocytes	0.312	10^9/L	.	.
			Neutrophils	5.179	10^9/L	.	.
			Platelets	288	10^9/L	.	.
			Erythrocytes	4.43	10^12/L	.	.

Vital Signs - COVID-19

No Vital Signs - COVID-19

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging						
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam
1	COVID Illness Visit 1	06OCT2020 (48)	17OCT2020	CHEST		CT SCAN

Imaging			
Assessment Number	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	NA	ABNORMAL	heterogeneous diffuse opacity involving both lungs, bilateral pleural effusion. Mediastinic adenopathies

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312635, a 71-year-old white male with a height of 185 cm, a weight of 80.45 kg, and a BMI of 23.5 kg/m2, received Dose 1 on 20 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 20). The subject had a reported medical history of hypertension (since 01 Jan 1990) and chronic obstructive pulmonary disease (since 01 Sep 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Oct 2020 (Day 48), the subject was diagnosed with COVID-19 pneumonia and reported asthenia, chills, fever, new or increased cough, new or increased sore throat, and nasal congestion, with the first symptom starting on 04 Oct 2020, 26 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Oct 2020 (Day 48) was positive. The local laboratory SARS-CoV-2 NAAT result(s) at the time of the COVID-19 illness on 06 Oct 2020 (Day 48) was positive and on 27 Oct 2020 (Day 69) was negative. The subject visited his primary care physician (once), had a telephone consultation (5 times) and had an urgent care visit (once). The subject was hospitalized on 17 Oct 2020 (Day 59) for 4 days and discharged on 20 Oct 2020 (Day 62).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	75 kg	25.1 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	13:25
2	Placebo	10SEP2020 (21)	14:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (21)	10SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16OCT2020 (57)/ 14OCT2020 (55)/ 01NOV2020 (73)	NO		Asthenia
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	16OCT2020 (57)	COVID 19 disease	15OCT2020 (56)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	16OCT2020 (57)	16OCT2020 (57)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	16OCT2020 (57)	15OCT2020 (56)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE
2	COVID Illness Visit 1	16OCT2020 (57)	16OCT2020 (57)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	the volunteer had performed a nasopharyngeal swab for local entities on 10/15/20, at the Dr Federico Alberto Abete Hospital (Pablo Nogues); Real Time-PCR technique with positive result.	OTHER	NALT Unknown
2		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	16OCT2020 (57)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	13NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312867, a 40-year-old white female with a height of 173 cm, a weight of 75 kg, and a BMI of 25.1 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 21). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 15 Oct 2020 (Day 56), the subject was diagnosed with COVID-19 and reported asthenia, diarrhea, fever, headache, and new loss of taste or smell, with the first symptom starting on 14 Oct 2020, 34 days after receiving Dose 2, and the last symptom resolved on 01 Nov 2020 (Day 73). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 16 Oct 2020 (Day 57) was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 15 Oct 2020 (Day 56) and 16 Oct 2020 (Day 57) were positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	103 kg	35.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	16:00
2	Placebo	14SEP2020 (25)	11:00

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Atrioventricular block second degree	Second degree AV block (Mobitz II)	10NOV2020 (82)	10:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	2	58	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (25)	14SEP2020 (25)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25AUG2020 (5)/ 24AUG2020 (4)/ 16SEP2020 (27)	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea
COVID Illness Visit 2 / 29OCT2020 (70)/ 26OCT2020 (67)/ ONGOING	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 2	29OCT2020 (70)	COVID-19 pharyngitis.	29OCT2020 (70)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	25AUG2020 (5)	25AUG2020 (5)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	29OCT2020 (70)	29OCT2020 (70)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	25AUG2020 (5)	25AUG2020 (5)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	25AUG2020 (5)	10SEP2020 (21)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 2	29OCT2020 (70)	29OCT2020 (70)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
3	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	25AUG2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	29OCT2020 (70)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	3	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 2	29OCT2020 (70)	HOSPITALIZATION STATUS	HOSPITAL	06NOV2020 (78)	14NOV2020 (86)

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 2	29OCT2020 (70)	06NOV2020 (78)	1					92 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 2	29OCT2020 (70)	02NOV2020	CHEST		X-RAY	NA	ABNORMAL	Right lung base abnormal.

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312914, a 50-year-old white male with a height of 171 cm, a weight of 103 kg, and a BMI of 35.2 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 25). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 29 Oct 2020 (Day 70), the subject was diagnosed with severe COVID-19 and reported fever, fatigue, headache, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 26 Oct 2020, 42 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 70) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 70) was positive. On 02 Nov 2020 (Day 74), a chest radiograph revealed right lung base abnormal. On 06 Nov 2020 (Day 78), the subject was admitted to the hospital for COVID-19 pneumonia, with the symptoms of bradycardia and 2 episodes of second grade atrioventricular (AV) block (Mobitz II). On 06 Nov 2020 (Day 78), the subject had an oxygen saturation of 92%. The subject was transferred to a coronary unit on 10 Nov 2020 (Day 82). An electrocardiogram (ECG) showed sinus rhythm without ST elevation; second grade AV block (Mobitz II). On the same day (Day 82), the subject was diagnosed with a serious adverse event of atrioventricular block second degree, resulting in prolonged hospitalization. On 11 Nov 2020 (Day 83), the subject's troponin (unknown subtype) was reported to be normal at 4.5 ng/L and 2.6 ng/L on 13 Nov 2020 (Day 85) (normal ranges not reported). On 12 Nov 2020 (Day 84), an ECG showed sinus rhythm without blockages and echocardiogram was normal. On 13 Nov 2020 (Day 85), an ECG was normal with a cardiac frequency of 76 beats per minute, normal sinus rhythm and no electrical disturbances. The subject remained stable without oxygen requirement and did not receive any treatment for this transitory episode. A 24-hour Holter in 3 channels was scheduled. On 14 Nov 2020 (Day 86), the subject was discharged from the hospital. The atrioventricular block second degree was ongoing as of the last available report. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ⩽93%).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	87 kg	27.5 kg/m2	22AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	15:03
2	Placebo	11SEP2020 (21)	14:25

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Palpitations	palpitations	24SEP2020 (34)	08:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: Unknown	2	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22AUG2020 (1)	22AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22AUG2020 (1)	22AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (21)	11SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25SEP2020 (35)/ 20SEP2020 (30)/ 19OCT2020 (59)	NO		Asthenia
	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	NO		Ocular discomfort

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	25SEP2020 (35)	Pharyngitis due to COVID-19	25SEP2020 (35)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	25SEP2020 (35)	25SEP2020 (35)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	25SEP2020 (35)	24SEP2020 (34)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	25SEP2020 (35)	25SEP2020 (35)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown
2	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	25SEP2020 (35)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313182, a 33-year-old white male with a height of 178 cm, a weight of 87 kg, and a BMI of 27.5 kg/m2, received Dose 1 on 22 Aug 2020 and Dose 2 on 11 Sep 2020 (Day 21). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 25 Sep 2020 (Day 35), the subject was diagnosed with COVID-19 and reported asthenia, fatigue, headache, new loss of taste or smell, new or increased shortness of breath, and ocular discomfort, with the first symptom starting on 20 Sep 2020, 9 days after receiving Dose 2, and the last symptom resolved on 19 Oct 2020 (Day 59). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 25 Sep 2020 (Day 35) was positive. The local laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 24 Sep 2020 (Day 34) and 25 Sep 2020 (Day 35) were positive. The subject went to the emergency room (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	96.9 kg	40.3 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	10AUG2015	Present
Type 2 diabetes	Type 2 diabetes mellitus	10AUG2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	18:53
2	Placebo	10SEP2020 (20)	15:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22AUG2020 (1)	22AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22AUG2020 (1)	22AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (20)	10SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 06OCT2020 (46)/ 04OCT2020 (44)/ 20OCT2020 (60)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06OCT2020 (46)	COVID 19 INFECTION	06OCT2020 (46)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06OCT2020 (46)	06OCT2020 (46)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	06OCT2020 (46)	06OCT2020 (46)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	06OCT2020 (46)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313296, a 49-year-old white female with a height of 155 cm, a weight of 96.9 kg, and a BMI of 40.3 kg/m2, received Dose 1 on 22 Aug 2020 and Dose 2 on 10 Sep 2020 (Day 20). The subject had a reported medical history of hypertension and type 2 diabetes mellitus (both since 10 Aug 2015). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Oct 2020 (Day 46), the subject was diagnosed with COVID-19 and reported new loss of taste or smell and new or increased cough, with the first symptom starting on 04 Oct 2020, 24 days after receiving Dose 2, and the last symptom resolved on 20 Oct 2020 (Day 60). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Oct 2020 (Day 46) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Oct 2020 (Day 46) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	88.6 kg	31 kg/m2	23AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	01JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	11:07
2	Placebo	13SEP2020 (22)	18:27

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	VASC	Hypertension	Hypertension	10OCT2020 (49)	10:30	10OCT2020 (49)	14:30	1
2	CARD	Palpitations	Palpitations	10OCT2020 (49)	10:30	10OCT2020 (49)	14:30	1

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (10OCT2020)	NOT RELATED/OTHER: work stress	2	28	N
2	1	N	N	Resolved (10OCT2020)	NOT RELATED/OTHER: Work stress	2	28	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23AUG2020 (1)	23AUG2020 (1)	SERUM	NEGATIVE
Visit 2	13SEP2020 (22)	13SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 2	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03SEP2020 (12)/ 30AUG2020 (8)/ 07SEP2020 (16)	YES	NEW OR INCREASED SORE THROAT	
COVID Illness Visit 2 / 21OCT2020 (60)/ 19OCT2020 (58)/ 28OCT2020 (67)	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 2	21OCT2020 (60)	COVID-19	21OCT2020 (60)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03SEP2020 (12)	03SEP2020 (12)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	21OCT2020 (60)	21OCT2020 (60)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	03SEP2020 (12)	04SEP2020 (13)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	21OCT2020 (60)	21OCT2020 (60)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	
2	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03SEP2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	21OCT2020 (60)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	emergency medical assistance at home

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	12OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313400, a 46-year-old white male with a height of 169 cm, a weight of 88.6 kg, and a BMI of 31 kg/m2, received Dose 1 on 23 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 22). The subject had a reported medical history of hypertension (since 01 Jan 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 21 Oct 2020 (Day 60), the subject was diagnosed with COVID-19 and reported chills, new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 19 Oct 2020, 36 days after receiving Dose 2, and the last symptom resolved on 28 Oct 2020 (Day 67). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 21 Oct 2020 (Day 60) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 21 Oct 2020 (Day 60) was positive. The subject required emergency medical assistance at home (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	88 kg	29.7 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	12:15
2	Placebo	15SEP2020 (24)	19:05

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23AUG2020 (1)	23AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (24)	15SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29OCT2020 (68)/ 28OCT2020 (67)/ ONGOING	NO		Asthenia
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	29OCT2020 (68)	COVID-19 and Bilateral pneumonia	02NOV2020 (72)	4	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	29OCT2020 (68)	29OCT2020 (68)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	29OCT2020 (68)	29OCT2020 (68)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	29OCT2020 (68)	01NOV2020 (71)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	POSITIVE	swab performed at the san camilo clinic	OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29OCT2020 (68)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	29OCT2020 (68)	HOSPITALIZATION STATUS	HOSPITAL	01NOV2020 (71)	ONGOING
COVID Illness Visit 1	29OCT2020 (68)	HOSPITALIZATION STATUS	ICU	06NOV2020 (76)	ONGOING

Respiratory Treatment						
Visit	**Visit Date (Study Day)**	**Treatment Identifier**	**Prespecified Concomitant Nondrug Treatment**	**Treatment**	**Start Date (Study Day)**	**End Date or Ongoing (Study Day)**
COVID Illness Visit 1	29OCT2020 (68)	1	YES	MECHANICAL VENTILATION	06NOV2020 (76)	12NOV2020 (82)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	29OCT2020 (68)	06NOV2020 (76)	Alkaline Phosphatase	1.12	ukat/L	0.63	2.1
			Alanine Aminotransferase	1.76702	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	0.8335	ukat/L	0.08335	0.6668
			Bilirubin	12	umol/L	3.4	20.5
			Creatinine	70.7	umol/L	53	110.5
			C Reactive Protein	149.89	mg/L	0.1	10
			Urea Nitrogen	12.14	mmol/L	5	16.07
		07NOV2020 (77)	Alkaline Phosphatase	0.95	ukat/L	0.63	2.1
			Alanine Aminotransferase	1.26692	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	0.5001	ukat/L	0.08335	0.6668
			Bilirubin	10.3	umol/L	3.4	20.5
			Creatinine	70.7	umol/L	53	110.5
			C Reactive Protein	149.89	mg/L	0.1	10
			Urea Nitrogen	14.28	mmol/L	5	16.07
		10NOV2020 (80)	Alkaline Phosphatase	1.15	ukat/L	0.63	2.1
			Alanine Aminotransferase	3.95079	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	1.56698	ukat/L	0.08335	0.6668
			Bilirubin	0.5	umol/L	0.3	2.1
			Creatinine	53	umol/L	53	106.1
			Urea Nitrogen	46	mg/L	14	45

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	29OCT2020 (68)	06NOV2020 (76)	Basophils	0	10^9/L	0	200000
			Eosinophils	0	10^9/L	0	700000
			Hematocrit	0.41	L/L	0.4	0.54
			Hemoglobin	144	g/L	126	161
			Lymphocytes	695000	10^9/L	600000	2600000
			Monocytes	2000	10^9/L	0	900000
			Neutrophils	7246000	10^9/L	1700000	7600000
			Platelets	262	10^9/L	150	400
		07NOV2020 (77)	Basophils	52000	10^9/L	0	200000
			Eosinophils	3000	10^9/L	0	700000
			Hematocrit	0.33	L/L	0.4	0.54
			Hemoglobin	117	g/L	126	161
			Lymphocytes	327000	10^9/L	600000	2600000
			Monocytes	225000	10^9/L	0	900000
			Neutrophils	5265000	10^9/L	1700000	7600000
			Platelets	238	10^9/L	150	400
			Erythrocytes	4.01	10^9/L	4.25	5.9
		10NOV2020 (80)	Basophils	37000	10^9/L	0	200000
			Eosinophils	25000	10^9/L	0	700000
			Hematocrit	0.33	L/L	0.4	0.54
			Hemoglobin	111	g/L	126	161
			Lymphocytes	1012000	10^9/L	600000	2600000
			Monocytes	232000	10^9/L	0	900000
			Neutrophils	3672000	10^9/L	1700000	7600000
			Platelets	306	10^9/L	150	400

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Erythrocytes	3.94	10^9/L	4.25	5.9

Vital Signs - COVID-19

No Vital Signs - COVID-19

Oxygenation Parameters

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Arterial Blood Gases PaO2 (mmHg)	FiO2 (Fraction of Inhaled Oxygen)
COVID Illness Visit 1	29OCT2020 (68)	07NOV2020 (77)	103	0.5
COVID Illness Visit 1	29OCT2020 (68)	09NOV2020 (79)	390	0.4

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging						
Assessment Number	**Visit**	**Visit Date (Study Day)**	**Date of Assessment**	**Location of Assessment**	**If Other, Specify**	**Type of Imaging Exam**
1	COVID Illness Visit 1	29OCT2020 (68)	01NOV2020	CHEST		CT SCAN
2	COVID Illness Visit 1	29OCT2020 (68)	06NOV2020	CHEST		X-RAY
3	COVID Illness Visit 1	29OCT2020 (68)	07NOV2020	CHEST		X-RAY
4	COVID Illness Visit 1	29OCT2020 (68)	10NOV2020	CHEST		X-RAY

Imaging			
Assessment Number	**If Other, Specify**	**Overall Assessment**	**If Abnormal, Specify Findings**
1	NA	ABNORMAL	bilateral peripheral pneumonic infiltrate
2	NA	ABNORMAL	Bilateral cottony infiltrates are observed with effacement of the right phrenic cost sinus
3	NA	ABNORMAL	bilateral cottony infiltrate
4	NA	ABNORMAL	Bilateral pulmonary parenchymal infiltrate with imaging improvement with respect to previous ones

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313422, a 34-year-old white male with a height of 172 cm, a weight of 88 kg, and a BMI of 29.7 kg/m2, received Dose 1 on 23 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 24). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result is pending. On 29 Oct 2020 (Day 68), the subject was diagnosed with severe COVID-19 and reported asthenia, diarrhea, fever, headache, new or increased cough, and new or increased shortness of breath, with the first symptom starting on 28 Oct 2020, 43 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 68) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 68) was negative and on 01 Nov 2020 (Day 71) was positive. The subject did not have any contact with nonstudy healthcare personnel. The subject was hospitalized on 01 Nov 2020 (Day 71), and he remained hospitalized as of the last available report. On 01 Nov 2020 (Day 71), the subject required noninvasive positive pressure ventilation. The subject therefore had severe COVID-19 per study protocol criteria (ie, confirmed COVID-19 and requirement for non-invasive positive pressure ventilation). On 03 Nov 2020 (Day 73), a computed tomographic scan of the chest showed bilateral peripheral pneumonic infiltrate.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	58.4 kg	23.1 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	16:23
2	Placebo	15SEP2020 (24)	11:48

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23AUG2020 (1)	23AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (24)	15SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25SEP2020 (34)/ 22SEP2020 (31)/ 09OCT2020 (48)	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	25SEP2020 (34)	Covid-19 disease	25SEP2020 (34)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	25SEP2020 (34)	25SEP2020 (34)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	25SEP2020 (34)	25SEP2020 (34)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	25SEP2020 (34)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	23OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313520, a 28-year-old white female with a height of 159 cm, a weight of 58.4 kg, and a BMI of 23.1 kg/m2, received Dose 1 on 23 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 24). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 25 Sep 2020 (Day 34), the subject was diagnosed with COVID-19 and reported fatigue, new loss of taste or smell, new or increased cough, new or increased sore throat, and nasal congestion, with the first symptom starting on 22 Sep 2020, 7 days after receiving Dose 2, and the last symptom resolved on 09 Oct 2020 (Day 48). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 25 Sep 2020 (Day 34) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 25 Sep 2020 (Day 34) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	33	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	64.9 kg	20.5 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	17:35
2	Placebo	13SEP2020 (21)	19:02

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE
Visit 2	13SEP2020 (21)	13SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25SEP2020 (33)/ 24SEP2020 (32)/ 02OCT2020 (40)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	25SEP2020 (33)	COVID-19	25SEP2020 (33)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	25SEP2020 (33)	25SEP2020 (33)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	25SEP2020 (33)	25SEP2020 (33)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	25SEP2020 (33)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313668, a 33-year-old white male with a height of 178 cm, a weight of 64.9 kg, and a BMI of 20.5 kg/m2, received Dose 1 on 24 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 21). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 25 Sep 2020 (Day 33), the subject was diagnosed with COVID-19 and reported new loss of taste or smell and new or increased sore throat, with the first symptom starting on 24 Sep 2020, 11 days after receiving Dose 2, and the last symptom resolved on 02 Oct 2020 (Day 40). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 25 Sep 2020 (Day 33) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 25 Sep 2020 (Day 33) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	136 kg	42 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	09:50
2	Placebo	16SEP2020 (23)	09:27

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (23)	16SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04NOV2020 (72)/ 02NOV2020 (70)/ 05NOV2020 (73)	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04NOV2020 (72)	COVID-19	04NOV2020 (72)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	04NOV2020 (72)	04NOV2020 (72)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	04NOV2020 (72)	04NOV2020 (72)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	04NOV2020 (72)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313787, a 58-year-old white male with a height of 180 cm, a weight of 136 kg, and a BMI of 42 kg/m2, received Dose 1 on 25 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 23). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 04 Nov 2020 (Day 72), the subject was diagnosed with COVID-19 and reported new or increased cough and new or increased sore throat, with the first symptom starting on 02 Nov 2020, 47 days after receiving Dose 2, and the last symptom resolved on 05 Nov 2020 (Day 73). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 72) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 04 Nov 2020 (Day 72) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	50	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	52.5 kg	22.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Familial hypercholesterolemia	Type IIa hyperlipidaemia	09OCT1990	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	13:03
2	Placebo	13SEP2020 (20)	19:20

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	13SEP2020 (20)	13SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07OCT2020 (44)/ 03OCT2020 (40)/ 17OCT2020 (54)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	07OCT2020 (44)	covid 19	03OCT2020 (40)	4	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	07OCT2020 (44)	07OCT2020 (44)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	07OCT2020 (44)	03OCT2020 (40)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07OCT2020 (44)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	07OCT2020 (44)	HOSPITALIZATION STATUS	HOSPITAL	03OCT2020 (40)	06OCT2020 (43)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	07OCT2020 (44)	03OCT2020 (40)	Creatinine	70.7	umol/L	.	.
			C Reactive Protein	4.9	mg/L	.	.
			Urea Nitrogen	10.36	mmol/L	.	.

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	07OCT2020 (44)	03OCT2020 (40)	Hematocrit	0.41	L/L	.	.
			Hemoglobin	130	g/L	.	.
			Lymphocytes	1.148	10^9/L	.	.
			Neutrophils	3.094	10^9/L	.	.
			Platelets	138.4	10^9/L	.	.

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	07OCT2020 (44)	03OCT2020	CHEST		CT SCAN	NA	ABNORMAL	subpleural bilateral pneumonic infiltrate

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313895, a 50-year-old white female with a height of 154 cm, a weight of 52.5 kg, and a BMI of 22.1 kg/m2, received Dose 1 on 25 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 20). The subject had a reported medical history of type IIa hyperlipidemia (since 09 Oct 1990). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 03 Oct 2020 (Day 40), the subject was diagnosed with COVID-19 and reported new loss of taste or smell, new or increased cough, and new or increased muscle pain, with the first symptom starting on 03 Oct 2020, 20 days after receiving Dose 2, and the last symptom resolved on 17 Oct 2020 (Day 54). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Oct 2020 (Day 44) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Oct 2020 (Day 40) was positive. The subject was hospitalized on 03 Oct 2020 (Day 40) for 4 days and discharged on 06 Oct 2020 (Day 43). The subject went to the emergency room (once). On 03 Oct 2020 (Day 40), a computed tomographic scan of the chest showed subpleural bilateral pneumonic infiltrate.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	80 kg	32.5 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	10:12
2	Placebo	17SEP2020 (23)	10:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	26AUG2020 (1)	26AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	26AUG2020 (1)	26AUG2020 (1)	SERUM	NEGATIVE
Visit 2	17SEP2020 (23)	17SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29OCT2020 (65)/ 28OCT2020 (64)/ 02NOV2020 (69)	NO		Asthenia
	NO		Headache
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	29OCT2020 (65)	COVID-19 disease	29OCT2020 (65)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	29OCT2020 (65)	29OCT2020 (65)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	29OCT2020 (65)	29OCT2020 (65)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29OCT2020 (65)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314112, a 52-year-old white male with a height of 157 cm, a weight of 80 kg, and a BMI of 32.5 kg/m2, received Dose 1 on 26 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 23). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 29 Oct 2020 (Day 65), the subject was diagnosed with COVID-19 and reported asthenia, headache, and new or increased cough, with the first symptom starting on 28 Oct 2020, 41 days after receiving Dose 2, and the last symptom resolved on 02 Nov 2020 (Day 69). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 65) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 65) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	68.4 kg	28.1 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Superficial venous insufficiency	Peripheral venous disease	01MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	17:55
2	Placebo	16SEP2020 (22)	16:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	26AUG2020 (1)	26AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	26AUG2020 (1)	26AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (22)	16SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01OCT2020 (37)/ 30SEP2020 (36)/ 11OCT2020 (47)	NO		Arthralgia
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01OCT2020 (37)	Covid 19	01OCT2020 (37)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	01OCT2020 (37)	01OCT2020 (37)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	01OCT2020 (37)	01OCT2020 (37)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	01OCT2020 (37)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314308, a 31-year-old white female with a height of 156 cm, a weight of 68.4 kg, and a BMI of 28.1 kg/m2, received Dose 1 on 26 Aug 2020 and Dose 2 on 16 Sep 2020 (Day 22). The subject had a reported medical history of peripheral venous disease (since 01 Mar 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 01 Oct 2020 (Day 37), the subject was diagnosed with COVID-19 and reported arthralgia, fatigue, new or increased cough, new or increased muscle pain, new or increased sore throat, and vomiting, with the first symptom starting on 30 Sep 2020, 14 days after receiving Dose 2, and the last symptom resolved on 11 Oct 2020 (Day 47). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Oct 2020 (Day 37) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Oct 2020 (Day 37) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2001	18	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	63.6 kg	25.5 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	15:14
2	Placebo	15SEP2020 (20)	10:55

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (20)	15SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 08OCT2020 (43)/ 05OCT2020 (40)/ 09OCT2020 (44)	NO		Catarrh
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	08OCT2020 (43)	COVID-19 illness	08OCT2020 (43)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	08OCT2020 (43)	08OCT2020 (43)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	08OCT2020 (43)	08OCT2020 (43)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	08OCT2020 (43)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314534, an 18-year-old white female with a height of 158 cm, a weight of 63.6 kg, and a BMI of 25.5 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 20). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 08 Oct 2020 (Day 43), the subject was diagnosed with COVID-19 and reported catarrh, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 05 Oct 2020, 20 days after receiving Dose 2, and the last symptom resolved on 09 Oct 2020 (Day 44). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Oct 2020 (Day 43) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Oct 2020 (Day 43) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	32	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	79.3 kg	32.2 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	18:15
2	Placebo	17SEP2020 (22)	16:35

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	17SEP2020 (22)	17SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03OCT2020 (38)/ 01OCT2020 (36)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	03OCT2020 (38)	COVID-19	03OCT2020 (38)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	03OCT2020 (38)	03OCT2020 (38)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	03OCT2020 (38)	03OCT2020 (38)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03OCT2020 (38)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12314622, a 32-year-old white female with a height of 157 cm, a weight of 79.3 kg, and a BMI of 32.2 kg/m2, received Dose 1 on 27 Aug 2020 and Dose 2 on 17 Sep 2020 (Day 22). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 03 Oct 2020 (Day 38), the subject was diagnosed with COVID-19 and reported chills, fever, headache, new loss of taste or smell, new or increased cough, new or increased muscle pain, and new or increased shortness of breath, with the first symptom starting on 01 Oct 2020, 14 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Oct 2020 (Day 38) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Oct 2020 (Day 38) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151 cm	58 kg	25.4 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	16:37
2	Placebo	19SEP2020 (20)	15:37

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31AUG2020 (1)	31AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31AUG2020 (1)	31AUG2020 (1)	SERUM	NEGATIVE
Visit 2	19SEP2020 (20)	19SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (57)/ 23OCT2020 (54)/ ONGOING	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (57)	COVID-19 disease	26OCT2020 (57)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (57)	26OCT2020 (57)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26OCT2020 (57)	26OCT2020 (57)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (57)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315636, a 53-year-old white female with a height of 151 cm, a weight of 58 kg, and a BMI of 25.4 kg/m2, received Dose 1 on 31 Aug 2020 and Dose 2 on 19 Sep 2020 (Day 20). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 26 Oct 2020 (Day 57), the subject was diagnosed with COVID-19 and reported headache, new or increased cough, and new or increased sore throat, with the first symptom starting on 23 Oct 2020, 34 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 57) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 57) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153 cm	68.8 kg	29.4 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	16:55
2	Placebo	19SEP2020 (20)	12:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31AUG2020 (1)	31AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31AUG2020 (1)	31AUG2020 (1)	SERUM	NEGATIVE
Visit 2	19SEP2020 (20)	19SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01OCT2020 (32)/ 29SEP2020 (30)/ 08OCT2020 (39)	NO		Arthralgia
	YES	CHILLS	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01OCT2020 (32)	COVID-19 illness	01OCT2020 (32)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	01OCT2020 (32)	01OCT2020 (32)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	01OCT2020 (32)	01OCT2020 (32)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	01OCT2020 (32)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315637, a 40-year-old white female with a height of 153 cm, a weight of 68.8 kg, and a BMI of 29.4 kg/m2, received Dose 1 on 31 Aug 2020 and Dose 2 on 19 Sep 2020 (Day 20). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 01 Oct 2020 (Day 32), the subject was diagnosed with COVID-19 and reported arthralgia, chills, fever, new loss of taste or smell, and new or increased muscle pain, with the first symptom starting on 29 Sep 2020, 10 days after receiving Dose 2, and the last symptom resolved on 08 Oct 2020 (Day 39). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Oct 2020 (Day 32) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 01 Oct 2020 (Day 32) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	109.09 kg	33.5 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	2010	Present
Hypertension	Hypertension	2010	Present
Allergic Rhinitis	Rhinitis allergic	2010	Present
Dyslipidemia	Dyslipidaemia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	09:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	14SEP2020 (1)	14SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14SEP2020 (1)	14SEP2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22SEP2020 (9)/ 21SEP2020 (8)/ 25SEP2020 (12)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	22SEP2020 (9)	COVID-19 ILLNESS	22SEP2020 (9)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	LSU EVT Lab- PCR analysis-CLIA-certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	22SEP2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	22SEP2020 (9)	HOSPITALIZATION STATUS	ICU	22SEP2020 (9)	26SEP2020 (13)

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	Alkaline Phosphatase	1.15	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.61699	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.73348	ukat/L	0.1667	0.6668
			Bilirubin	8.6	umol/L	1.7	17.1
			Creatinine	88.4	umol/L	44.2	123.8
			C Reactive Protein	13.5	mg/L	0	9
			Urea Nitrogen	4.64	mmol/L	2.14	7.14
		23SEP2020 (10)	Alkaline Phosphatase	1.1	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.56698	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.8335	ukat/L	0.1667	0.6668
			Bilirubin	6.8	umol/L	1.7	17.1
			Creatinine	70.7	umol/L	44.2	123.8
			C Reactive Protein	17.7	mg/L	0	9
			Urea Nitrogen	4.29	mmol/L	2.14	7.14
		24SEP2020 (11)	Alkaline Phosphatase	0.97	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.30026	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.6668	ukat/L	0.1667	0.6668
			Bilirubin	6.8	umol/L	1.7	17.1
			Creatinine	68.1	umol/L	44.2	123.8
			C Reactive Protein	0.78	mg/L	0	0.9
			Urea Nitrogen	3.21	mmol/L	2.14	7.14
		25SEP2020 (12)	Alkaline Phosphatase	1.03	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.35027	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.65013	ukat/L	0.1667	0.6668
			Bilirubin	5.1	umol/L	1.7	17.1

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Creatinine	64.5	umol/L	44.2	123.8
			Urea Nitrogen	4.29	mmol/L	2.14	7.14
		26SEP2020 (13)	Alkaline Phosphatase	1	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.1669	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.46676	ukat/L	0.1667	0.6668
			Bilirubin	5.1	umol/L	1.7	17.1
			Creatinine	70.7	umol/L	44.2	123.8
			Urea Nitrogen	4.29	mmol/L	2.14	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	22SEP2020 (9)	23SEP2020 (10)	Basophils	0.03	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.41	L/L	0.37	0.47
			Hemoglobin	138	g/L	125	163
			Lymphocytes	1.4	10^9/L	1	4.8
			Monocytes	1.1	10^9/L	0.3	1
			Neutrophils	2.4	10^9/L	1.8	7.7
			Platelets	224	10^9/L	150	350
			Erythrocytes	4.2	10^12/L	4.6	6.2
			Leukocytes	5.03	10^9/L	3.9	12.7
		24SEP2020 (11)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.39	L/L	0.37	0.47
			Hemoglobin	131	g/L	125	163
			Lymphocytes	1.7	10^9/L	1	4.8
			Monocytes	0.8	10^9/L	0.3	1
			Neutrophils	1.4	10^9/L	1.8	7.7
			Platelets	199	10^9/L	150	350
			Erythrocytes	4.07	10^12/L	4.6	6.2
			Leukocytes	4.01	10^9/L	3.9	12.7
		25SEP2020 (12)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.42	L/L	0.37	0.47
			Hemoglobin	143	g/L	125	163
			Lymphocytes	2.3	10^9/L	1	4.8

Laboratory Results - Hematology							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
			Monocytes	0.6	10^9/L	0.3	1
			Neutrophils	1.1	10^9/L	1.8	7.7
			Platelets	217	10^9/L	150	350
			Erythrocytes	4.4	10^12/L	4.6	6.2
			Leukocytes	4.11	10^9/L	3.9	12.7
		26SEP2020 (13)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.41	L/L	0.37	0.47
			Hemoglobin	140	g/L	125	163
			Lymphocytes	2.3	10^9/L	1	4.8
			Monocytes	0.6	10^9/L	0.3	1
			Neutrophils	1.3	10^9/L	1.8	7.7
			Platelets	211	10^9/L	150	350
			Erythrocytes	4.33	10^12/L	4.6	6.2
			Leukocytes	4.42	10^9/L	3.9	12.7

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	1	131 mmHg	95 mmHg	26 breaths/min	111 beats/min	96 %
		23SEP2020 (10)	2	145 mmHg	94 mmHg	11 breaths/min	70 beats/min	95 %
		24SEP2020 (11)	3	120 mmHg	80 mmHg	20 breaths/min	83 beats/min	93 %
		25SEP2020 (12)	4	182 mmHg	72 mmHg	15 breaths/min	90 beats/min	97 %
		26SEP2020 (13)	5	118 mmHg	79 mmHg	16 breaths/min	80 beats/min	96 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020	CHEST		X-RAY	NA	ABNORMAL	Minimal bibasilar infiltrates

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14SEP2020	
Withdrawn	VACCINATION	22SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1235 12351071, a 50-year-old white male with a height of 180.34 cm, a weight of 109.09 kg, and a BMI of 33.5 kg/m2, received Dose 1 on 14 Sep 2020. The subject had a reported medical history of asthma, hypertension, and allergic rhinitis (all since 2010); and dyslipidemia (since 2015). The central laboratory SARS-CoV-2 NAAT result was negative at Visit 1. The central laboratory N-binding antibody result was negative at Visit 1. On 22 Sep 2020 (Day 9), the subject was symptomatic of possible COVID-19 disease and was diagnosed with severe COVID-19, and experienced chills, a mild fever with a body temperature of 100.9 F°, myalgia, and pharyngitis and reported new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 21 Sep 2020, 7 days after receiving Dose 1, and the last symptom resolved on 25 Sep 2020 (Day 12). He notified the investigator on 22 Sep 2020 (Day 9). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Sep 2020 (Day 9) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Sep 2020 (Day 9) was positive. The subject had a telephone consultation (once). The subject went to the emergency room and was admitted to the intensive care unit on 22 Sep 2020 (Day 9) for further treatment. The subject was treated with remdesivir 200 mg intravenously (IV) (on 22 Sep 2020), which was later reduced to 100 mg IV (from 23 Sep 2020 to 26 Sep 2020). Additionally, he received ondansetron as needed (PRN) for nausea and acetaminophen PRN for pain. He remained afebrile throughout the hospitalization. On 22 Sep 2020 (Day 9), the subject had a heart rate of 111 beats per minute (bpm), blood pressure (BP) of 131/95 mmHg, respiratory rate of 26 breaths per minute, and oxygen saturation of 96%. On 23 Sep 2020 (Day 10), the subject had a heart rate of 70 bpm, BP of 145/94 mmHg, respiratory rate of 11 breaths per minute, and oxygen saturation of 95%. On 24 Sep 2020 (Day 11), the subject had a heart rate of 83 bpm, BP of 120/80 mmHg, respiratory rate of 20 breaths per minute, and oxygen saturation of 93%. On 25 Sep 2020 (Day 12), the subject had a heart rate of 90 bpm, BP of 182/72 mmHg, respiratory rate of 15 breaths per minute, and oxygen saturation of 97%. On 26 Sep 2020 (Day 13), the subject had a heart rate of 80 bpm, BP of 118/79 mmHg, respiratory rate of 16 breaths per minute, and oxygen saturation of 96%. The subject did not receive supplemental oxygen prior to or during the hospitalization. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an intensive care unit, and oxygen saturation of ≤ 93%). On 22 Sep 2020 (Day 9), the chest x-ray showed minimal bibasilar infiltrates. The complete blood count, ferritin, and serum electrolytes were normal; however, C-reactive protein (CRP) was elevated at 13.5 mg/L (normal range [NR]: 0 - 9 mg/L) and fibrin D-dimer was normal at 365 ng/mL (NR: <500 ng/mL). The subject's CRP on 24 Sep 2020 (Day 11) returned to normal at 0.78 mg/L and the fibrin D-dimer remained normal at 296 ng/mL on 24 Sep 2020 (Day 11). The subject recovered from COVID-19 on 26 Sep 2020 (Day 13) and was discharged from the hospital. The subject was discontinued from the study intervention on 22 Sep 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	63.64 kg	24 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
contraception	Contraception	FEB2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	14:42
2	BNT162b2	08OCT2020 (23)	16:19

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16SEP2020 (1)	16SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16SEP2020 (1)	16SEP2020 (1)	SERUM	NEGATIVE
Visit 2	08OCT2020 (23)	08OCT2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (57)/ 08NOV2020 (54)/ 14NOV2020 (60)	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (57)	COVID 19 infection	06NOV2020 (52)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11NOV2020 (57)	11NOV2020 (57)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11NOV2020 (57)	06NOV2020 (52)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11NOV2020 (57)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1235 12351093, a 30-year-old Asian female with a height of 162.56 cm, a weight of 63.64 kg, and a BMI of 24 kg/m2, received Dose 1 on 16 Sep 2020 and Dose 2 on 08 Oct 2020 (Day 23). The subject had a reported medical history of contraception (since Feb 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 06 Nov 2020 (Day 52), the subject was diagnosed with COVID-19 and reported a new loss of taste or smell starting on 08 Nov 2020, 31 days after receiving Dose 2, that resolved on 14 Nov 2020 (Day 60). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 11 Nov 2020 (Day 57) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 06 Nov 2020 (Day 52) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	86.7 kg	26.8 kg/m2	28SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	NOV1999	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28SEP2020 (1)	16:37
2	Placebo	21OCT2020 (24)	14:16

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28SEP2020 (1)	28SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28SEP2020 (1)	28SEP2020 (1)	SERUM	NEGATIVE
Visit 2	21OCT2020 (24)	21OCT2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (33)/ 29OCT2020 (32)/ ONGOING	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30OCT2020 (33)	Covid-19	10NOV2020 (44)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (33)	30OCT2020 (33)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30OCT2020 (33)	31OCT2020 (34)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	30OCT2020 (33)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12412017, a 59-year-old white male with a height of 180 cm, a weight of 86.7 kg, and a BMI of 26.8 kg/m2, received Dose 1 on 28 Sep 2020 and Dose 2 on 21 Oct 2020 (Day 24). The subject had a reported medical history of hypertension (since Nov 1999). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 10 Nov 2020 (Day 44), the subject was diagnosed with COVID-19 and reported fever, headache, new or increased muscle pain, and rhinorrhea, with the first symptom starting on 29 Oct 2020, 8 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 33) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 31 Oct 2020 (Day 34) was positive. The subject had a telephone consultation (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	69.8 kg	23.6 kg/m2	28SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Intermittent allergic rhinitis	Rhinitis allergic	1990	Present
Knee orthopedic surgery	Orthopaedic procedure	2011	Past
Breast cancer	Breast cancer	2012	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28SEP2020 (1)	16:43
2	Placebo	21OCT2020 (24)	14:19

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28SEP2020 (1)	28SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28SEP2020 (1)	28SEP2020 (1)	SERUM	NEGATIVE
Visit 2	21OCT2020 (24)	21OCT2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 30OCT2020 (33)/ 28OCT2020 (31)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Odynophagia

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30OCT2020 (33)	Covid-19	05NOV2020 (39)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (33)	30OCT2020 (33)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30OCT2020 (33)	31OCT2020 (34)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	30OCT2020 (33)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12412018, a 55-year-old white female with a height of 172 cm, a weight of 69.8 kg, and a BMI of 23.6 kg/m2, received Dose 1 on 28 Sep 2020 and Dose 2 on 21 Oct 2020 (Day 24). The subject had a reported medical history of rhinitis allergic (since 1990), orthopedic procedure (knee orthopedic surgery, in 2011), and breast cancer (in 2012). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 05 Nov 2020 (Day 39), the subject was diagnosed with COVID-19 and reported fever, new or increased sore throat, and odynophagia, with the first symptom starting on 28 Oct 2020, 7 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 30 Oct 2020 (Day 33) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 31 Oct 2020 (Day 34) was positive. The subject had a telephone consultation (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	Black or African American	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	94.77 kg	31.2 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Smoker	Tobacco user	1999	Present
Tubal Ligation	Female sterilisation	03JAN2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	15:39
2	Placebo	01OCT2020 (21)	09:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	11SEP2020 (1)	11SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11SEP2020 (1)	11SEP2020 (1)	SERUM	NEGATIVE
Visit 2	01OCT2020 (21)	01OCT2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27OCT2020 (47)/ 26OCT2020 (46)/ 29OCT2020 (49)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	27OCT2020 (47)	COVID 19	26OCT2020 (46)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	27OCT2020 (47)	28OCT2020 (48)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	27OCT2020 (47)	26OCT2020 (46)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	27OCT2020 (47)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1251 12511159, a 37-year-old black or African American female with a height of 173.99 cm, a weight of 94.77 kg, and a BMI of 31.2 kg/m2, received Dose 1 on 11 Sep 2020 and Dose 2 on 01 Oct 2020 (Day 21). The subject had a reported medical history of tobacco use (since 1999) and female sterilization (on 03 Jan 2018). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 26 Oct 2020 (Day 46), the subject was diagnosed with COVID-19 and reported new loss of taste or smell, new or increased cough, and new or increased muscle pain, with the first symptom starting on 26 Oct 2020, 25 days after receiving Dose 2, and the last symptom resolved on 29 Oct 2020 (Day 49). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Oct 2020 (Day 48) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 46) was positive. The subject went to her primary care physician (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185 cm	78 kg	22.8 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	01SEP2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	15:58
2	Placebo	12OCT2020 (22)	15:22

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE
Visit 2	12OCT2020 (22)	12OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 08NOV2020 (49)/ 03NOV2020 (44)/ ONGOING	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Pyrexia

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	08NOV2020 (49)	Covid-19	08NOV2020 (49)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	08NOV2020 (49)	08NOV2020 (49)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	08NOV2020 (49)	08NOV2020 (49)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	08NOV2020 (49)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		SPECIALIST	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44441092, a 64-year-old white male with a height of 185 cm, a weight of 78 kg, and a BMI of 22.8 kg/m2, received Dose 1 on 21 Sep 2020 and Dose 2 on 12 Oct 2020 (Day 22). The subject had a reported medical history of depression (since 01 Sep 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 08 Nov 2020 (Day 49), the subject was diagnosed with COVID-19 and reported headache, new loss of taste or smell, new or increased cough, new or increased muscle pain, new or increased shortness of breath, new or increased sore throat, and pyrexia, with the first symptom starting on 03 Nov 2020, 22 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Nov 2020 (Day 49) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 08 Nov 2020 (Day 49) was positive. The subject went to a specialist (once).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	118 kg	35.6 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Inguinal hernia repair	Inguinal hernia repair	01JUN2007	Past
Scrotal varices	Varicocele	01JUN2007	Past
Pneumonia	Pneumonia	22DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	18:20
2	Placebo	13OCT2020 (23)	18:20

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Diarrhoea	diarrhea	09OCT2020 (19)	22:00	10OCT2020 (20)	12:00	2	2	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (10OCT2020)	NOT RELATED/OTHER: consumption of a food that is probably spoiled	1	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE
Visit 2	13OCT2020 (23)	13OCT2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10NOV2020 (51)/ 07NOV2020 (48)/ ONGOING	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10NOV2020 (51)	10NOV2020 (51)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	10NOV2020 (51)	10NOV2020 (51)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	10NOV2020 (51)	11NOV2020 (52)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	10NOV2020 (51)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44441144, a 38-year-old white male with a height of 182 cm, a weight of 118 kg, and a BMI of 35.6 kg/m2, received Dose 1 on 21 Sep 2020 and Dose 2 on 13 Oct 2020 (Day 23). The subject had a reported medical history of inguinal hernia repair and varicocele (both on 01 Jun 2007) and pneumonia (on 22 Dec 2019). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported diarrhea, fever, new loss of taste or smell, and new or increased muscle pain, with the first symptom starting on 07 Nov 2020, 25 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 51) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 10 Nov 2020 (Day 51) was negative and on 11 Nov 2020 (Day 52) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	100 kg	40.1 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	04APR1989	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	19:51
2	BNT162b2	13OCT2020 (23)	17:12

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE
Visit 2	13OCT2020 (23)	13OCT2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (44)/ 02NOV2020 (43)/ ONGOING	NO		Asthenia
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03NOV2020 (44)	COVID-19	04NOV2020 (45)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03NOV2020 (44)	03NOV2020 (44)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	03NOV2020 (44)	02NOV2020 (43)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03NOV2020 (44)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
	VACCINATION		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44441204, a 59-year-old white female with a height of 158 cm, a weight of 100 kg, and a BMI of 40.1 kg/m2, received Dose 1 on 21 Sep 2020 and Dose 2 on 13 Oct 2020 (Day 23). The subject had a reported medical history of hypertension (since 04 Apr 1989). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 04 Nov 2020 (Day 45), the subject was diagnosed with COVID-19 and reported asthenia, new loss of taste or smell, and new or increased muscle pain, with the first symptom starting on 02 Nov 2020, 20 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Nov 2020 (Day 44) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 02 Nov 2020 (Day 43) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	90.6 kg	31.7 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	01JUL2005	Present
Sinus bradycardia	Sinus bradycardia	01SEP2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	20:10
2	Placebo	13OCT2020 (23)	09:35

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE
Visit 2	13OCT2020 (23)	13OCT2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (36)/ 25OCT2020 (35)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (36)	COVID-19 disease	26OCT2020 (36)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (36)	26OCT2020 (36)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	26OCT2020 (36)	26OCT2020 (36)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (36)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Withdrawn	VACCINATION	12NOV2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	12NOV2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 4444 44441224, a 52-year-old white male with a height of 169 cm, a weight of 90.6 kg, and a BMI of 31.7 kg/m2, received Dose 1 on 21 Sep 2020 and Dose 2 on 13 Oct 2020 (Day 23). The subject had a reported medical history of hypertension (since 01 Jul 2005) and sinus bradycardia (since 01 Sep 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 26 Oct 2020 (Day 36), the subject was diagnosed with COVID-19 and reported fever, new or increased muscle pain and new or increased shortness of breath, with the first symptom starting on 25 Oct 2020, 12 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 36) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Oct 2020 (Day 36) was positive. The subject had a telephone consultation (once). The subject requested withdrawal from the study on 12 Nov 2020.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	112 kg	36.6 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vitiligo	Vitiligo	01JAN2007	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	10:17
2	Placebo	14OCT2020 (22)	17:45

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23SEP2020 (1)	23SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23SEP2020 (1)	23SEP2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (22)	14OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22OCT2020 (30)/ 21OCT2020 (29)/ ONGOING	YES	DIARRHEA	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	22OCT2020 (30)	covid-19 disease	22OCT2020 (30)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	22OCT2020 (30)	22OCT2020 (30)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	22OCT2020 (30)	22OCT2020 (30)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	22OCT2020 (30)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	13NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44441563, a 38-year-old white male with a height of 175 cm, a weight of 112 kg, and a BMI of 36.6 kg/m2, received Dose 1 on 23 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 22). The subject had a reported medical history of vitiligo (since 01 Jan 2007). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 22 Oct 2020 (Day 30), the subject was diagnosed with COVID-19 and reported diarrhea, headache, and new loss of taste or smell, with the first symptom starting on 21 Oct 2020, 7 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Oct 2020 (Day 30) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Oct 2020 (Day 30) was positive. The subject did not have any contact with nonstudy healthcare personnel.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	94 kg	32.9 kg/m2	27SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	01NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27SEP2020 (1)	17:30
2	Placebo	15OCT2020 (19)	14:13

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_Eval_Severe/profile Date of Generation: 20NOV2020 (22:43)

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	METAB	Hyperglycaemia	hyperglycemia	29OCT2020 (33)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27SEP2020 (1)	27SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27SEP2020 (1)	27SEP2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (19)	15OCT2020 (19)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27OCT2020 (31)/ 26OCT2020 (30)/ 11NOV2020 (46)	NO		Asthenia
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	27OCT2020 (31)	COVID-19 illness	27OCT2020 (31)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	27OCT2020 (31)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	1	140 mmHg	80 mmHg	20 breaths/min	125 beats/min	

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 4444 44442304, a 49-year-old white male with a height of 169 cm, a weight of 94 kg, and a BMI of 32.9 kg/m2, received Dose 1 on 27 Sep 2020 and Dose 2 on 15 Oct 2020 (Day 19). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 27 Oct 2020 (Day 31), the subject was diagnosed with severe COVID-19 and reported asthenia, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 26 Oct 2020, 11 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 31) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 31) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 27 Oct 2020 (Day 31), the subject had a heart rate of 125 beats per minute (bpm), blood pressure of 140/80 mmHg, and respiratory rate of 20 breaths per minute. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and heart rate $\geqslant$ 125 bpm).

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	88.45 kg	30 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CHOLECYSTECTOMY	Cholecystectomy	2013	Past
ANXIETY	Anxiety	2018	Present
DEPRESSION	Depression	2018	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	OCT2019	Present
IRRITABLE BOWEL SYNDROME	Irritable bowel syndrome	DEC2019	Present
OVERWEIGHT	Overweight	DEC2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	12:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21OCT2020 (1)	21OCT2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	21OCT2020 (1)	21OCT2020 (1)	SERUM	NEGATIVE
Visit 2	12NOV2020 (23)	12NOV2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 23OCT2020 (3)/ 22OCT2020 (2)/ ONGOING	YES	DIARRHEA	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	23OCT2020 (3)	COVID-19	23OCT2020 (3)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	23OCT2020 (3)	24OCT2020 (4)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	23OCT2020 (3)	23OCT2020 (3)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	23OCT2020 (3)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	COVID swab at work

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21OCT2020	
Withdrawn	VACCINATION	22OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.56 cm	136.55 kg	42.7 kg/m2	04NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPOTHYROID	Hypothyroidism	1968	Present
OVERWEIGHT	Overweight	1987	Present
OSTEOARTHRITIS	Osteoarthritis	2002	Present
MENOPAUSE	Menopause	2005	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04NOV2020 (1)	11:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	INJECTION SITE PAIN	04NOV2020 (1)	20:00	07NOV2020 (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	2	TC	N	Resolved (07NOV2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04NOV2020 (1)	04NOV2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04NOV2020 (1)	04NOV2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 09NOV2020 (6)/ 07NOV2020 (4)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	09NOV2020 (6)	COVID 19	09NOV2020 (6)	1	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	09NOV2020 (6)	09NOV2020 (6)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	09NOV2020 (6)	09NOV2020 (6)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Lab Con SARS-COV2 BY REAL TIME-PCR

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	09NOV2020 (6)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04NOV2020	
Withdrawn	VACCINATION	07NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	99.1 kg	28.6 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesteraemia	Hypercholesterolaemia	2006	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	09:56

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22OCT2020 (1)	22OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22OCT2020 (1)	22OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06NOV2020 (16)/ 02NOV2020 (12)/ ONGOING	YES	DIARRHEA	
	NO		Myalgia
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06NOV2020 (16)	covid-19	05NOV2020 (15)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06NOV2020 (16)	06NOV2020 (16)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	06NOV2020 (16)	05NOV2020 (15)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	CLIA certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06NOV2020 (16)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	Test and Protect drive through clinic

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22OCT2020	
Withdrawn	VACCINATION	05NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	36.2 kg	15.3 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Simple febrile seizure	Febrile convulsion	2007	Past
Asthma-like condition	Asthma	2009	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22OCT2020 (1)	11:29

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccination	INFLUENZA VACCINE	25SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22OCT2020 (1)	22OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22OCT2020 (1)	22OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02NOV2020 (12)/ 31OCT2020 (10)/ 04NOV2020 (14)	YES	FEVER	
	NO		Headache
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02NOV2020 (12)	COVID-19	02NOV2020 (12)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02NOV2020 (12)	02NOV2020 (12)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02NOV2020 (12)	02NOV2020 (12)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Copan & distributed by BD; CLIA certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02NOV2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22OCT2020	
Withdrawn	VACCINATION	31OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.91 cm	69.45 kg	24.3 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High cholesterol	Blood cholesterol increased	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	11:44
2	Placebo	06OCT2020 (22)	10:39

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	15SEP2020 (1)	15SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15SEP2020 (1)	15SEP2020 (1)	SERUM	NEGATIVE
Visit 2	06OCT2020 (22)	06OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 08OCT2020 (24)/ 06OCT2020 (22)/ 16OCT2020 (32)	NO		Asthenia
	YES	CHILLS	
	YES	FEVER	
	NO		Fatigue
	NO		Lung disorder
	NO		Lung disorder
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	08OCT2020 (24)	COVID 19	08OCT2020 (24)	2	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	08OCT2020 (24)	08OCT2020 (24)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location	Test Result
1	COVID Illness Visit 1	08OCT2020 (24)	08OCT2020 (24)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	RAPID COVID BD- POSITIVE- PER HEALTH CLINIC	OTHER	NALT

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	08OCT2020 (24)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	08OCT2020 (24)	08OCT2020 (24)	1	125 mmHg	77 mmHg	16 breaths/min	98 beats/min	96 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	144.27 kg	41.9 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present
Vasectomy	Vasectomy	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	09:45

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
quadrivalent influenza vaccination prophylaxis intramuscular 0.5 ml once	INFLUENZA VACCINE	22OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	25SEP2020 (1)	25SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25SEP2020 (1)	25SEP2020 (1)	SERUM	NEGATIVE
Visit 2	16OCT2020 (22)	16OCT2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29SEP2020 (5)/ 26SEP2020 (2)/ ONGOING	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Rhinorrhoea
	NO		Sinus congestion

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	29SEP2020 (5)	covid 19	29SEP2020 (5)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	29SEP2020 (5)	29SEP2020 (5)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	29SEP2020 (5)	29SEP2020 (5)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		QUEST SARS-COV-2 RRT-PCR	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29SEP2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	29SEP2020 (5)	29SEP2020 (5)	1	142 mmHg	82 mmHg	18 breaths/min	81 beats/min	98 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	29SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	110 kg	39.1 kg/m2	09OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Degenerative disc disease L5-S1	Intervertebral disc degeneration	2002	Present
Bilateral tinnitus	Tinnitus	2005	Present
Insomnia	Insomnia	2008	Present
Vasectomy	Vasectomy	2016	Past
Sleep apnea	Sleep apnoea syndrome	2017	Present
Anxiety	Anxiety	2019	Present
Hypertension	Hypertension	JAN2020	Present
Diabetes type II	Type 2 diabetes mellitus	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09OCT2020 (1)	13:32
2	Placebo	28OCT2020 (20)	10:50

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	10OCT2020 (2)		11OCT2020 (3)	
2	MUSC	Myalgia	Muscle aches	10OCT2020 (2)		11OCT2020 (3)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (11OCT2020)	Study Treatment	1	2	N
2	2	1	N	N	Resolved (11OCT2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	09OCT2020 (1)	09OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09OCT2020 (1)	09OCT2020 (1)	SERUM	NEGATIVE
Visit 2	28OCT2020 (20)	28OCT2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04NOV2020 (27)/ 03NOV2020 (26)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Pain
	NO		Pyrexia
	NO		Sinus operation

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04NOV2020 (27)	covid 19	06NOV2020 (29)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	04NOV2020 (27)	04NOV2020 (27)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	04NOV2020 (27)	04NOV2020 (27)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	04NOV2020 (27)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09OCT2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	73.09 kg	29.4 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	1960	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1980	Present
Hypertension	Hypertension	1982	Present
Vasectomy	Vasectomy	1987	Past
L spine stenosis	Lumbar spinal stenosis	2010	Present
Left leg sciatica	Sciatica	2010	Present
L spine osteoarthritis	Spinal osteoarthritis	2010	Present
Chronic L spine pain	Spinal pain	2010	Present
Diabetes type II	Type 2 diabetes mellitus	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	2015	Present
Contact dermatitis	Dermatitis contact	2017	Present
Bilateral cataracts	Cataract	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	14:38

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19OCT2020 (1)	19OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19OCT2020 (1)	19OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (8)/ 24OCT2020 (6)/ ONGOING	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Respiratory tract congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (8)	26OCT2020 (8)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (8)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19OCT2020	
Withdrawn	VACCINATION	24OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	67.45 kg	23.9 kg/m2	29OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Phenylketonuria	Phenylketonuria	1983	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29OCT2020 (1)	10:30

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	29OCT2020 (1)	29OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29OCT2020 (1)	29OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (14)/ 10NOV2020 (13)/ ONGOING	NO		Eye pruritus
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (14)	COVID 19	10NOV2020 (13)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	11NOV2020 (14)	11NOV2020 (14)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	11NOV2020 (14)	10NOV2020 (13)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	11NOV2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29OCT2020	
Withdrawn	VACCINATION	10NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	89.82 kg	36.1 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1990	Present
bilateral tubal ligation	Female sterilisation	2015	Present
sulfa allergy	Drug hypersensitivity	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	09:43

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16OCT2020 (1)	16OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16OCT2020 (1)	16OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (19)/ 03NOV2020 (19)/ ONGOING	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	03NOV2020 (19)	03NOV2020 (19)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03NOV2020 (19)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	03NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	21	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	67.73 kg	25.6 kg/m2	27OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
acne to face	Acne	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27OCT2020 (1)	16:46

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	08OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27OCT2020 (1)	27OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27OCT2020 (1)	27OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06NOV2020 (11)/ 05NOV2020 (10)/ ONGOING	YES	CHILLS	
	NO		Dizziness
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06NOV2020 (11)	COVID-19	05NOV2020 (10)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06NOV2020 (11)	06NOV2020 (11)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	06NOV2020 (11)	05NOV2020 (10)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		LABCORP COVID-19 RT-PCR TEST	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06NOV2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27OCT2020	
Withdrawn	VACCINATION	05NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	77.27 kg	23.7 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergic Rhinitis	Seasonal allergy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07OCT2020 (1)	11:14
2	Placebo	29OCT2020 (23)	10:28

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	07OCT2020 (1)	07OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07OCT2020 (1)	07OCT2020 (1)	SERUM	NEGATIVE
Visit 2	29OCT2020 (23)	29OCT2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (30)/ 04NOV2020 (29)/ ONGOING	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	05NOV2020 (30)	COVID-19	06NOV2020 (31)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05NOV2020 (30)	05NOV2020 (30)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	05NOV2020 (30)	06NOV2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (30)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07OCT2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.6 cm	72.5 kg	25.8 kg/m2	08OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HUMAN IMMUNODEFICIENCY VIRUS	HIV test positive	2002	Present
HYPERTENSION	Hypertension	2002	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08OCT2020 (1)	11:04

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	08OCT2020 (1)	08OCT2020 (1)	NASAL_SWAB	POSITIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	08OCT2020 (1)	08OCT2020 (1)	SERUM	NEGATIVE
Visit 2	27OCT2020 (20)	27OCT2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 14OCT2020 (7)/ 11OCT2020 (4)/ ONGOING	NO		Fatigue
	NO		Hyperaesthesia
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	14OCT2020 (7)	COVID-19	12OCT2020 (5)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	14OCT2020 (7)	14OCT2020 (7)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	14OCT2020 (7)	12OCT2020 (5)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	14OCT2020 (7)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
COVID Illness Visit 1	14OCT2020 (7)	11NOV2020 (35)	Alkaline Phosphatase	0.98	ukat/L	0.57	1.73
			Alanine Aminotransferase	0.31673	ukat/L	0.11669	0.86684
			Aspartate Aminotransferase	0.3334	ukat/L	0.21671	0.65013
			Bilirubin	15.4	umol/L	5.1	17.1
			Creatinine	93.7	umol/L	61.9	114.9
			C Reactive Protein	2.1		.	.
			Urea Nitrogen	6.07	mmol/L	2.5	8.93
		14OCT2020 (7)	Alkaline Phosphatase	1.17	ukat/L	0.57	1.73
			Alanine Aminotransferase	0.25005	ukat/L	0.11669	0.86684
			Aspartate Aminotransferase	0.28339	ukat/L	0.21671	0.65013
			Bilirubin	6.8	umol/L	5.1	17.1
			Creatinine	97.2	umol/L	6.2	114.9
			C Reactive Protein	10.3	mg/L	.	9.9
			Urea Nitrogen	5.71	mmol/L	2.5	8.93

Laboratory Results - Hematology							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
COVID Illness Visit 1	14OCT2020 (7)	11NOV2020 (35)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.47	L/L	0.37	0.49
			Hemoglobin	137	g/L	126	167
			Lymphocytes	2.1	10^9/L	1	4.8
			Monocytes	0.5	10^9/L	0	0.8
			Neutrophils	3.9	10^9/L	1.5	7.5
			Platelets	199	10^9/L	139	361
			Erythrocytes	4.51	10^12/L	4	5.65
			Leukocytes	6.6	10^9/L	4.4	10.5
		14OCT2020 (7)	Eosinophils	1	%	1	5
			Hematocrit	0.48	L/L	0.37	0.49
			Hemoglobin	130	g/L	126	167
			Lymphocytes	61	%	20	44
			Monocytes	9	%	2	8
			Neutrophils	1.2	10^9/L	1.6	6
			Platelets	179	10^9/L	139	361
			Erythrocytes	4.2	10^12/L	4	5.65
			Leukocytes	4.2	10^9/L	4.4	10.5

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	14OCT2020 (7)	14OCT2020 (7)	1	124 mmHg	90 mmHg	15 breaths/min	63 beats/min	100 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08OCT2020	
Withdrawn	VACCINATION	11OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2004	16	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	99 kg	28.7 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right great toe pain	Pain in extremity	10OCT2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13OCT2020 (1)	11:10
2	Placebo	02NOV2020 (21)	10:25

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	13OCT2020 (1)	13OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13OCT2020 (1)	13OCT2020 (1)	SERUM	NEGATIVE
Visit 2	02NOV2020 (21)	02NOV2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (30)/ 09NOV2020 (28)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11NOV2020 (30)	11NOV2020 (30)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	11NOV2020 (30)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2004	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.77 cm	70 kg	22.6 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	08MAR2007	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	15:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16OCT2020 (1)	16OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16OCT2020 (1)	16OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02NOV2020 (18)/ 01NOV2020 (17)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02NOV2020 (18)	COVID-19	02NOV2020 (18)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02NOV2020 (18)	02NOV2020 (18)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02NOV2020 (18)	02NOV2020 (18)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		BD SARS-COV-2REAGENTS FOR BD MAX SYSTEM	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02NOV2020 (18)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	01NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159.51 cm	111.18 kg	43.6 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	OCT2015	Past
seasonal allergies	Seasonal allergy	OCT2015	Present
sore throat	Oropharyngeal pain	12OCT2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	15:53
2	Placebo	04NOV2020 (20)	14:41

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16OCT2020 (1)	16OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16OCT2020 (1)	16OCT2020 (1)	SERUM	NEGATIVE
Visit 2	04NOV2020 (20)	04NOV2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10NOV2020 (26)/ 09NOV2020 (25)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	10NOV2020 (26)	covid 19	10NOV2020 (26)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10NOV2020 (26)	10NOV2020 (26)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	10NOV2020 (26)	10NOV2020 (26)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		BD BIOGX SARS-COV-2 REAGENTS FOR BD MAX SYSTEM	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	10NOV2020 (26)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	98.91 kg	36.8 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	JUN2014	Present
hysterectomy	Hysterectomy	JUN2014	Past
type II diabetes	Type 2 diabetes mellitus	NOV2015	Present
seasonal allergies	Seasonal allergy	APR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22OCT2020 (1)	16:22

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22OCT2020 (1)	22OCT2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22OCT2020 (1)	22OCT2020 (1)	SERUM	NEGATIVE
Visit 2	13NOV2020 (23)	13NOV2020 (23)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02NOV2020 (12)/ 31OCT2020 (10)/ ONGOING	YES	DIARRHEA	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02NOV2020 (12)	02NOV2020 (12)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02NOV2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22OCT2020	
Withdrawn	VACCINATION	31OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	70.45 kg	23.6 kg/m2	20OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HIV	HIV test positive	1995	Present
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20OCT2020 (1)	10:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20OCT2020 (1)	20OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20OCT2020 (1)	20OCT2020 (1)	SERUM	NEGATIVE
Visit 2	11NOV2020 (23)	11NOV2020 (23)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29OCT2020 (10)/ 28OCT2020 (9)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	29OCT2020 (10)	COVID-19	31OCT2020 (12)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	29OCT2020 (10)	29OCT2020 (10)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	29OCT2020 (10)	31OCT2020 (12)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	SARS-CoV-2 POC

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29OCT2020 (10)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20OCT2020	
Withdrawn	VACCINATION	28OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	81.45 kg	29.8 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ankle Pain, Bilateral	Arthralgia	2007	Present
Chronic Knee Pain, Bilateral	Arthralgia	2007	Present
Chronic Back Pain, Lower Back	Back pain	2010	Present
Post Menopausal	Postmenopause	2010	Present
Allergic Rhinitis	Rhinitis allergic	2015	Present
Congestion secondary to allergic rhinitis	Rhinitis allergic	2015	Present
Fracture, Right Lower Rib	Rib fracture	2017	Past
Hypothyroidism	Hypothyroidism	03NOV2017	Present
Seborrheic Dermatitis	Seborrhoeic dermatitis	03OCT2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	14:27
2	Placebo	08OCT2020 (23)	09:45

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Pyrexia	fever	14OCT2020 (29)		15OCT2020 (30)		2
2	NERV	Dizziness	Lightheaded	16SEP2020 (1)	14:30	16SEP2020 (1)	15:32	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (15OCT2020)	Study Treatment	2	7	N
2	2	N	N	Resolved (16SEP2020)	NOT RELATED/OTHER: Glasses	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16SEP2020 (1)	16SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16SEP2020 (1)	16SEP2020 (1)	SERUM	NEGATIVE
Visit 2	08OCT2020 (23)	08OCT2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22OCT2020 (37)/ 14OCT2020 (29)/ 09NOV2020 (55)	YES	CHILLS	
	NO		Myalgia
	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion
	NO		Nausea
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	22OCT2020 (37)	COVID 19	23OCT2020 (38)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	22OCT2020 (37)	22OCT2020 (37)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	22OCT2020 (37)	23OCT2020 (38)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown CLIA certified lab

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	22OCT2020 (37)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	95.64 kg	27.8 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety	Anxiety	1985	Present
allergic rhinitis	Rhinitis allergic	1985	Present
umbilical hernia	Umbilical hernia	1998	Past
umbilical hernia	Umbilical hernia	1998	Past
alcohol problem	Alcohol problem	2001	Past
gallbladder polyp	Gallbladder polyp	2003	Present
insomnia	Insomnia	2014	Present
irritability	Irritability	2014	Present
hypertrophy of nasal turbinates	Nasal turbinate hypertrophy	2014	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
disturbance in sleep behavior	Sleep disorder	2014	Present
snoring	Snoring	2014	Present
giant papillary conjunctivitis bilateral	Giant papillary conjunctivitis	31JUL2014	Past
breast enlargement bilateral	Breast enlargement	2015	Present
colonoscopy	Colonoscopy	17SEP2020	Past
colon polypectomy benign	Large intestinal polypectomy	17SEP2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	08:24
2	Placebo	15OCT2020 (22)	07:45

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24SEP2020 (1)	24SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24SEP2020 (1)	24SEP2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (22)	15OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 18OCT2020 (25)/ 17OCT2020 (24)/ ONGOING	YES	CHILLS	
	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Pain
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	18OCT2020 (25)	COVID 19	20OCT2020 (27)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	18OCT2020 (25)	18OCT2020 (25)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	18OCT2020 (25)	19OCT2020 (26)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	18OCT2020 (25)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24SEP2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2002	18	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.5 cm	50 kg	18.7 kg/m2	08OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08OCT2020 (1)	14:37
2	Placebo	03NOV2020 (27)	09:45

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08OCT2020 (1)	08OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08OCT2020 (1)	08OCT2020 (1)	SERUM	NEGATIVE
Visit 2	03NOV2020 (27)	03NOV2020 (27)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22OCT2020 (15)/ 18OCT2020 (11)/ ONGOING	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	22OCT2020 (15)	22OCT2020 (15)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	22OCT2020 (15)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168.91 cm	55 kg	19.2 kg/m2	29OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	2001	Past
tonsillitis	Tonsillitis	2001	Past
right collar bone fracture	Clavicle fracture	2003	Past
anemia	Anaemia	2008	Present
condom allergy	Rubber sensitivity	2012	Present
latex allergy	Rubber sensitivity	2012	Present
malathion allergy	Drug hypersensitivity	2013	Present
right wrist fracture	Wrist fracture	2013	Past
benzoyl peroxide allergy	Drug hypersensitivity	2014	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
anxiety	Anxiety	2015	Present
depression	Depression	2015	Present
seasonal allergies	Seasonal allergy	2015	Present
asthma	Asthma	2016	Present
aspartame allergy	Reaction to food additive	2016	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2017	Present
karatosis pilaris	Keratosis pilaris	2017	Present
seborrheic dermatitis	Seborrhoeic dermatitis	2017	Present
obesity	Obesity	2019	Present
bilateral low back pain	Back pain	JUL2019	Present
post traumatic stress disorder	Post-traumatic stress disorder	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29OCT2020 (1)	09:30

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	29OCT2020 (1)	29OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29OCT2020 (1)	29OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04NOV2020 (7)/ 04NOV2020 (7)/ ONGOING	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	NO		Nausea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04NOV2020 (7)	COVID-19	05NOV2020 (8)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	04NOV2020 (7)	04NOV2020 (7)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	04NOV2020 (7)	05NOV2020 (8)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown. CLIA certified lab.

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	04NOV2020 (7)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29OCT2020	
Withdrawn	VACCINATION	04NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	20	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	81.82 kg	24.4 kg/m2	08SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	09:44
2	Placebo	30SEP2020 (23)	09:32

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (23)	30SEP2020 (23)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 23OCT2020 (46)/ 01OCT2020 (24)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	23OCT2020 (46)	COVID-19	16OCT2020 (39)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	23OCT2020 (46)	22OCT2020 (45)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	23OCT2020 (46)	16OCT2020 (39)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Hologic Aptima SARS-CoV-2 assay

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	23OCT2020 (46)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	YES	2	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	71.82 kg	28.9 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Codeine	Drug hypersensitivity	1990	Present
Uterine Fibroids	Uterine leiomyoma	MAY2017	Past
Hysterectomy	Hysterectomy	NOV2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	13:44
2	Placebo	30SEP2020 (23)	13:23

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (23)	30SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 08OCT2020 (31)/ 04OCT2020 (27)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	08OCT2020 (31)	COVID-19	05OCT2020 (28)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	08OCT2020 (31)	08OCT2020 (31)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	08OCT2020 (31)	05OCT2020 (28)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Aptima, Hologic

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	08OCT2020 (31)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	117.7 kg	43.2 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	(b) (6) 1994	Present
seasonal allergic rhinitis	Seasonal allergy	2004	Present
anxiety	Anxiety	OCT2017	Present
carpal tunnel syndrom	Carpal tunnel syndrome	JUN2019	Past
carpal tunnel surgery	Carpal tunnel decompression	MAY2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	08:38

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	POSITIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE
Visit 2	17SEP2020 (24)	17SEP2020 (24)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28AUG2020 (4)/ 25AUG2020 (1)/ 14SEP2020 (21)	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28AUG2020 (4)	COVID-19	27AUG2020 (3)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28AUG2020 (4)	28AUG2020 (4)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	28AUG2020 (4)	27AUG2020 (3)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28AUG2020 (4)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	Employer Provided Test

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	17SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Not reported	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	90.7 kg	25.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	1974	Present
mild intermittent asthma without complication	Asthma	1976	Past
recurrent major depressive disorder	Major depression	1985	Past
impaired fasting glucose	Impaired fasting glucose	2005	Present
elbow pain, left	Arthralgia	10AUG2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	12:20
2	Placebo	16SEP2020 (24)	09:31

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	SKIN	Skin induration	Firm swelling induration on left arm	29AUG2020 (6)	16:00	ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			1	N	N	Yes	Study Treatment	1	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (24)	16SEP2020 (24)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 17SEP2020 (25)/ 15SEP2020 (23)/ 21OCT2020 (59)	YES	CHILLS	
	NO		Chest discomfort
	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion
	NO		Upper-airway cough syndrome

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	17SEP2020 (25)	COVID-19 infection	17SEP2020 (25)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	17SEP2020 (25)	17SEP2020 (25)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	17SEP2020 (25)	17SEP2020 (25)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	Quidel Sofia 2 SARS Antigen FIA rapid test

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	17SEP2020 (25)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.7 cm	71.7 kg	24 kg/m2	09OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPOTHYROIDISM	Hypothyroidism	1982	Present
HYSTERECTOMY	Hysterectomy	1983	Past
Allergy to Codiene	Drug hypersensitivity	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09OCT2020 (1)	09:55

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	09OCT2020 (1)	09OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09OCT2020 (1)	09OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (5)/ 12OCT2020 (4)/ 17OCT2020 (9)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	13OCT2020 (5)	COVID-19	13OCT2020 (5)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	13OCT2020 (5)	13OCT2020 (5)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	13OCT2020 (5)	13OCT2020 (5)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13OCT2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09OCT2020	
Withdrawn	VACCINATION	13OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Withdrawn	FOLLOW-UP	12NOV2020	

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	132 kg	43 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SEASONAL ALLERGIES	Seasonal allergy	1990	Present
HYPERLIPIDEMIA	Hyperlipidaemia	1995	Present
HYPERTENSION	Hypertension	1999	Present
HYSTERECTOMY	Hysterectomy	1999	Past
VENTRAL ABDOMINAL INCISIONAL HERNIA	Abdominal hernia	2000	Present
ALLERGY TO SULFA	Drug hypersensitivity	2000	Present
ALLERGY TO ZANTAC	Drug hypersensitivity	2000	Present
OBESITY	Obesity	2000	Present
DIABETES TYPE II	Type 2 diabetes mellitus	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral lower extremity neuropathy	Neuropathy peripheral	2009	Present
ASTHMA	Asthma	JUL2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15OCT2020 (1)	15:35
2	BNT162b2	05NOV2020 (22)	15:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	15OCT2020 (1)	15OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15OCT2020 (1)	15OCT2020 (1)	SERUM	NEGATIVE
Visit 2	05NOV2020 (22)	05NOV2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 10NOV2020 (27)/ 09NOV2020 (26)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	10NOV2020 (27)	10NOV2020 (27)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10NOV2020 (27)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	60 kg	22.7 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1997	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	11:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	26AUG2020 (1)	26AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	26AUG2020 (1)	26AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10SEP2020 (16)/ 06SEP2020 (12)/ 20SEP2020 (26)	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	10SEP2020 (16)	COVID-19	10SEP2020 (16)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10SEP2020 (16)	10SEP2020 (16)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	10SEP2020 (16)	10SEP2020 (16)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE	other	ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10SEP2020 (16)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	Medical Practioner - Parking Lot

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	06SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	20	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189 cm	78.3 kg	21.9 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Inflammatory Demyelinating Polyneuropathy	Chronic inflammatory demyelinating polyradiculoneuropathy	2007	Past
Seasonal Allergies	Seasonal allergy	2017	Present
Hair Loss	Alopecia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	14:13
2	Placebo	26AUG2020 (7)	09:19

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	26AUG2020 (7)	26AUG2020 (7)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12OCT2020 (54)/ 09OCT2020 (51)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nausea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	12OCT2020 (54)	COVID 19	10OCT2020 (52)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	12OCT2020 (54)	12OCT2020 (54)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	12OCT2020 (54)	09OCT2020 (51)	RESPIRATORY SECRETIONS	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ORIG3N 2019 NOVEL CORONAVIRUS (COVID-19) TEST	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	12OCT2020 (54)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	132.18 kg	40.6 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic sinus infection	Chronic sinusitis	1990	Past
Intermittent Headache	Headache	1990	Present
tonsillitis	Tonsillitis	1993	Past
bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2002	Past
bilateral carpal tunnel repair	Carpal tunnel decompression	2003	Past
obesity	Obesity	2004	Present
balloon sinuplasty	Sinuplasty	2011	Past
allergy to cedar	Allergy to plants	2013	Present
allergy to oak	Allergy to plants	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2013	Present
heartburn	Dyspepsia	2018	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2018	Present
anxiety	Anxiety	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	12:21

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	Paroxysmal Atrial fibrillation with rapid ventricular response	23AUG2020 (20)		08SEP2020 (36)	00:00	17
2	CARD	Atrial flutter	Atrial Flutter	02SEP2020 (30)	00:00	08SEP2020 (36)	00:00	7
3	VASC	Hypertension	Hypertension	24AUG2020 (21)	00:00	ONGOING		
4	CARD	Left atrial enlargement	Left Atrial Enlargement	09SEP2020 (37)	00:00	ONGOING		
5	CARD	Left ventricular hypertrophy	Left Ventricular Hypertrophy	24AUG2020 (21)	00:00	ONGOING		
6	CARD	Mitral valve incompetence	Mitral Regurgitation	09SEP2020 (37)	00:00	ONGOING		
7	CARD	Mitral valve prolapse	Bileaflet mitral valve prolapse	09SEP2020 (37)	00:00	ONGOING		

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
8	CARD	Myocardial infarction	Prior Septual Myocardinal Infarction	08SEP2020 (36)	00:00	08SEP2020 (36)	00:00	1
9	INJ&P	Skin laceration	Laceration-Left Index Finger	01SEP2020 (29)	00:00	15SEP2020 (43)	00:00	15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN/P	Y	Resolved (08SEP2020)	NOT RELATED/OTHER: Heart Disease	1	20	N
2	3	TC/TCN	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Cardiac Disease	1	30	N
3	1	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
4	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
5	1	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
6	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
7	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
8	1	N	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Heart Disease	1	36	N
9	2	TCN	N	Resolved (15SEP2020)	NOT RELATED/OTHER: Hobby Injury	1	29	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	04AUG2020 (1)	04AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04AUG2020 (1)	04AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09NOV2020 (98)/ 07NOV2020 (96)/ ONGOING	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	
	NO		Pain

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09NOV2020 (98)	POSITIVE TEST RESULT FOR Covid-19	07NOV2020 (96)	1	SARS-CoV-2 test positive

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (98)	09NOV2020 (98)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	09NOV2020 (98)	07NOV2020 (96)			POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1			

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	09NOV2020 (98)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	**Visit Date (Study Day)**	**Date Collected (Study Day)**	**Record Identifier**	**Systolic Blood Pressure**	**Diastolic Blood Pressure**	**Respiratory Rate**	**Heart Rate**	**Oxygen Saturation**
COVID Illness Visit 1	09NOV2020 (98)	09NOV2020 (98)	1	139 mmHg	86 mmHg	16 breaths/min	57 beats/min	

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Withdrawn	VACCINATION	23AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	75 kg	30.2 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	1996	Past
Cholelithiasis	Cholelithiasis	1996	Past
Ectopic Pregnancy	Ectopic pregnancy	1998	Past
Hysterectomy	Hysterectomy	1999	Past
Anxiety	Anxiety	2011	Present
Post Menopausal	Postmenopause	2012	Present
Previous Hepatitis C Infection	Hepatitis C	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	13:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	09SEP2020 (1)	09SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09SEP2020 (1)	09SEP2020 (1)	SERUM	NEGATIVE
Visit 2	05NOV2020 (58)	05NOV2020 (58)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06OCT2020 (28)/ 02OCT2020 (24)/ 13OCT2020 (35)	NO		Fatigue
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06OCT2020 (28)	COVID 19	06OCT2020 (28)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06OCT2020 (28)	06OCT2020 (28)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	06OCT2020 (28)	06OCT2020 (28)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		QUEST SARS-COV-2 RRT-PCR	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	06OCT2020 (28)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	12OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Withdrawn	FOLLOW-UP	05NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	21	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	74.2 kg	29 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ANXIETY	Anxiety	JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	12:03

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Tachycardia	TACHYCARDIA	24SEP2020 (39)		30SEP2020 (45)		7	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (30SEP2020)	NOT RELATED/OTHER: COVID INFECTION	1	39	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	17AUG2020 (1)	17AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17AUG2020 (1)	17AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 07SEP2020 (22)/ 04SEP2020 (19)/ 30SEP2020 (45)	YES	FEVER	
	NO		Fatigue

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	07SEP2020 (22)	COVID-19	06SEP2020 (21)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	07SEP2020 (22)	07SEP2020 (22)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location	Test Result
1	COVID Illness Visit 1	07SEP2020 (22)	06SEP2020 (21)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	Lab processed by LabCorp (a CLIA certified lab)	OTHER	COVID-19 SARS Antigen Test, CLIA-certified lab

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	07SEP2020 (22)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	STUDENT HEALTH CENTER

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Withdrawn	VACCINATION	04SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.98 cm	70 kg	22.3 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	15:27

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25AUG2020 (1)	25AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25AUG2020 (1)	25AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02SEP2020 (9)/ 31AUG2020 (7)/ 03SEP2020 (10)	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02SEP2020 (9)	COVID-19	03SEP2020 (10)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02SEP2020 (9)	02SEP2020 (9)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	02SEP2020 (9)	03SEP2020 (10)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	Component = SARS-CoV-2, NAA. Value = Detected. Ref Rang = Not detected.	OTHER	LabCorp COVID-19, NAA/PCR

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02SEP2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	31AUG2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Withdrawn	FOLLOW-UP	01OCT2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	56.27 kg	21.2 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1970	Present
hysterectomy	Hysterectomy	2002	Past
cosmetic breast implants	Mammoplasty	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	14:58
2	BNT162b2	21SEP2020 (22)	12:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	31AUG2020 (1)	31AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31AUG2020 (1)	31AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (22)	21SEP2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11SEP2020 (12)/ 04SEP2020 (5)/ 12SEP2020 (13)	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11SEP2020 (12)	11SEP2020 (12)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11SEP2020 (12)	15SEP2020 (16)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		OTHER	MAKO Medical Laboratories-CLIA certified lab

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	11SEP2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.4 cm	122.1 kg	41.1 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ligament repair surgery Left ankle	Ligament operation	1997	Past
Torn Ligament L ankle	Ligament rupture	1997	Past
Vasectomy	Vasectomy	2000	Past
L wrist tendonitis surgery	Tendon operation	2009	Past
L Wrist Tendonitis	Tendonitis	2009	Past
Small Pituitary Tumor Benign	Pituitary tumour benign	2010	Present
R rotator cuff surgery	Rotator cuff repair	2010	Past
Torn R rotator cuff	Rotator cuff syndrome	2010	Past
Low Testosterone	Blood testosterone decreased	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Erectile Dysfunction	Erectile dysfunction	2013	Present
Hypothyroidism	Hypothyroidism	2015	Present
Broken Nose	Facial bones fracture	2016	Past
Septoplasty	Nasal septal operation	2016	Past
Lap-band surgery	Gastric banding	2017	Past
Septoplasty	Nasal septal operation	2017	Past
Seasonal Allergies	Seasonal allergy	2017	Present
Allergy Dogs	Allergy to animal	2019	Present
Allergy Dust Mites	Mite allergy	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	12:02
2	Placebo	20AUG2020 (21)	11:13

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31JUL2020 (1)	31JUL2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31JUL2020 (1)	31JUL2020 (1)	SERUM	NEGATIVE
Visit 2	20AUG2020 (21)	20AUG2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (96)/ 03NOV2020 (96)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03NOV2020 (96)	COVID-19	03NOV2020 (96)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03NOV2020 (96)	03NOV2020 (96)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	03NOV2020 (96)	03NOV2020 (96)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03NOV2020 (96)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	22SEP2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.8 cm	59.1 kg	23.4 kg/m2	05NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
menorrhagia	Menorrhagia	AUG2013	Present
tree nut allergy	Food allergy	2016	Present
ADHD	Attention deficit hyperactivity disorder	05AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05NOV2020 (1)	15:24

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	05NOV2020 (1)	05NOV2020 (1)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06NOV2020 (2)/ 06NOV2020 (2)/ ONGOING	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nausea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	06NOV2020 (2)	08NOV2020 (4)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	06NOV2020 (2)	09NOV2020 (5)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	LabCorp NAA

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06NOV2020 (2)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05NOV2020	
Withdrawn	VACCINATION	09NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	62.55 kg	20.3 kg/m2	03SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	15:12
2	Placebo	15OCT2020 (43)	08:47

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	03SEP2020 (1)	03SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	03SEP2020 (1)	03SEP2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (43)	15OCT2020 (43)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13SEP2020 (11)/ 12SEP2020 (10)/ 21SEP2020 (19)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	13SEP2020 (11)	13SEP2020 (11)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13SEP2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.78 cm	64 kg	23.5 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hysterectomy	Hysterectomy	2006	Past
hypothyroidism	Hypothyroidism	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22OCT2020 (1)	10:50

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22OCT2020 (1)	22OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22OCT2020 (1)	22OCT2020 (1)	SERUM	NEGATIVE
Visit 2	12NOV2020 (22)	12NOV2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (5)/ 23OCT2020 (2)/ 28OCT2020 (7)	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (5)	26OCT2020 (5)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	26OCT2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	26OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186.69 cm	82.82 kg	23.7 kg/m2	18AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	08:21
2	Placebo	08SEP2020 (22)	13:56

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINATION	INFLUENZA VACCINE	29SEP2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	18AUG2020 (1)	18AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18AUG2020 (1)	18AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (22)	08SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16SEP2020 (30)/ 08SEP2020 (22)/ 16SEP2020 (30)	YES	CHILLS	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	16SEP2020 (30)	16SEP2020 (30)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	16SEP2020 (30)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186.69 cm	151.45 kg	43.4 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
MIGRAINE HEADACHES	Migraine	2010	Present
PRE-DIABETES	Glucose tolerance impaired	2015	Present
OBESITY	Obesity	2015	Present
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	12:36

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 21SEP2020 (29)/ 16SEP2020 (24)/ 10NOV2020 (79)	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	21SEP2020 (29)	21SEP2020 (29)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	21SEP2020 (29)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	16SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	21	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	118.64 kg	37.4 kg/m2	22SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22SEP2020 (1)	18:56
2	Placebo	12OCT2020 (21)	11:38

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22SEP2020 (1)	22SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22SEP2020 (1)	22SEP2020 (1)	SERUM	NEGATIVE
Visit 2	12OCT2020 (21)	12OCT2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (22)/ 12OCT2020 (21)/ ONGOING	YES	DIARRHEA	
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	13OCT2020 (22)	13OCT2020 (22)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13OCT2020 (22)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22SEP2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	51.82 kg	18.4 kg/m2	09OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right knee injury	Joint injury	JUN2018	Past
Right knee medial patellofemeral ligament replacement	Ligament operation	JUN2018	Past
Right knee tibial tubercle osteotomy	Osteotomy	JUN2018	Past
Stomach virus	Gastroenteritis viral	11SEP2020	Past
Nausea	Nausea	11SEP2020	Past
Vomiting	Vomiting	11SEP2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09OCT2020 (1)	17:11

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	09OCT2020 (1)	09OCT2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	09OCT2020 (1)	09OCT2020 (1)	SERUM	NEGATIVE
Visit 2	29OCT2020 (21)	29OCT2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (5)/ 12OCT2020 (4)/ 15OCT2020 (7)	NO		Headache
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	13OCT2020 (5)	COVID-19	13OCT2020 (5)	1	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	13OCT2020 (5)	14OCT2020 (6)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	13OCT2020 (5)	13OCT2020 (5)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	13OCT2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09OCT2020	
Withdrawn	VACCINATION	29OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	85.45 kg	31.3 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYSTERECTOMY	Hysterectomy	1988	Past
RIGHT KNEE REPLACEMENT	Knee arthroplasty	2012	Past
ESSENTIAL HYPERTENSION	Essential hypertension	02APR2018	Present
HYPERLIPIDEMIA	Hyperlipidaemia	02APR2018	Present
SEASONAL ALLERGIES	Seasonal allergy	02APR2018	Present
DIABETES MELLITUS TYPE II	Type 2 diabetes mellitus	02APR2018	Present
DEPRESSIVE DISORDER	Depression	23JUL2018	Present
BLEPHARAPLASTY	Blepharoplasty	NOV2019	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
EXCISION OF MELANOMA	Skin neoplasm excision	NOV2019	Past
CONSTIPATION	Constipation	09DEC2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:34
2	Placebo	28SEP2020 (21)	10:36

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (21)	28SEP2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05OCT2020 (28)/ 25SEP2020 (18)/ 03OCT2020 (26)	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	05OCT2020 (28)	COVID-19	29SEP2020 (22)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05OCT2020 (28)	05OCT2020 (28)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	05OCT2020 (28)	29SEP2020 (22)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE	CLIA Certified Lab	OTHER	Mako Medical RT-qPCR - CLIA certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05OCT2020 (28)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	2	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	80.91 kg	28.7 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PROLAPSED DISC REPAIR	Intervertebral disc operation	10APR2000	Past
bilateral knee replacements	Knee arthroplasty	2018	Past
BILATERAL SHOULDER REPLACEMENTS	Shoulder arthroplasty	2018	Past
ESSENTIAL HYPERTENSION	Essential hypertension	02APR2018	Present
HYPERLIPIDEMIA	Hyperlipidaemia	02APR2018	Present
NEUROPATHY	Neuropathy peripheral	02APR2018	Present
GLAUCOMA	Glaucoma	18APR2018	Present
COUGH	Cough	14JUN2018	Present
PNEUMONIA	Pneumonia	14JUN2018	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SPINAL STENOSIS	Spinal stenosis	18MAR2019	Present
OSTEOARTHRITIS	Osteoarthritis	20JUL2019	Present
LAMINECTOMY L4-S1	Spinal laminectomy	07JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	11:35
2	BNT162b2	28SEP2020 (21)	10:37

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (21)	28SEP2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19

Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 05OCT2020 (28)/ 25SEP2020 (18)/ 06OCT2020 (29)	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	05OCT2020 (28)	COVID-19	29SEP2020 (22)	1	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05OCT2020 (28)	05OCT2020 (28)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	05OCT2020 (28)	29SEP2020 (22)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE	CLIA Certified Lab	OTHER	CLIA Certified Laboratory (Mako)

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	05OCT2020 (28)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	2	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	95.45 kg	31 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	15:36

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 31AUG2020 (11)/ 31AUG2020 (11)/ 01SEP2020 (12)	YES	FEVER	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	31AUG2020 (11)	31AUG2020 (11)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	31AUG2020 (11)	01SEP2020 (12)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	31AUG2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	11SEP2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	11SEP2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.3 cm	70.25 kg	25.1 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral cataracts	Cataract	1970	Present
anemia	Anaemia	1985	Present
intermittent migraines	Migraine	1985	Present
intermittent urinary tract infections	Urinary tract infection	1985	Present
bilateral tubal ligation	Female sterilisation	2009	Past
hypertension	Hypertension	2015	Present
anxiety	Anxiety	2018	Present
high cholesterol	Blood cholesterol increased	2018	Present
GERD	Gastrooesophageal reflux disease	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	10:53

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	09SEP2020 (1)	09SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	09SEP2020 (1)	09SEP2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 29SEP2020 (21)/ 19SEP2020 (11)/ 07OCT2020 (29)	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Sinus congestion

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	29SEP2020 (21)	COVID-19	29SEP2020 (21)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	29SEP2020 (21)	01OCT2020 (23)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	29SEP2020 (21)	25SEP2020 (17)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	The subject was tested on 9/25/2020, but did not contact the site until 9/29/2020 when she received the positive results. She is not sure of the trade name, but the information has been requested.	OTHER	Logix Smart Coronavirus Disease 2019 (COVID-19)kit

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29SEP2020 (21)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	29SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	70.91 kg	23.7 kg/m2	04OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04OCT2020 (1)	11:28

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	04OCT2020 (1)	04OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	04OCT2020 (1)	04OCT2020 (1)	SERUM	NEGATIVE
Visit 2	24OCT2020 (21)	24OCT2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12OCT2020 (9)/ 11OCT2020 (8)/ 16OCT2020 (13)	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	12OCT2020 (9)	12OCT2020 (9)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	12OCT2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	12OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	48 kg	18.2 kg/m2	31JUL2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31JUL2020 (1)	17:21

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	31JUL2020 (1)	31JUL2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	31JUL2020 (1)	31JUL2020 (1)	SERUM	NEGATIVE
Visit 2	21AUG2020 (22)	21AUG2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11AUG2020 (12)/ 01AUG2020 (2)/ 16AUG2020 (17)	YES	CHILLS	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11AUG2020 (12)	Covid-19	11AUG2020 (12)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11AUG2020 (12)	11AUG2020 (12)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11AUG2020 (12)	05AUG2020 (6)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	"SARS COV-2 test CLIA-certified BioReference Labor

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11AUG2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		URGENT CARE	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	11AUG2020 (12)	06AUG2020 (7)	1	110 mmHg	71 mmHg	16 breaths/min	87 beats/min	98 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31JUL2020	
Withdrawn	VACCINATION	21SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	93.32 kg	27.8 kg/m2	11AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	15:20
2	Placebo	25SEP2020 (46)	09:25

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	11AUG2020 (1)	11AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11AUG2020 (1)	11AUG2020 (1)	SERUM	NEGATIVE
Visit 2	25SEP2020 (46)	25SEP2020 (46)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29SEP2020 (50)/ 28SEP2020 (49)/ ONGOING	YES	DIARRHEA	
	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	29SEP2020 (50)	Covid 19 Illness	01OCT2020 (52)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	29SEP2020 (50)	01OCT2020 (52)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	29SEP2020 (50)	01OCT2020 (52)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE	CLIA-certified lab	LABCORP COVID-19 RT-PCR TEST	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29SEP2020 (50)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	13NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	23	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	94.09 kg	27.3 kg/m2	25SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	16:50
2	Placebo	14OCT2020 (20)	16:19

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25SEP2020 (1)	25SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25SEP2020 (1)	25SEP2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (20)	14OCT2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (32)/ 20OCT2020 (26)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (32)	COVID-19	23OCT2020 (29)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (32)	26OCT2020 (32)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (32)	23OCT2020 (29)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	Unable to verify trade name at this time	OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (32)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	26OCT2020 (32)	26OCT2020 (32)	1	130 mmHg	78 mmHg	19 breaths/min	81 beats/min	98 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.5 cm	132.5 kg	53.4 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1961	Present
left knee pain	Arthralgia	1975	Present
obesity	Obesity	2000	Present
seasonal allergies	Seasonal allergy	2000	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2010	Present
migraines	Migraine	2010	Present
post menopausal	Postmenopause	2013	Present
hypertension	Hypertension	2019	Present
osteoporosis	Osteoporosis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	13:46

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16OCT2020 (1)	16OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16OCT2020 (1)	16OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (11)/ 23OCT2020 (8)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (11)	26OCT2020 (11)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	26OCT2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	26OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	88.36 kg	27.9 kg/m2	09SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	12:04
2	Placebo	28SEP2020 (20)	11:11

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	09SEP2020 (1)	09SEP2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (20)	28SEP2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (58)/ 05NOV2020 (58)/ ONGOING	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05NOV2020 (58)	06NOV2020 (59)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (58)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	60	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	95.2 kg	38.6 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Erythromycin allergy	Drug hypersensitivity	1972	Present
Tetracyclim allergy	Drug hypersensitivity	1972	Present
MENOPAUSE	Menopause	2012	Present
Hypothyroidism	Hypothyroidism	APR2018	Present
Vagina atrophy	Atrophic vulvovaginitis	OCT2018	Present
Seasonal allergies	Seasonal allergy	JUL2019	Present
Uterine fibroids	Uterine leiomyoma	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	17:39
2	Placebo	24AUG2020 (22)	15:05

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EYE	Conjunctival hyperaemia	RIGHT EYE CONJUNCTIVE ERYTHEMA	24AUG2020 (22)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: UNKNOWN	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	03AUG2020 (1)	03AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	03AUG2020 (1)	03AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (101)/ 08NOV2020 (98)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (101)	COVID-19	11NOV2020 (101)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11NOV2020 (101)	11NOV2020 (101)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11NOV2020 (101)	09NOV2020 (99)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	11NOV2020 (101)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	21SEP2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	20	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187 cm	73.4 kg	21 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2010	Present
Attention deficit disorder	Attention deficit hyperactivity disorder	2011	Present
Cat allergy	Allergy to animal	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	14:10
2	Placebo	04SEP2020 (23)	11:16

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	13AUG2020 (1)	13AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13AUG2020 (1)	13AUG2020 (1)	SERUM	NEGATIVE
Visit 2	04SEP2020 (23)	04SEP2020 (23)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 17AUG2020 (5)/ 16AUG2020 (4)/ 27AUG2020 (15)	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	17AUG2020 (5)	Covid-19	22AUG2020 (10)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	17AUG2020 (5)	17AUG2020 (5)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	17AUG2020 (5)	21AUG2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	17AUG2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	72 kg	25.8 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	16:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	14OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29AUG2020 (10)/ 28AUG2020 (9)/ 19SEP2020 (31)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	29AUG2020 (10)	30AUG2020 (11)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29AUG2020 (10)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	30SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	96.8 kg	29.2 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic back pain	Back pain	2012	Present
Lavender scent allergy	Allergy to chemicals	2016	Present
Nickel allergy	Allergy to metals	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	10:15
2	Placebo	02OCT2020 (22)	09:20

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	11SEP2020 (1)	11SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 2	02OCT2020 (22)	02OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (54)/ 02NOV2020 (53)/ ONGOING	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03NOV2020 (54)	03NOV2020 (54)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	03NOV2020 (54)	03NOV2020 (54)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03NOV2020 (54)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	124.1 kg	44.2 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PCN allergy	Drug hypersensitivity	2008	Present
Discectomy L5 S1	Intervertebral disc operation	MAY2008	Past
Type 2 diabetes	Type 2 diabetes mellitus	2010	Present
Cholestasis	Cholestasis	2017	Past
Morphine allergy	Drug hypersensitivity	2017	Present
Cholecystectomy	Cholecystectomy	APR2017	Past
Anxiety	Anxiety	2018	Present
Depression	Depression	2018	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	15:44

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Headache	Headache	06OCT2020 (13)		07OCT2020 (14)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (07OCT2020)	NOT RELATED/OTHER: unknown	1	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24SEP2020 (1)	24SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24SEP2020 (1)	24SEP2020 (1)	SERUM	NEGATIVE
Visit 2	22OCT2020 (29)	22OCT2020 (29)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07OCT2020 (14)/ 06OCT2020 (13)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nausea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	07OCT2020 (14)	Covid-19	08OCT2020 (15)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	07OCT2020 (14)	07OCT2020 (14)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	07OCT2020 (14)	07OCT2020 (14)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07OCT2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24SEP2020	
Withdrawn	VACCINATION	06OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	89.5 kg	30.6 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2014	Present
Elevated diastolic blood pressure	Blood pressure diastolic increased	JUN2020	Present
Hyperlipidemia	Hyperlipidaemia	AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19OCT2020 (1)	15:32

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	19OCT2020 (1)	19OCT2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	19OCT2020 (1)	19OCT2020 (1)	SERUM	NEGATIVE
Visit 2	09NOV2020 (22)	09NOV2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02NOV2020 (15)/ 26OCT2020 (8)/ 03NOV2020 (16)	YES	CHILLS	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02NOV2020 (15)	COVID-19	02NOV2020 (15)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02NOV2020 (15)	02NOV2020 (15)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02NOV2020 (15)	31OCT2020 (13)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02NOV2020 (15)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Withdrawn	VACCINATION	09NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.15 cm	103.64 kg	30.5 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to sulfa	Drug hypersensitivity	1966	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Hypertension	Hypertension	2010	Present
Anxiety	Anxiety	2015	Present
Umbilical hernia	Umbilical hernia	2015	Past
Umbilical hernia repair	Umbilical hernia repair	2015	Past
Right shoulder pain	Arthralgia	2019	Present
generalized osteoarthritis	Osteoarthritis	2019	Present
Osteopenia	Osteopenia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	09:18
2	Placebo	20OCT2020 (55)	09:17

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Muscle injury	muscle sprain of lower back	12SEP2020 (17)	17:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: unknown	1	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	20OCT2020 (55)	20OCT2020 (55)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28OCT2020 (63)/ 22OCT2020 (57)/ ONGOING	YES	CHILLS	
	YES	FEVER	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28OCT2020 (63)	Covid-19	27OCT2020 (62)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28OCT2020 (63)	28OCT2020 (63)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	28OCT2020 (63)	26OCT2020 (61)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Cobas (R) SARS-CoV-2 Test

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	28OCT2020 (63)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	106.82 kg	40.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2000	Present
Anal fissures	Anal fissure	2005	Past
Anal fistulotomy	Anal fistula repair	2005	Past
Chronic constipation	Constipation	2005	Present
Endometriosis	Endometriosis	2010	Past
Hysterectomy	Hysterectomy	2010	Past
Postmenopausal	Postmenopause	2010	Present
Bilateral itching feet	Pruritus	2018	Present
Bilateral itching hands	Pruritus	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	16:53

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	02SEP2020 (1)	02SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	02SEP2020 (1)	02SEP2020 (1)	SERUM	NEGATIVE
Visit 2	07OCT2020 (36)	07OCT2020 (36)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16SEP2020 (15)/ 14SEP2020 (13)/ 23SEP2020 (22)	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	16SEP2020 (15)	16SEP2020 (15)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	16SEP2020 (15)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Withdrawn	VACCINATION	14OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	85	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	66.36 kg	25.1 kg/m2	28OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PENICILLIN ALLERGY	Drug hypersensitivity	1956	Present
Sulfa allergy	Drug hypersensitivity	1956	Present
Hysterectomy	Hysterectomy	1975	Past
Menorrhagia	Menorrhagia	1975	Past
Seasonal allergies	Seasonal allergy	1975	Present
Macrobid allergy	Drug hypersensitivity	2004	Present
Arthritis of bilateral hands	Arthritis	2005	Present
Atrial Fibrillation	Atrial fibrillation	2005	Present
Hyperlipidemia	Hyperlipidaemia	2005	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2005	Present
Edema bilateral legs	Oedema peripheral	2005	Present
Hypothyroidism	Hypothyroidism	2014	Present
Right shoulder fracture	Upper limb fracture	JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28OCT2020 (1)	10:35

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Seasonal influenza vaccine	INFLUENZA VACCINE	13OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	28OCT2020 (1)	28OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28OCT2020 (1)	28OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (9)/ 02NOV2020 (6)/ ONGOING	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	NO		Rhinorrhoea
	NO		Sputum increased

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05NOV2020 (9)	05NOV2020 (9)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28OCT2020	
Withdrawn	VACCINATION	05NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	52.73 kg	20.5 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dander allergy	Allergy to animal	2005	Present
Attention deficit disorder	Attention deficit hyperactivity disorder	AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	14:32

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22OCT2020 (1)	22OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22OCT2020 (1)	22OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (13)/ 02NOV2020 (12)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Nasal congestion
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03NOV2020 (13)	03NOV2020 (13)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03NOV2020 (13)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22OCT2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	68.2 kg	22.5 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
myopia	Myopia	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	18:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE
Visit 2	20OCT2020 (63)	20OCT2020 (63)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10SEP2020 (23)/ 08SEP2020 (21)/ 16SEP2020 (29)	YES	CHILLS	
	NO		Fatigue
	NO		Lymphadenopathy
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Pain

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	10SEP2020 (23)	COVID 19	09SEP2020 (22)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10SEP2020 (23)	10SEP2020 (23)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	10SEP2020 (23)	09SEP2020 (22)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10SEP2020 (23)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	university campus clinic

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	09SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	83.2 kg	29.1 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
alopecia	Alopecia	JAN2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	11:39

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25SEP2020 (1)	25SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25SEP2020 (1)	25SEP2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 20OCT2020 (26)/ 11OCT2020 (17)/ ONGOING	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	20OCT2020 (26)	CORONAVIRUS (SARS-CoV-2)	13OCT2020 (19)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	20OCT2020 (26)	20OCT2020 (26)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	20OCT2020 (26)	12OCT2020 (18)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE
2	COVID Illness Visit 1	20OCT2020 (26)	13OCT2020 (19)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	THERE ARE NO INDICATIONS AS OF THE TRADE NAME USED ONLY THE RESULT IS INDICATED.Confirmed with subject that test was done with a Nasal Swab	OTHER	NALT Unknown
2	There are no indications as of the trade name used, only the result. Confirmed with subject that test was a Nasal Swab	OTHER	NALT Unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	20OCT2020 (26)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	2	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	20OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	95.5 kg	31.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral myopia	Myopia	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	16:13
2	Placebo	08SEP2020 (23)	14:27

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	17AUG2020 (1)	17AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	17AUG2020 (1)	17AUG2020 (1)	SERUM	NEGATIVE
Visit 2	08SEP2020 (23)	08SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 15SEP2020 (30)/ 10SEP2020 (25)/ 20SEP2020 (35)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	15SEP2020 (30)	COVID-19	14SEP2020 (29)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	15SEP2020 (30)	15SEP2020 (30)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	15SEP2020 (30)	14SEP2020 (29)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	RT-PCR

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	15SEP2020 (30)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	15SEP2020 (30)	14SEP2020 (29)	Alkaline Phosphatase	0.67	ukat/L	0.5	1.92
			Bilirubin	13.7	umol/L	0	17.1
			Creatinine	88.4	umol/L	44.2	106.1
			Urea Nitrogen	6.07	mmol/L	2.86	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	15SEP2020 (30)	14SEP2020 (29)	Basophils	0	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.7
			Hematocrit	0.46	L/L	0.37	0.47
			Hemoglobin	157	g/L	140	180
			Lymphocytes	0.8	10^9/L	1.2	3.4
			Monocytes	0.39	10^9/L	0.11	0.59
			Neutrophils	2	10^9/L	1.5	6.5
			Platelets	144	10^9/L	130	400

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	15SEP2020 (30)	14SEP2020 (29)	1	113 mmHg	73 mmHg	18 breaths/min	84 beats/min	96 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	15SEP2020 (30)	14SEP2020	CHEST		X-RAY	NA	NORMAL	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184 cm	97.2 kg	28.7 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ventricular septal defect	Ventricular septal defect	1990	Past
seasonal allergies	Seasonal allergy	2012	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	16:44
2	Placebo	24AUG2020 (22)	13:27

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	03AUG2020 (1)	03AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	03AUG2020 (1)	03AUG2020 (1)	SERUM	NEGATIVE
Visit 2	24AUG2020 (22)	24AUG2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30AUG2020 (28)/ 29AUG2020 (27)/ 04SEP2020 (33)	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30AUG2020 (28)	Covid-19	30AUG2020 (28)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	30AUG2020 (28)	30AUG2020 (28)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	30AUG2020 (28)	30AUG2020 (28)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	30AUG2020 (28)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Not reported	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	81.82 kg	25.8 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypercholesterolemia	Hypercholesterolaemia	FEB2005	Present
reactive depression	Adjustment disorder with depressed mood	MAR2016	Present
essential hypertension	Essential hypertension	JUN2018	Present
elevated coronary artery calcium score	Arteriosclerosis coronary artery	08JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	13:04

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	03AUG2020 (1)	03AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	03AUG2020 (1)	03AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26AUG2020 (24)/ 24AUG2020 (22)/ 28AUG2020 (26)	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	26AUG2020 (24)	COVID-19 illness	25AUG2020 (23)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	26AUG2020 (24)	26AUG2020 (24)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	26AUG2020 (24)	25AUG2020 (23)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	26AUG2020 (24)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	26AUG2020 (24)	25AUG2020 (23)	1				77 beats/min	97 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Withdrawn	VACCINATION	29SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	88.18 kg	28.6 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hyperlipidemia	Hyperlipidaemia	25FEB2010	Present
lipoma of flank	Lipoma	SEP2015	Present
idiopathic stabbing headache, recurrent	Headache	22OCT2015	Present
left sided sciatica	Sciatica	JAN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	12:51

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	06AUG2020 (1)	06AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	06AUG2020 (1)	06AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 24AUG2020 (19)/ 23AUG2020 (18)/ 11SEP2020 (37)	YES	CHILLS	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion
	NO		Pharyngeal erythema

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	24AUG2020 (19)	COVID-19 illness	24AUG2020 (19)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	24AUG2020 (19)	24AUG2020 (19)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	24AUG2020 (19)	24AUG2020 (19)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	24AUG2020 (19)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	24AUG2020 (19)	24AUG2020 (19)	1	112 mmHg	83 mmHg		86 beats/min	99 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Withdrawn	VACCINATION	23SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.5 cm	83.3 kg	25 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1990	Present
hypothyroid	Hypothyroidism	2000	Present
thyroid cancer	Thyroid cancer	2000	Past
Thyroidectomy	Thyroidectomy	MAR2014	Past
Hemorrhoids	Haemorrhoids	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	15:12

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (50)	30SEP2020 (50)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25AUG2020 (14)/ 24AUG2020 (13)/ 04SEP2020 (24)	YES	FEVER	
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	25AUG2020 (14)	COVID-19	25AUG2020 (14)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	25AUG2020 (14)	30AUG2020 (19)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	25AUG2020 (14)	25AUG2020 (14)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	Healthvana CLIA-certified lab

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	25AUG2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	28OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.2 cm	74 kg	26.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 1 Diabetes	Type 1 diabetes mellitus	AUG2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	11:44

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	VASC	Deep vein thrombosis	DEEP VEIN THROMBOSIS	31AUG2020 (12)		09SEP2020 (21)		10	3	TC
2	MUSC	Musculoskeletal stiffness	right shoulder stiffness	05SEP2020 (17)		07SEP2020 (19)		3	1	TCN
3	RESP	Pulmonary embolism	PULMONARY EMBOLISM	31AUG2020 (12)		02SEP2020 (14)		3	3	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: MEDICAL HISTORY - TYPE 1 DIABETES	1	12	N
2	N	Resolved (07SEP2020)	NOT RELATED/OTHER: unknown new medical condition	1	17	N
3	N	Resolved (02SEP2020)	NOT RELATED/OTHER: DEEP VEIN THROMBOSIS	1	12	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (35)	23SEP2020 (35)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01SEP2020 (13)/ 30AUG2020 (11)/ 01SEP2020 (13)	YES	NEW OR INCREASED COUGH	
COVID Illness Visit 2 / 02NOV2020 (75)/ 01NOV2020 (74)/ 04NOV2020 (77)	YES	DIARRHEA	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01SEP2020 (13)	COVID-19 PNEUMONIA	31AUG2020 (12)	1	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	01SEP2020 (13)	02SEP2020 (14)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	02NOV2020 (75)	02NOV2020 (75)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	01SEP2020 (13)	31AUG2020 (12)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		CEPHEID XPERT XPRESS SARS-COV-2 TEST	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	01SEP2020 (13)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
COVID Illness Visit 2	02NOV2020 (75)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details					
Visit	**Visit Date (Study Day)**	**Hospitalization Category**	**Hospitalization Term**	**Admission Date (Study Day)**	**Discharge Date or Ongoing (Study Day)**
COVID Illness Visit 1	01SEP2020 (13)	HOSPITALIZATION STATUS	HOSPITAL	31AUG2020 (12)	02SEP2020 (14)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	01SEP2020 (13)	01SEP2020 (13)	C Reactive Protein	8.1	mg/L	0.1	3
		31AUG2020 (12)	Alkaline Phosphatase	1.68	ukat/L	0.67	2.15
			Alanine Aminotransferase	0.11669	ukat/L	0	0.68347
			Aspartate Aminotransferase	0.18337	ukat/L	0	0.63346
			Bilirubin	6.8	umol/L	0	17.1
			Creatinine	97.2	umol/L	61.9	106.1
			C Reactive Protein	11.5	mg/L	0.1	3
			Urea Nitrogen	3.57	mmol/L	2.14	8.21

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	01SEP2020 (13)	31AUG2020 (12)	Basophils	0	10^9/L	0	0.08
			Eosinophils	0	10^9/L	0	0.3
			Hematocrit	0.43	L/L	0.39	0.49
			Hemoglobin	134	g/L	127	163
			Lymphocytes	1.7	10^9/L	1.1	3.2
			Monocytes	0.5	10^9/L	0.3	0.8
			Neutrophils	4.4	10^9/L	2.2	5.7
			Platelets	311	10^9/L	142	396
			Erythrocytes	5	10^12/L	4.07	5.6
			Leukocytes	6.7	10^9/L	4.67	9.11

Vital Signs - COVID-19

No Vital Signs - COVID-19

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	**Visit**	**Visit Date (Study Day)**	**Date of Assessment**	**Location of Assessment**	**If Other, Specify**	**Type of Imaging Exam**	**If Other, Specify**	**Overall Assessment**
1	COVID Illness Visit 1	01SEP2020 (13)	31AUG2020	CHEST		OTHER	CTA	ABNORMAL

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	Patchy peripheral opacities are seen bilaterally likely reflecting an infectious process. Given the HX, is most likely covid infection. A concomitant/superimposed infectious process is possible.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	08SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	55	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159.6 cm	62.1 kg	24.4 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Smoker	Tobacco user	1978	Present
Hypertension	Hypertension	1985	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2000	Present
tummy tuck surgery	Abdominoplasty	2003	Past
low back syndrome	Back pain	2003	Present
hysterectomy complete	Hysterectomy	2003	Past
cervical spine arthritis	Spondylitis	2003	Present
Anxiety	Anxiety	04JUN2010	Present
hyperlipidemia	Hyperlipidaemia	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	16JUN2016	Present
diabetic peripheral neuropathy	Diabetic neuropathy	26JUN2016	Present
tenosynovitis of right hand	Tenosynovitis	2017	Past
nonalcoholic steatohepatitis	Non-alcoholic steatohepatitis	28NOV2018	Present
atherosclerotic aorta without aneurysmal dilatation	Aortic arteriosclerosis	2019	Present
gastritis	Gastritis	18APR2019	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	18APR2019	Present
hemorrhoids	Haemorrhoids	18APR2019	Present
disorder of vitamin D	Vitamin D abnormal	21FEB2020	Present
chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	06APR2020	Present
carpal tunnel surgery right hand	Carpal tunnel decompression	24JUN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	10:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	26AUG2020 (1)	26AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	26AUG2020 (1)	26AUG2020 (1)	SERUM	NEGATIVE
Visit 2	29SEP2020 (35)	29SEP2020 (35)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 08SEP2020 (14)/ 05SEP2020 (11)/ 26SEP2020 (32)	NO		Arthralgia
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	08SEP2020 (14)	COVID-19	08SEP2020 (14)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	08SEP2020 (14)	08SEP2020 (14)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	08SEP2020 (14)	08SEP2020 (14)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	08SEP2020 (14)	22SEP2020 (28)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		LABCORP COVID-19 RT-PCR TEST	
2	NEGATIVE		LABCORP COVID-19 RT-PCR TEST	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	08SEP2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	10SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	23	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.5 cm	67.2 kg	27.1 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillitis	Tonsillitis	2010	Past
tonsillectomy	Tonsillectomy	2012	Past
cesarean section	Caesarean section	24SEP2019	Past
head trauma	Head injury	08AUG2020	Past
injury of neck	Neck injury	08AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	10:53
2	BNT162b2	22SEP2020 (25)	10:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	29AUG2020 (1)	29AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	29AUG2020 (1)	29AUG2020 (1)	SERUM	NEGATIVE
Visit 2	22SEP2020 (25)	22SEP2020 (25)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06SEP2020 (9)/ 04SEP2020 (7)/ 18SEP2020 (21)	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06SEP2020 (9)	06SEP2020 (9)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	06SEP2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.5 cm	72.2 kg	21 kg/m2	06AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06AUG2020 (1)	12:57
2	BNT162b2	28AUG2020 (23)	14:11

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	06AUG2020 (1)	06AUG2020 (1)	SERUM	NEGATIVE
Visit 2	28AUG2020 (23)	28AUG2020 (23)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12AUG2020 (7)/ 10AUG2020 (5)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	12AUG2020 (7)	12AUG2020 (7)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	12AUG2020 (7)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	28	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	74.32 kg	26.8 kg/m2	03SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	10:17
2	Placebo	23SEP2020 (21)	09:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Fatigue	Fatigue	04SEP2020 (2)		05SEP2020 (3)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Seasonal Influenza Vaccine	INFLUENZA VACCINE	08OCT2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	03SEP2020 (1)	03SEP2020 (1)	SERUM	NEGATIVE
Visit 2	23SEP2020 (21)	23SEP2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (41)/ 11OCT2020 (39)/ ONGOING	NO		Dizziness
	NO		Fatigue
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	13OCT2020 (41)	COVID19	12OCT2020 (40)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	13OCT2020 (41)	13OCT2020 (41)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	13OCT2020 (41)	12OCT2020 (40)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13OCT2020 (41)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	32	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	102.91 kg	32.5 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Attention Deficit Disorder	Attention deficit hyperactivity disorder	2017	Present
Anxiety	Anxiety	11OCT2019	Present
Gerd	Gastrooesophageal reflux disease	22OCT2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16SEP2020 (1)	13:23

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16SEP2020 (1)	16SEP2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16SEP2020 (1)	16SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30OCT2020 (45)	30OCT2020 (45)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02OCT2020 (17)/ 01OCT2020 (16)/ 11OCT2020 (26)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02OCT2020 (17)	Covid 19 Infection	02OCT2020 (17)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02OCT2020 (17)	02OCT2020 (17)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02OCT2020 (17)	01OCT2020 (16)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		HOLOGIC PANTHER FUSION SARS-COV-2	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02OCT2020 (17)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Withdrawn	VACCINATION	02OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	73.18 kg	23.8 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	1989	Past
Seasonal Allergies	Seasonal allergy	1990	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2007	Present
Benign Prostatic Hyperplasia	Benign prostatic hyperplasia	2017	Past
Hyperlipidemia	Hyperlipidaemia	2017	Present
Internal Urethrotomy	Urethrotomy	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	10:47
2	Placebo	07OCT2020 (20)	10:34

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	18SEP2020 (1)	18SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18SEP2020 (1)	18SEP2020 (1)	SERUM	NEGATIVE
Visit 2	07OCT2020 (20)	07OCT2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 13OCT2020 (26)/ 11OCT2020 (24)/ ONGOING	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	13OCT2020 (26)	13OCT2020 (26)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	13OCT2020 (26)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	61.82 kg	22.6 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
wisdom teeth extraction	Wisdom teeth removal	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	12:34
2	Placebo	01OCT2020 (21)	14:55

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	11SEP2020 (1)	11SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11SEP2020 (1)	11SEP2020 (1)	SERUM	NEGATIVE
Visit 2	01OCT2020 (21)	01OCT2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 14OCT2020 (34)/ 05OCT2020 (25)/ ONGOING	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	14OCT2020 (34)	upper respiratory infection	14OCT2020 (34)	1	Upper respiratory tract infection

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	14OCT2020 (34)	14OCT2020 (34)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	14OCT2020 (34)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	103.36 kg	34.1 kg/m2	01OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sleep Apnea	Sleep apnoea syndrome	1995	Present
High Cholesterol	Blood cholesterol increased	1998	Present
Esophageal Reflux	Gastrooesophageal reflux disease	1998	Present
Hiatal Hernia	Hiatus hernia	1998	Present
Osteoarthritis	Osteoarthritis	2008	Present
Hypertension	Hypertension	2012	Present
Seasonal Allergies	Seasonal allergy	2012	Present
Urge Incontinence	Urge incontinence	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2013	Present
Chronic episodic diarrhea	Diarrhoea	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01OCT2020 (1)	15:55
2	BNT162b2	21OCT2020 (21)	10:51

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	01OCT2020 (1)	01OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	01OCT2020 (1)	01OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30OCT2020 (30)/ 27OCT2020 (27)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30OCT2020 (30)	01NOV2020 (32)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	30OCT2020 (30)	EMERGENCY ROOM	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		OTHER	YES	1	Williamson Country Agriculture Center

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	36	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	101.55 kg	31.2 kg/m2	24OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pericarditis	Pericarditis	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24OCT2020 (1)	09:57

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24OCT2020 (1)	24OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24OCT2020 (1)	24OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (11)/ 31OCT2020 (8)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03NOV2020 (11)	COVID-19	02NOV2020 (10)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03NOV2020 (11)	03NOV2020 (11)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	03NOV2020 (11)	02NOV2020 (10)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	Positive per Subject, pending formal subject lab paperwork to be uploaded	OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03NOV2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24OCT2020	
Withdrawn	VACCINATION	03NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	78.8 kg	22.8 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic sinusitis	Chronic sinusitis	1999	Past
Pertussis	Pertussis	JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19OCT2020 (1)	19:02

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19OCT2020 (1)	19OCT2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	19OCT2020 (1)	19OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26OCT2020 (8)/ 24OCT2020 (6)/ ONGOING	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	26OCT2020 (8)	Covid-19	26OCT2020 (8)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26OCT2020 (8)	26OCT2020 (8)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26OCT2020 (8)	26OCT2020 (8)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26OCT2020 (8)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		SPECIALIST	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	26OCT2020 (8)	26OCT2020 (8)	1	130 mmHg	76 mmHg	16 breaths/min	74 beats/min	98 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Withdrawn	VACCINATION	26OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176 cm	84.4 kg	27.2 kg/m2	21OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21OCT2020 (1)	10:41

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INFEC	Oral herpes	herpes labialis	07NOV2020 (18)	13:00	ONGOING	
2	INFEC	Rhinitis	rhinitis	02NOV2020 (13)	08:00	ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		1	N	N	Yes	NOT RELATED/OTHER: unknown	1	18	N
2		1	TC	N	Yes	NOT RELATED/OTHER: unknown	1	13	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21OCT2020 (1)	21OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21OCT2020 (1)	21OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 29OCT2020 (9)/ 26OCT2020 (6)/ 30OCT2020 (10)	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	29OCT2020 (9)	COVID-19 illness	11NOV2020 (22)	1	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	29OCT2020 (9)	29OCT2020 (9)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29OCT2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21OCT2020	
Withdrawn	VACCINATION	26OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	72 kg	26.1 kg/m2	28OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28OCT2020 (1)	11:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28OCT2020 (1)	28OCT2020 (1)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06NOV2020 (10)/ 04NOV2020 (8)/ ONGOING	YES	CHILLS	
	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06NOV2020 (10)	06NOV2020 (10)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	06NOV2020 (10)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28OCT2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	13NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	72.1 kg	26.5 kg/m2	02NOV2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02NOV2020 (1)	16:22

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Chest pain	Chest Pain	08NOV2020 (7)		09NOV2020 (8)		2	1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (09NOV2020)	NOT RELATED/OTHER: Harsh climate conditions	1	7	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	02NOV2020 (1)	02NOV2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	02NOV2020 (1)	02NOV2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 09NOV2020 (8)/ 07NOV2020 (6)/ 09NOV2020 (8)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	09NOV2020 (8)	09NOV2020 (8)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09NOV2020 (8)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02NOV2020	
Withdrawn	VACCINATION	10NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	Multiple	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	100.3 kg	33.5 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	13:52
2	Placebo	11SEP2020 (22)	11:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (22)	11SEP2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 14SEP2020 (25)/ 11SEP2020 (22)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	14SEP2020 (25)	14SEP2020 (25)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

No SARS-COV-2 Test - Local Laboratory

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	14SEP2020 (25)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	14SEP2020 (25)	14SEP2020 (25)	1	127 mmHg	80 mmHg	24 breaths/min	85 beats/min	96 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.7 cm	84.1 kg	25.8 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
onychomycosis	Onychomycosis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	12:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	25SEP2020 (1)	25SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	25SEP2020 (1)	25SEP2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (21)	15OCT2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30SEP2020 (6)/ 29SEP2020 (5)/ 02OCT2020 (8)	YES	CHILLS	
	YES	FEVER	
	NO		Malaise
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30SEP2020 (6)	COVID-19	30SEP2020 (6)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30SEP2020 (6)	30SEP2020 (6)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30SEP2020 (6)	29SEP2020 (5)	RESPIRATORY SECRETIONS	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	30SEP2020 (6)	OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	30SEP2020 (6)	30SEP2020 (6)	1	114 mmHg	64 mmHg	16 breaths/min	92 beats/min	96 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	29SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	88.1 kg	31.2 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	12:20

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	14OCT2020 (1)	14OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14OCT2020 (1)	14OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (21)/ 27OCT2020 (14)/ 01NOV2020 (19)	NO		Headache
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03NOV2020 (21)	COVID-19	30OCT2020 (17)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	03NOV2020 (21)	03NOV2020 (21)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location	Test Result
1	COVID Illness Visit 1	03NOV2020 (21)	30OCT2020 (17)	SWABBED MATERIAL	LOWER RESPIRATORY SYSTEM	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1		OTHER	NALT Unkown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03NOV2020 (21)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	03NOV2020 (21)	03NOV2020 (21)	1	120 mmHg	70 mmHg	12 breaths/min	83 beats/min	97 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Withdrawn	VACCINATION	27OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.6 cm	119.3 kg	35 kg/m2	17OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2005	Present
bariatric surgery	Metabolic surgery	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17OCT2020 (1)	10:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	17OCT2020 (1)	17OCT2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	17OCT2020 (1)	17OCT2020 (1)	SERUM	NEGATIVE
Visit 2	07NOV2020 (22)	07NOV2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 20OCT2020 (4)/ 18OCT2020 (2)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	20OCT2020 (4)	20OCT2020 (4)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	20OCT2020 (4)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	20OCT2020 (4)	20OCT2020 (4)	1	104 mmHg	72 mmHg	16 breaths/min	72 beats/min	96 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17OCT2020	
Withdrawn	VACCINATION	18OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	74.75 kg	26.5 kg/m2	11AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	14:07

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	11AUG2020 (1)	11AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	11AUG2020 (1)	11AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19AUG2020 (9)/ 18AUG2020 (8)/ 18AUG2020 (8)	YES	FEVER	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	19AUG2020 (9)	SARSCV-2 infection	19AUG2020 (9)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	19AUG2020 (9)	19AUG2020 (9)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	19AUG2020 (9)	19AUG2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19AUG2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	24SEP2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	24SEP2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	78.05 kg	28 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Glaucoma	Glaucoma	01AUG1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	12:47

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	12AUG2020 (1)	12AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	12AUG2020 (1)	12AUG2020 (1)	SERUM	NEGATIVE
Visit 2	19SEP2020 (39)	19SEP2020 (39)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27AUG2020 (16)/ 26AUG2020 (15)/ 15SEP2020 (35)	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nausea
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	27AUG2020 (16)	SARS.CoV.2 infection	27AUG2020 (16)	4	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	27AUG2020 (16)	27AUG2020 (16)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	27AUG2020 (16)	27AUG2020 (16)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	27AUG2020 (16)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	27AUG2020 (16)	HOSPITALIZATION STATUS	HOSPITAL	29AUG2020 (18)	07SEP2020 (27)

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	27AUG2020 (16)		CHEST		X-RAY	NA	UNKNOWN	

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	19SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Withdrawn	FOLLOW-UP	19SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	31	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	161 kg	48.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	01JUN2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	15:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	13AUG2020 (1)	13AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13AUG2020 (1)	13AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (64)	15OCT2020 (64)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19AUG2020 (7)/ 17AUG2020 (5)/ 30AUG2020 (18)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	19AUG2020 (7)	COVID-19	19AUG2020 (7)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	19AUG2020 (7)	19AUG2020 (7)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	19AUG2020 (7)	19AUG2020 (7)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19AUG2020 (7)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Withdrawn	VACCINATION	19AUG2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	75 kg	26.3 kg/m2	14AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	12:45

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Conjunctivitis	Conjunctivitis	20AUG2020 (7)	09:00	21AUG2020 (8)	21:35	2

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (21AUG2020)	NOT RELATED/OTHER: UNKNOWN	1	7	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	14AUG2020 (1)	14AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14AUG2020 (1)	14AUG2020 (1)	SERUM	NEGATIVE
Visit 2	22SEP2020 (40)	22SEP2020 (40)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 29AUG2020 (16)/ 29AUG2020 (16)/ 10OCT2020 (58)	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	29AUG2020 (16)	COVID-19	29AUG2020 (16)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	29AUG2020 (16)	29AUG2020 (16)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	29AUG2020 (16)	29AUG2020 (16)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	29AUG2020 (16)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Withdrawn	VACCINATION	22SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	50 kg	18.1 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Celiac disease	Coeliac disease	09JUN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	14:38

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	15AUG2020 (1)	15AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15AUG2020 (1)	15AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 12SEP2020 (29)/ 31AUG2020 (17)/ 18SEP2020 (35)	NO		Arthralgia
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	12SEP2020 (29)	covid-19	01SEP2020 (18)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	12SEP2020 (29)	12SEP2020 (29)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	12SEP2020 (29)	01SEP2020 (18)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT Unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	12SEP2020 (29)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Withdrawn	VACCINATION	17OCT2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	17OCT2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	28	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	98.5 kg	32.9 kg/m2	15AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Amoxicillin Allergy	Drug hypersensitivity	12JUN1993	Present
Gestational Hypertention	Gestational hypertension	04APR2016	Past
Premature birth. (Delivery - Gestational age 35 weeks)	Premature baby	04APR2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	16:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	15AUG2020 (1)	15AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15AUG2020 (1)	15AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28AUG2020 (14)/ 24AUG2020 (10)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28AUG2020 (14)	COVID 19 illness	19SEP2020 (36)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28AUG2020 (14)	28AUG2020 (14)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	28AUG2020 (14)	28AUG2020 (14)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28AUG2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Withdrawn	VACCINATION	28AUG2020	NO LONGER MEETS ELIGIBILITY CRITERIA
Withdrawn	FOLLOW-UP	02NOV2020	LOST TO FOLLOW-UP

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	21	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	63 kg	22.3 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	19:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	15AUG2020 (1)	15AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15AUG2020 (1)	15AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 18AUG2020 (4)/ 17AUG2020 (3)/ 07SEP2020 (24)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	18AUG2020 (4)	COVID-19	18AUG2020 (4)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	18AUG2020 (4)	18AUG2020 (4)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	18AUG2020 (4)	18AUG2020 (4)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	18AUG2020 (4)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15AUG2020	
Withdrawn	VACCINATION	10SEP2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	10SEP2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	86 kg	31.2 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16AUG2020 (1)	11:51

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	VASC	Hypertension	arterial hypertension	27AUG2020 (12)	19:25	30AUG2020 (15)	15:03	4	1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (30AUG2020)	NOT RELATED/OTHER: arterial hypertension	1	12	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	07SEP2020 (23)	07SEP2020 (23)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 24AUG2020 (9)/ 23AUG2020 (8)/ 25AUG2020 (10)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	24AUG2020 (9)	SARSCV-2 infection	24AUG2020 (9)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	24AUG2020 (9)	24AUG2020 (9)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	24AUG2020 (9)	24AUG2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	24AUG2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16AUG2020	
Withdrawn	VACCINATION	07SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	43.3 kg	17.8 kg/m2	16AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arterial hypertension	Hypertension	01MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	12:55

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (37)	21SEP2020 (37)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30AUG2020 (15)/ 28AUG2020 (13)/ 13SEP2020 (29)	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30AUG2020 (15)	COVID-19	30AUG2020 (15)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30AUG2020 (15)	30AUG2020 (15)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30AUG2020 (15)	30AUG2020 (15)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	30AUG2020 (15)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Withdrawn	VACCINATION	21SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	78 kg	24.6 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	13:55

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (37)	21SEP2020 (37)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 24AUG2020 (9)/ 21AUG2020 (6)/ 10SEP2020 (26)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	24AUG2020 (9)	COVID 19 disease	31AUG2020 (16)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	24AUG2020 (9)	24AUG2020 (9)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	24AUG2020 (9)	24AUG2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	24AUG2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Withdrawn	VACCINATION	21SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	25	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	95.6 kg	31.6 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16AUG2020 (1)	16:51

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	13SEP2020 (29)	13SEP2020 (29)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 27AUG2020 (12)/ 25AUG2020 (10)/ 15SEP2020 (31)	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	27AUG2020 (12)	COVID-19 Illness	27AUG2020 (12)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	27AUG2020 (12)	27AUG2020 (12)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	27AUG2020 (12)	27AUG2020 (12)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	27AUG2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Withdrawn	VACCINATION	13SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	20	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	73.55 kg	26.7 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16AUG2020 (1)	17:25

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	16AUG2020 (1)	16AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16AUG2020 (1)	16AUG2020 (1)	SERUM	NEGATIVE
Visit 2	24SEP2020 (40)	24SEP2020 (40)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10SEP2020 (26)/ 08SEP2020 (24)/ 20SEP2020 (36)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	10SEP2020 (26)	covid-19	10SEP2020 (26)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	10SEP2020 (26)	10SEP2020 (26)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	10SEP2020 (26)	10SEP2020 (26)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10SEP2020 (26)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Withdrawn	VACCINATION	24SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	72 kg	25.8 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial Hypertension	Hypertension	20JAN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	11:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	18AUG2020 (1)	18AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18AUG2020 (1)	18AUG2020 (1)	SERUM	NEGATIVE
Visit 2	24SEP2020 (38)	24SEP2020 (38)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27AUG2020 (10)/ 25AUG2020 (8)/ 30AUG2020 (13)	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	27AUG2020 (10)	Covid-19 illness	27AUG2020 (10)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	27AUG2020 (10)	27AUG2020 (10)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	27AUG2020 (10)	27AUG2020 (10)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	27AUG2020 (10)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Withdrawn	VACCINATION	24SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	73.55 kg	28.4 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	01JAN1981	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	19:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	18AUG2020 (1)	18AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	18AUG2020 (1)	18AUG2020 (1)	SERUM	NEGATIVE
Visit 2	24SEP2020 (38)	24SEP2020 (38)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26AUG2020 (9)/ 20AUG2020 (3)/ 27AUG2020 (10)	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	26AUG2020 (9)	26AUG2020 (9)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	26AUG2020 (9)	26AUG2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26AUG2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	26AUG2020 (9)	HOSPITALIZATION STATUS	HOSPITAL	20AUG2020 (3)	27AUG2020 (10)

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	26AUG2020 (9)	20AUG2020	CHEST		X-RAY	NA	ABNORMAL	bilateral pulmonary infiltrates

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Withdrawn	VACCINATION	24SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	71.5 kg	25.6 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	15:49

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	EAR	Vertigo	vertiginous syndrome	08SEP2020 (21)	08:00	21SEP2020 (34)	09:00	14
2	EAR	Vertigo	vertiginous syndrome	20SEP2020 (33)	14:00	16OCT2020 (59)	08:00	27

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (21SEP2020)	NOT RELATED/OTHER: unknown	1	21	N
2	2	TC	N	Resolved (16OCT2020)	NOT RELATED/OTHER: Physical effort	1	33	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19OCT2020 (62)/ 18OCT2020 (61)/ ONGOING	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	19OCT2020 (62)	COVID 19 infection	19OCT2020 (62)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	19OCT2020 (62)	19OCT2020 (62)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	19OCT2020 (62)	19OCT2020 (62)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	19OCT2020 (62)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	18OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	40	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	67.35 kg	24.1 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	17:20

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE
Visit 2	19SEP2020 (32)	19SEP2020 (32)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03SEP2020 (16)/ 02SEP2020 (15)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03SEP2020 (16)	covid-19	03SEP2020 (16)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03SEP2020 (16)	03SEP2020 (16)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	03SEP2020 (16)	03SEP2020 (16)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	03SEP2020 (16)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	19SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	22	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	61 kg	23 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	23JUL2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	16:37

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE
Visit 2	25SEP2020 (38)	25SEP2020 (38)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27AUG2020 (9)/ 24AUG2020 (6)/ 23SEP2020 (36)	NO		Asthenia
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	27AUG2020 (9)	COVID-19	28AUG2020 (10)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	27AUG2020 (9)	27AUG2020 (9)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	27AUG2020 (9)	27AUG2020 (9)	RESPIRATORY SECRETIONS	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	27AUG2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	25SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	66.4 kg	25 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	01FEB2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	18:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE
Visit 2	13SEP2020 (26)	13SEP2020 (26)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 30AUG2020 (12)/ 27AUG2020 (9)/ 07SEP2020 (20)	NO		Abdominal pain
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	30AUG2020 (12)	COVID 19	30AUG2020 (12)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	30AUG2020 (12)	30AUG2020 (12)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	30AUG2020 (12)	30AUG2020 (12)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	30AUG2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	13SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	79.5 kg	25.1 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
myocardial infarction	Myocardial infarction	24DEC2012	Past
stent implant	Stent placement	25DEC2012	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	13:51

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16SEP2020 (28)	16SEP2020 (28)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02SEP2020 (14)/ 01SEP2020 (13)/ 13SEP2020 (25)	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	02SEP2020 (14)	covid-19	14SEP2020 (26)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	02SEP2020 (14)	02SEP2020 (14)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	02SEP2020 (14)	02SEP2020 (14)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02SEP2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	16SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	73.75 kg	24.9 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	17:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (56)	14OCT2020 (56)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11SEP2020 (23)/ 11SEP2020 (23)/ 23SEP2020 (35)	NO		Asthenia
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11SEP2020 (23)	COVID disease with nonspecific symptoms	11SEP2020 (23)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	11SEP2020 (23)	11SEP2020 (23)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11SEP2020 (23)	11SEP2020 (23)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11SEP2020 (23)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	14OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	97 kg	31.7 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Psoriasis	Psoriasis	02MAR2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	18:11
2	Placebo	11SEP2020 (23)	11:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	20AUG2020 (1)	20AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	20AUG2020 (1)	20AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (23)	11SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19SEP2020 (31)/ 14SEP2020 (26)/ 14NOV2020 (87)	YES	DIARRHEA	
	YES	FEVER	
	NO		Fatigue
	NO		Myalgia
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	19SEP2020 (31)	covid-19	20SEP2020 (32)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	19SEP2020 (31)	19SEP2020 (31)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	19SEP2020 (31)	19SEP2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19SEP2020 (31)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	36	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	76 kg	26.3 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Gilbert's syndrome	Gilbert's syndrome	12FEB2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	10:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	29SEP2020 (40)	29SEP2020 (40)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09SEP2020 (20)/ 06SEP2020 (17)/ 24SEP2020 (35)	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09SEP2020 (20)	SarsCoV2 infection	09SEP2020 (20)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	09SEP2020 (20)	09SEP2020 (20)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	09SEP2020 (20)	09SEP2020 (20)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	09SEP2020 (20)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	09SEP2020 (20)	21SEP2020 (32)	Alkaline Phosphatase	0.97	ukat/L	0.67	2.5
			Alanine Aminotransferase	1.18357	ukat/L	0	0.91685
			Aspartate Aminotransferase	0.60012	ukat/L	0.08335	0.56678
			Bilirubin	32.7	umol/L	3.4	17.1
			Creatinine	97.2	umol/L	61.9	114.9

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	09SEP2020 (20)	21SEP2020 (32)	Basophils	1	%	0	2
			Eosinophils	2	%	1	3
			Hematocrit	0.47	L/L	0.4	0.54
			Hemoglobin	162	g/L	140	180
			Lymphocytes	35	%	18	42
			Monocytes	8	%	2	11
			Neutrophils	54	%	50	70
			Platelets	358.4	10^9/L	140	425
			Erythrocytes	5.35	10^12/L	4.6	6
			Leukocytes	7.25	10^9/L	4.5	11.5

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	09SEP2020 (20)	22SEP2020	CHEST		X-RAY	NA	NORMAL	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	29SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	73.95 kg	27.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	10:53

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	24SEP2020 (35)	24SEP2020 (35)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 10SEP2020 (21)/ 08SEP2020 (19)/ ONGOING	NO		Anosmia
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	10SEP2020 (21)	COVID-19	10SEP2020 (21)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	10SEP2020 (21)	10SEP2020 (21)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	10SEP2020 (21)	10SEP2020 (21)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	10SEP2020 (21)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	24SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	80.5 kg	25.4 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	11:46
2	BNT162b2	28SEP2020 (39)	12:25

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (39)	28SEP2020 (39)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 08SEP2020 (19)/ 06SEP2020 (17)/ 08SEP2020 (19)	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	08SEP2020 (19)	08SEP2020 (19)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	08SEP2020 (19)	08SEP2020 (19)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	08SEP2020 (19)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	50	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	67 kg	20.9 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Psoriasis	Psoriasis	01MAR1984	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	19:20

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (21)	10SEP2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27AUG2020 (7)/ 22AUG2020 (2)/ 30AUG2020 (10)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	27AUG2020 (7)	27AUG2020 (7)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	27AUG2020 (7)	27AUG2020 (7)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	27AUG2020 (7)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	10SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	41	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	101 kg	31.5 kg/m2	22AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	10:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22AUG2020 (1)	22AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22AUG2020 (1)	22AUG2020 (1)	SERUM	NEGATIVE
Visit 2	13SEP2020 (23)	13SEP2020 (23)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28AUG2020 (7)/ 26AUG2020 (5)/ 31AUG2020 (10)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28AUG2020 (7)	Covid 19 infection	28AUG2020 (7)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28AUG2020 (7)	28AUG2020 (7)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	28AUG2020 (7)	28AUG2020 (7)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	28AUG2020 (7)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Withdrawn	VACCINATION	13SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	108.7 kg	30.8 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral Orchidectomy	Bilateral orchidectomy	30AUG1997	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	10:02

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22AUG2020 (1)	22AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22AUG2020 (1)	22AUG2020 (1)	SERUM	NEGATIVE
Visit 2	25SEP2020 (35)	25SEP2020 (35)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03SEP2020 (13)/ 30AUG2020 (9)/ 19SEP2020 (29)	NO		Dysgeusia
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03SEP2020 (13)	COVID-19 illness	03SEP2020 (13)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	03SEP2020 (13)	03SEP2020 (13)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	03SEP2020 (13)	03SEP2020 (13)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03SEP2020 (13)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Withdrawn	VACCINATION	25SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	57	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	70 kg	27.3 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Dyslipidemia	Dyslipidaemia	03JUL2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	11:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22AUG2020 (1)	22AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22AUG2020 (1)	22AUG2020 (1)	SERUM	NEGATIVE
Visit 2	16OCT2020 (56)	16OCT2020 (56)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25SEP2020 (35)/ 03SEP2020 (13)/ 28SEP2020 (38)	YES	FEVER	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	25SEP2020 (35)	Pneumonia due to COVID-19 disease	11SEP2020 (21)	2	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	25SEP2020 (35)	25SEP2020 (35)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	25SEP2020 (35)	11SEP2020 (21)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	25SEP2020 (35)	25SEP2020 (35)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unkown
2	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	25SEP2020 (35)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details					
Visit	**Visit Date (Study Day)**	**Hospitalization Category**	**Hospitalization Term**	**Admission Date (Study Day)**	**Discharge Date or Ongoing (Study Day)**
COVID Illness Visit 1	25SEP2020 (35)	HOSPITALIZATION STATUS	HOSPITAL	11SEP2020 (21)	14SEP2020 (24)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	25SEP2020 (35)	11SEP2020 (21)	Alkaline Phosphatase	0.95	ukat/L	0.5	2
			Alanine Aminotransferase	0.55011	ukat/L	0	0.8335
			Aspartate Aminotransferase	0.43342	ukat/L	0	0.8335
			Bilirubin	8.4	umol/L	5.1	20.5
			Creatinine	85.7	umol/L	79.6	114.9
			C Reactive Protein	12.4	mg/L	0	5
			Urea Nitrogen	10.36	mmol/L	4.64	16.07

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	25SEP2020 (35)	11SEP2020 (21)	Basophils	0,0228	10^9/L	.	.
			Eosinophils	0,0228	10^9/L	.	.
			Hematocrit	0.46	L/L	0.37	0.53
			Hemoglobin	150	g/L	130	175
			Lymphocytes	0,9291	10^9/L	.	.
			Monocytes	0,5301	10^9/L	.	.
			Neutrophils	4,195.2	10^9/L	.	.
			Platelets	178	10^9/L	150	440
			Erythrocytes	5	10^12/L	4.5	5.9
			Leukocytes	5.7	10^9/L	3.8	10.6

Vital Signs - COVID-19

No Vital Signs - COVID-19

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	**Visit**	**Visit Date (Study Day)**	**Date of Assessment**	**Location of Assessment**	**If Other, Specify**	**Type of Imaging Exam**	**If Other, Specify**	**Overall Assessment**
1	COVID Illness Visit 1	25SEP2020 (35)	11SEP2020	CHEST		CT SCAN	NA	ABNORMAL

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	Multiple rounded interstitial infiltrates in both upper lobes, predominantly in the upper right lobe, in the periphery of the ipsilateral lower lobe, lateral segment and lower lingular segment

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Withdrawn	VACCINATION	06OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	90.8 kg	32.2 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	01JUN2010	Present
Hyperuricemia	Hyperuricaemia	01JUN2012	Present
Dyslipidemia	Dyslipidaemia	01AUG2012	Present
Obstruction 70% Anterior descending artery	Arterial occlusive disease	30JUL2015	Present
Anterior coronary descending artery stent placement	Coronary arterial stent insertion	30SEP2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	11:07

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22AUG2020 (1)	22AUG2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	22AUG2020 (1)	22AUG2020 (1)	SERUM	NEGATIVE
Visit 2	21SEP2020 (31)	21SEP2020 (31)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04SEP2020 (14)/ 31AUG2020 (10)/ 10SEP2020 (20)	NO		Asthenia
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04SEP2020 (14)	covid 19	04SEP2020 (14)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	04SEP2020 (14)	04SEP2020 (14)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	04SEP2020 (14)	02SEP2020 (12)	RESPIRATORY SECRETIONS	NASOPHARYNX
2	COVID Illness Visit 1	04SEP2020 (14)	04SEP2020 (14)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown
2	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	04SEP2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	04SEP2020 (14)	03SEP2020	CHEST		CT SCAN	NA	NOT EVALUABLE	

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22AUG2020	
Withdrawn	VACCINATION	21SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	72.4 kg	21.9 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	01JAN2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	11:55

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22AUG2020 (1)	22AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	22AUG2020 (1)	22AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (24)	14SEP2020 (24)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25AUG2020 (4)/ 24AUG2020 (3)/ 01SEP2020 (11)	YES	NEW OR INCREASED SORE THROAT	
COVID Illness Visit 2 / 11NOV2020 (82)/ 05NOV2020 (76)/ ONGOING	NO		Asthenia
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	25AUG2020 (4)	pharyngitis due to COVID-19	25AUG2020 (4)	1	COVID-19
COVID Illness Visit 2	11NOV2020 (82)	COVID-19 DISEASE	06NOV2020 (77)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	25AUG2020 (4)	25AUG2020 (4)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	11NOV2020 (82)	11NOV2020 (82)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	25AUG2020 (4)	25AUG2020 (4)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE
2	COVID Illness Visit 2	11NOV2020 (82)	07NOV2020 (78)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE
3	COVID Illness Visit 2	11NOV2020 (82)	11NOV2020 (82)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	swabbed performed by the Hospital Aleman	OTHER	NALT unknown
3		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	25AUG2020 (4)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	11NOV2020 (82)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details					
Visit	**Visit Date (Study Day)**	**Hospitalization Category**	**Hospitalization Term**	**Admission Date (Study Day)**	**Discharge Date or Ongoing (Study Day)**
COVID Illness Visit 2	11NOV2020 (82)	HOSPITALIZATION STATUS	HOSPITAL	06NOV2020 (77)	09NOV2020 (80)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 2	11NOV2020 (82)	07NOV2020	CHEST		CT SCAN	NA	NORMAL	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Withdrawn	VACCINATION	14SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	81 kg	31.2 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	05AUG2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	22AUG2020 (1)	16:53

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	22AUG2020 (1)	22AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	22AUG2020 (1)	22AUG2020 (1)	SERUM	NEGATIVE
Visit 2	10SEP2020 (20)	10SEP2020 (20)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25AUG2020 (4)/ 24AUG2020 (3)/ 24AUG2020 (3)	YES	NEW LOSS OF TASTE OR SMELL	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	25AUG2020 (4)	COVID-19 illness	08OCT2020 (48)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	25AUG2020 (4)	25AUG2020 (4)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	25AUG2020 (4)	25AUG2020 (4)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	25AUG2020 (4)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 1	25AUG2020 (4)	28AUG2020	CHEST		X-RAY	NA	NORMAL	

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	22AUG2020	
Withdrawn	VACCINATION	10SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	86.45 kg	25.8 kg/m2	23AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Epilepsy	Epilepsy	23AUG2006	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	23AUG2020 (1)	10:10

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Pyrexia	Febrile Syndrome	25AUG2020 (3)	18:15	25AUG2020 (3)	19:40

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	3	TC	N	Resolved (25AUG2020)	Study Treatment	1	3	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23AUG2020 (1)	23AUG2020 (1)	SERUM	NEGATIVE
Visit 2	11SEP2020 (20)	11SEP2020 (20)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27AUG2020 (5)/ 25AUG2020 (3)/ 30AUG2020 (8)	YES	FEVER	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	27AUG2020 (5)	COVID-19	27AUG2020 (5)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	27AUG2020 (5)	27AUG2020 (5)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	27AUG2020 (5)	27AUG2020 (5)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	27AUG2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23AUG2020	
Withdrawn	VACCINATION	11SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	80.8 kg	28.6 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	11:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Rhinitis allergic	allergic rhinitis	04OCT2020 (43)	08:00	05OCT2020 (44)	20:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (05OCT2020)	NOT RELATED/OTHER: Unknown	1	43	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	23AUG2020 (1)	23AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (23)	14SEP2020 (23)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 24AUG2020 (2)/ 24AUG2020 (2)/ 31AUG2020 (9)	YES	NEW LOSS OF TASTE OR SMELL	
COVID Illness Visit 2 / 14OCT2020 (53)/ 04OCT2020 (43)/ 05OCT2020 (44)	NO		Rhinitis

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	24AUG2020 (2)	COVID-19 illness	24AUG2020 (2)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	24AUG2020 (2)	24AUG2020 (2)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	24AUG2020 (2)	24AUG2020 (2)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	24AUG2020 (2)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	14OCT2020 (53)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Withdrawn	VACCINATION	14SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	120 kg	36.6 kg/m2	23AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arterial hypertension	Hypertension	04FEB2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	12:42

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 2	24SEP2020 (33)	24SEP2020 (33)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28AUG2020 (6)/ 27AUG2020 (5)/ 18SEP2020 (27)	YES	FEVER	
	NO		Fatigue
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28AUG2020 (6)	SARS.CoV.2 infection	28AUG2020 (6)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28AUG2020 (6)	28AUG2020 (6)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	28AUG2020 (6)	28AUG2020 (6)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28AUG2020 (6)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23AUG2020	
Withdrawn	VACCINATION	24SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	72.9 kg	25.2 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	16:05

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 2	09OCT2020 (48)	09OCT2020 (48)	NASAL_SWAB	POSITIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 05SEP2020 (14)/ 04SEP2020 (13)/ 07SEP2020 (16)	NO		Asthenia
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
COVID Illness Visit 2 / 14NOV2020 (84)/ 30OCT2020 (69)/ 12NOV2020 (82)	YES	DIARRHEA	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	05SEP2020 (14)	COVID-19	05SEP2020 (14)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	05SEP2020 (14)	05SEP2020 (14)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	05SEP2020 (14)	05SEP2020 (14)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	14NOV2020 (84)	14NOV2020 (84)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	05SEP2020 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	14NOV2020 (84)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23AUG2020	
Withdrawn	VACCINATION	09OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	62.5 kg	25.4 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	17:03

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE
Visit 2	28SEP2020 (36)	28SEP2020 (36)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04SEP2020 (12)/ 03SEP2020 (11)/ 18SEP2020 (26)	NO		Asthenia
	YES	CHILLS	
	NO		Headache
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04SEP2020 (12)	SARS.CoV.2 infection	04SEP2020 (12)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	04SEP2020 (12)	04SEP2020 (12)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	04SEP2020 (12)	04SEP2020 (12)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	04SEP2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	28SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	64.5 kg	24 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	17:09

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE
Visit 2	18SEP2020 (26)	18SEP2020 (26)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01SEP2020 (9)/ 31AUG2020 (8)/ 10SEP2020 (18)	YES	DIARRHEA	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01SEP2020 (9)	covid-19	01SEP2020 (9)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	01SEP2020 (9)	01SEP2020 (9)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	01SEP2020 (9)	01SEP2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	01SEP2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	18SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	115 kg	37.6 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal bronchospasms	Bronchospasm	01AUG1990	Present
Sleep apnea	Sleep apnoea syndrome	01AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	18:33

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	24AUG2020 (1)	24AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24AUG2020 (1)	24AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (52)	14OCT2020 (52)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09SEP2020 (17)/ 06SEP2020 (14)/ 03OCT2020 (41)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	09SEP2020 (17)	COVID-19	10SEP2020 (18)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	09SEP2020 (17)	09SEP2020 (17)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	09SEP2020 (17)	09SEP2020 (17)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	09SEP2020 (17)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		SPECIALIST	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	14OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	92 kg	29.4 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	07AUG2013	Present
Type 2 diabetes	Type 2 diabetes mellitus	06AUG2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	17:32

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	26AUG2020 (1)	26AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	26AUG2020 (1)	26AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (21)	15SEP2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02SEP2020 (8)/ 29AUG2020 (4)/ 30SEP2020 (36)	NO		Fatigue
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02SEP2020 (8)	COVID-19 illness	09SEP2020 (15)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02SEP2020 (8)	02SEP2020 (8)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02SEP2020 (8)	02SEP2020 (8)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	02SEP2020 (8)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	15SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1987	33	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158 cm	50 kg	20 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	18:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	26AUG2020 (1)	26AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	26AUG2020 (1)	26AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29AUG2020 (4)/ 27AUG2020 (2)/ 29AUG2020 (4)	NO		Asthenia
	YES	FEVER	
	NO		Rhinitis

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	29AUG2020 (4)	COVID-19	29AUG2020 (4)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	29AUG2020 (4)	29AUG2020 (4)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	29AUG2020 (4)	29AUG2020 (4)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	29AUG2020 (4)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	21SEP2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	21SEP2020	WITHDRAWAL BY SUBJECT

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	36	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	66 kg	23.7 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	14:42
2	Placebo	18SEP2020 (23)	10:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Fatigue	fatigue	19SEP2020 (24)	00:00	21SEP2020 (26)	13:00	3
2	GENRL	Injection site pain	Injection site pain	19SEP2020 (24)	13:00	21SEP2020 (26)	13:00	3
3	MUSC	Myalgia	Generalized muscle pain	19SEP2020 (24)	13:00	21SEP2020 (26)	13:00	3
4	RESP	Rhinorrhoea	rhinorrhea	23SEP2020 (28)	10:00	03OCT2020 (38)	20:00	11

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (21SEP2020)	Study Treatment	2	2	N
2	1	N	N	Resolved (21SEP2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (21SEP2020)	Study Treatment	2	2	N
4	1	TC	N	Resolved (03OCT2020)	NOT RELATED/OTHER: unknown	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	POSITIVE
Visit 2	18SEP2020 (23)	18SEP2020 (23)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06OCT2020 (41)/ 03OCT2020 (38)/ 15OCT2020 (50)	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06OCT2020 (41)	covid 19 infection	06OCT2020 (41)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06OCT2020 (41)	06OCT2020 (41)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	06OCT2020 (41)	06OCT2020 (41)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	06OCT2020 (41)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	52.8 kg	19.2 kg/m2	27AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	13:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (20)	15SEP2020 (20)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 31AUG2020 (5)/ 28AUG2020 (2)/ 09SEP2020 (14)	YES	FEVER	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
COVID Illness Visit 2 / 13OCT2020 (48)/ 09OCT2020 (44)/ 15OCT2020 (50)	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	31AUG2020 (5)	covid-19 infection	30AUG2020 (4)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	31AUG2020 (5)	31AUG2020 (5)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	13OCT2020 (48)	13OCT2020 (48)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	31AUG2020 (5)	31AUG2020 (5)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 2	13OCT2020 (48)	13OCT2020 (48)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	31AUG2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	13OCT2020 (48)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Withdrawn	VACCINATION	15SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	100.25 kg	32.7 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial Hypertension	Hypertension	20MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	10:05

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28AUG2020 (1)	28AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	28AUG2020 (1)	28AUG2020 (1)	SERUM	NEGATIVE
Visit 2	18SEP2020 (22)	18SEP2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 04SEP2020 (8)/ 03SEP2020 (7)/ 04OCT2020 (38)	NO		Asthenia
	NO		Dizziness
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	04SEP2020 (8)	COVID-19	04SEP2020 (8)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	04SEP2020 (8)	04SEP2020 (8)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	04SEP2020 (8)	04SEP2020 (8)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	04SEP2020 (8)	03OCT2020 (37)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	04SEP2020 (8)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Withdrawn	VACCINATION	18SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	93.64 kg	31.3 kg/m2	06SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	2015	Present
Hypertension	Hypertension	2015	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2015	Present
Prostate Cancer	Prostate cancer	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06SEP2020 (1)	09:32

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	06SEP2020 (1)	06SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	06SEP2020 (1)	06SEP2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 24SEP2020 (19)/ 23SEP2020 (18)/ 03OCT2020 (28)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	24SEP2020 (19)	COVID-19 URI	23SEP2020 (18)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	24SEP2020 (19)	23SEP2020 (18)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	24SEP2020 (19)	23SEP2020 (18)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	24SEP2020 (19)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	24SEP2020 (19)	23SEP2020 (18)	1					96 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06SEP2020	
Withdrawn	VACCINATION	23SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	54.55 kg	20.6 kg/m2	16OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	09:46

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16OCT2020 (1)	16OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16OCT2020 (1)	16OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27OCT2020 (12)/ 23OCT2020 (8)/ ONGOING	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	27OCT2020 (12)	Covid 19 infection	24OCT2020 (9)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	27OCT2020 (12)	26OCT2020 (11)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	27OCT2020 (12)	24OCT2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE	performed at Walgreens	OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	27OCT2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	24OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	70.45 kg	27.5 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	1986	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16OCT2020 (1)	10:07

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	16OCT2020 (1)	16OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	16OCT2020 (1)	16OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22OCT2020 (7)/ 21OCT2020 (6)/ ONGOING	YES	CHILLS	
	NO		Headache
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	22OCT2020 (7)	COVID - 19	22OCT2020 (7)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	22OCT2020 (7)	22OCT2020 (7)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	22OCT2020 (7)	22OCT2020 (7)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	22OCT2020 (7)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	22OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.5 cm	84.5 kg	25.9 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	09:32

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19AUG2020 (1)	19AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19AUG2020 (1)	19AUG2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 06SEP2020 (19)/ 30AUG2020 (12)/ 13SEP2020 (26)	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	NO		Nasal obstruction

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	06SEP2020 (19)	Covid-19	14SEP2020 (27)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	06SEP2020 (19)	06SEP2020 (19)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	06SEP2020 (19)	08SEP2020 (21)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	06SEP2020 (19)	18SEP2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		OTHER	NALT unknown
2	POSITIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	06SEP2020 (19)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	30AUG2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	36.8 kg	12 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinosinusitis	Allergic sinusitis	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	15:51

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	15SEP2020 (1)	15SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15SEP2020 (1)	15SEP2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (30)	14OCT2020 (30)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29SEP2020 (15)/ 27SEP2020 (13)/ 15OCT2020 (31)	NO		Gingival bleeding
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	29SEP2020 (15)	Covid-19 illness	05OCT2020 (21)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	29SEP2020 (15)	29SEP2020 (15)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	29SEP2020 (15)	30SEP2020 (16)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	29SEP2020 (15)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Withdrawn	VACCINATION	27SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	106.8 kg	34.9 kg/m2	15SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15SEP2020 (1)	16:46

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	15SEP2020 (1)	15SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15SEP2020 (1)	15SEP2020 (1)	SERUM	NEGATIVE
Visit 2	16OCT2020 (32)	16OCT2020 (32)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 01OCT2020 (17)/ 18SEP2020 (4)/ 05OCT2020 (21)	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01OCT2020 (17)	Covid-19	01OCT2020 (17)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	01OCT2020 (17)	01OCT2020 (17)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	01OCT2020 (17)	23SEP2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	01OCT2020 (17)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Withdrawn	VACCINATION	18SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1997	23	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
193 cm	109.7 kg	29.5 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	10:57
2	BNT162b2	09OCT2020 (22)	10:44

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	18SEP2020 (1)	18SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	18SEP2020 (1)	18SEP2020 (1)	SERUM	POSITIVE
Visit 2	09OCT2020 (22)	09OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 23OCT2020 (36)/ 22OCT2020 (35)/ 24OCT2020 (37)	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	23OCT2020 (36)	23OCT2020 (36)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	23OCT2020 (36)	26OCT2020 (39)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	23OCT2020 (36)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	13NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1980	39	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	94.5 kg	29.2 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	1990	Present
Dipyrone allergy	Drug hypersensitivity	2000	Present
Non-steroidal anti-inflammatory allergy	Drug hypersensitivity	2000	Present
Migraine	Migraine	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	17:51
2	Placebo	04NOV2020 (21)	15:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	15OCT2020 (1)	15OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	15OCT2020 (1)	15OCT2020 (1)	SERUM	NEGATIVE
Visit 2	04NOV2020 (21)	04NOV2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 08NOV2020 (25)/ 06NOV2020 (23)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	08NOV2020 (25)	Covid-19	11NOV2020 (28)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	08NOV2020 (25)	07NOV2020 (24)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	08NOV2020 (25)	07NOV2020 (24)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	08NOV2020 (25)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15OCT2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	56 kg	21.1 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Benign tumor in the abdominal wall	Abdominal wall neoplasm	2018	Past
Removal of benign tumor in the abdominal wall	Abdominal wall operation	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	16:47

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	19OCT2020 (1)	19OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	19OCT2020 (1)	19OCT2020 (1)	SERUM	NEGATIVE
Visit 2	09NOV2020 (22)	09NOV2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22OCT2020 (4)/ 21OCT2020 (3)/ 04NOV2020 (17)	YES	DIARRHEA	
	NO		Headache
	YES	NEW LOSS OF TASTE OR SMELL	
	NO		Rhinorrhoea
	NO		Sneezing

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	22OCT2020 (4)	COVID-19	04NOV2020 (17)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	22OCT2020 (4)	22OCT2020 (4)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	22OCT2020 (4)	28OCT2020 (10)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	22OCT2020 (4)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Withdrawn	VACCINATION	09NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	72.1 kg	28.2 kg/m2	04NOV2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hepatitis C	Hepatitis C	1989	Past
Manopause	Menopause	2012	Present
Hypothyroidism	Hypothyroidism	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04NOV2020 (1)	15:13

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	04NOV2020 (1)	04NOV2020 (1)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 11NOV2020 (8)/ 10NOV2020 (7)/ ONGOING	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	11NOV2020 (8)	Covid-19	13NOV2020 (10)	1	COVID-19

SARS-COV-2 Test - Central Laboratory
No SARS-COV-2 Test - Central Laboratory

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	11NOV2020 (8)	12NOV2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		CEPHEID XPERT XPRESS SARS-COV-2 TEST	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	11NOV2020 (8)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04NOV2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	95 kg	37.1 kg/m2	28SEP2020 (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral tubal ligation	Female sterilisation	1997	Present
Post Menopausal	Postmenopause	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	29SEP2020 (1)	08:56

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Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	28SEP2020 (-1)	28SEP2020 (-1)	NASAL_SWAB	NEGATIVE
Visit 1	28SEP2020 (-1)	28SEP2020 (-1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 16OCT2020 (18)/ 15OCT2020 (17)/ ONGOING	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	16OCT2020 (18)	COVID-19	15OCT2020 (17)	3	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	16OCT2020 (18)	16OCT2020 (18)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	16OCT2020 (18)	23OCT2020 (25)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	Covid Illness confirmed by positive SARS_CoV_2 PCR test done at the National Health Laboratory Services in Cape Town South Africa	OTHER	CLIA-certified lab

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	16OCT2020 (18)	OTHER	NO		NA
		SPECIALIST	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		URGENT CARE	YES	1	NA
		TELEPHONE CONSULTATION	YES	7	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	16OCT2020 (18)	HOSPITALIZATION STATUS	HOSPITAL	22OCT2020 (24)	ONGOING

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28SEP2020	
Withdrawn	VACCINATION	10NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	82 kg	28 kg/m2	28SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Intermittent migraine	Migraine	1990	Present
Intermittent backache	Back pain	2010	Present
Postmenopausal	Postmenopause	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28SEP2020 (1)	16:32
2	Placebo	19OCT2020 (22)	09:41

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	28SEP2020 (1)	28SEP2020 (1)	SERUM	NEGATIVE
Visit 2	19OCT2020 (22)	19OCT2020 (22)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 31OCT2020 (34)/ 30OCT2020 (33)/ 03NOV2020 (37)	YES	CHILLS	
	YES	DIARRHEA	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	31OCT2020 (34)	Respiratory tract infection	31OCT2020 (34)	1	Respiratory tract infection

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	31OCT2020 (34)	02NOV2020 (36)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	31OCT2020 (34)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	3	NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28SEP2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	136.36 kg	43 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	2006	Present
ROTATOR CUFF SURGERY	Rotator cuff repair	2014	Past
SLEEP APNEA	Sleep apnoea syndrome	2017	Present
OSTEOARTHRITIS HANDS BILATERAL	Osteoarthritis	01MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	15:12

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	23SEP2020 (1)	23SEP2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	23SEP2020 (1)	23SEP2020 (1)	SERUM	NEGATIVE
Visit 2	14OCT2020 (22)	14OCT2020 (22)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01OCT2020 (9)/ 25SEP2020 (3)/ 29SEP2020 (7)	NO		Fatigue
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	01OCT2020 (9)	Covid 19	28SEP2020 (6)	1	COVID-19

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	01OCT2020 (9)	28SEP2020 (6)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	01OCT2020 (9)	28SEP2020 (6)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	NALT UNKNOWN

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	01OCT2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		SPECIALIST	YES	1	NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Withdrawn	VACCINATION	23SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	87.73 kg	26.2 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis - Knee	Osteoarthritis	01JAN2010	Present
Hypercholesterolemia	Hypercholesterolaemia	01JAN2015	Present
Anxiety	Anxiety	01FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	11:47
2	Placebo	13OCT2020 (20)	09:58

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	24SEP2020 (1)	24SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	24SEP2020 (1)	24SEP2020 (1)	SERUM	NEGATIVE
Visit 2	13OCT2020 (20)	13OCT2020 (20)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 19OCT2020 (26)/ 19OCT2020 (26)/ 02NOV2020 (40)	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	19OCT2020 (26)	Covid-19	19OCT2020 (26)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	19OCT2020 (26)	20OCT2020 (27)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	19OCT2020 (26)	19OCT2020 (26)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT unknown

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	19OCT2020 (26)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24SEP2020	
Completed	VACCINATION	11NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177 cm	95.9 kg	30.6 kg/m2	21SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	13:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE
Visit 2	23OCT2020 (33)	23OCT2020 (33)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01OCT2020 (11)/ 28SEP2020 (8)/ 05OCT2020 (15)	YES	FEVER	
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01OCT2020 (11)	Symptomatic SARS-CoV-2 infection	02OCT2020 (12)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	01OCT2020 (11)	01OCT2020 (11)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	01OCT2020 (11)	01OCT2020 (11)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	01OCT2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21SEP2020	
Withdrawn	VACCINATION	02OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	58 kg	21.8 kg/m2	21SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	14:15

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30OCT2020 (40)	30OCT2020 (40)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	Prespecified Event	Symptoms (Prespecified and Others)	MedDRA Preferred Term
COVID Illness Visit 1 / 05OCT2020 (15)/ 03OCT2020 (13)/ 10OCT2020 (20)	YES	DIARRHEA	
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness					
Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	05OCT2020 (15)	covid 19 illness	03OCT2020 (13)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05OCT2020 (15)	05OCT2020 (15)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	05OCT2020 (15)	05OCT2020 (15)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	05OCT2020 (15)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Withdrawn	VACCINATION	06OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	91 kg	30.1 kg/m2	21SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	20:20
2	Placebo	22OCT2020 (32)	17:35

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: dm, vs, mh, ex, ae, cm, mb, co, di, is, adc19ef, face, ce, ho, pr, lb, mo, ds Output File: ./nda2_unblinded/C4591001_SNAP_FA164_COVID19_Narratives_NotEval_NotSevere/profile Date of Generation: 22NOV2020 (10:31)

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	POSITIVE
Visit 2	22OCT2020 (32)	22OCT2020 (32)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02OCT2020 (12)/ 25SEP2020 (5)/ 09OCT2020 (19)	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasopharyngitis

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	02OCT2020 (12)	02OCT2020 (12)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	02OCT2020 (12)	02OCT2020 (12)	RESPIRATORY SECRETIONS	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	02OCT2020 (12)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21SEP2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	62 kg	23.1 kg/m2	23SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	10:40

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23SEP2020 (1)	23SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23SEP2020 (1)	23SEP2020 (1)	SERUM	NEGATIVE
Visit 2	22OCT2020 (30)	22OCT2020 (30)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 01OCT2020 (9)/ 29SEP2020 (7)/ 07OCT2020 (15)	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	01OCT2020 (9)	COVID-19	02OCT2020 (10)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	01OCT2020 (9)	01OCT2020 (9)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	01OCT2020 (9)	01OCT2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	01OCT2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Withdrawn	VACCINATION	02OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	67.6 kg	21.3 kg/m2	23SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	18:39
2	Placebo	13OCT2020 (21)	18:00

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23SEP2020 (1)	23SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23SEP2020 (1)	23SEP2020 (1)	SERUM	POSITIVE
Visit 2	13OCT2020 (21)	13OCT2020 (21)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 26SEP2020 (4)/ 26SEP2020 (4)/ 27SEP2020 (5)	NO		Decreased appetite
	NO		Discomfort
	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	26SEP2020 (4)	26SEP2020 (4)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	26SEP2020 (4)	26SEP2020 (4)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	26SEP2020 (4)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	65.4 kg	24.6 kg/m2	27SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27SEP2020 (1)	13:46
2	BNT162b2	15OCT2020 (19)	18:18

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27SEP2020 (1)	27SEP2020 (1)	NASAL_SWAB	POSITIVE
Visit 1	27SEP2020 (1)	27SEP2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (19)	15OCT2020 (19)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 09OCT2020 (13)/ 05OCT2020 (9)/ ONGOING	YES	NEW OR INCREASED COUGH	

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	09OCT2020 (13)	09OCT2020 (13)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	09OCT2020 (13)	09OCT2020 (13)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	09OCT2020 (13)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27SEP2020	
Completed	VACCINATION	13NOV2020	
	FOLLOW-UP		