

2.6.3.1 Pharmacology: Overview**Test Article: BNT162b2**

Type of Study	Test System	Method of Administration	Testing Facility	Study Number
Primary Pharmacodynamics				
Qualification Report for a Single-plex Direct Luminex Assay (dLIA) for Quantitation of IgG Antibodies to SARS-CoV-2 S1 Protein in Human Sera	Direct Luminex immunoassay	NA	PWRD	VR-MQR-10211
Qualification of the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay	In vitro cell culture	NA	University of Texas Medical Branch (Galveston, TX)	VR-MQR-10214
BNT162b2 (V9) Immunogenicity and Evaluation of Protection against SARS-CoV-2 Challenge in Rhesus Macaques	Rhesus macaques	IM	PWRD New Iberia Research Center (New Iberia, LA) SNPRC (San Antonio, TX)	VR-VTR-10671
<i>In Vitro</i> Expression of BNT162b2 Drug Substance and Drug Product	In vitro cell culture	IM	BioNTech (Mainz, Germany)	R-20-0211
COVID-19: Immunogenicity Study Of The LNP-Formulated ModRNA Encoding The Viral S Protein-V9	BALB/c mice	IM	BioNTech (Mainz, Germany)	R-20-0085
Characterizing the Immunophenotype In Spleen And Lymph Node Of Mice Treated With SARS-CoV-2 Vaccine Candidates	BALB/c mice	IM	BioNTech (Mainz, Germany)	R-20-0112
Structural and Biophysical Characterization of SARS-CoV-2 Spike Glycoprotein (P2 S) as a Vaccine Antigen	In vitro cell culture	NA	PWRD	VR-VTR-10741
Secondary Pharmacodynamics				
Studies not conducted				
Safety Pharmacology				
Studies not conducted				
Pharmacodynamic Drug Interactions				
Studies not conducted				

COVID-19 – Coronavirus disease 2019; dLIA – Direct Luminex Assay; IgG – immunoglobulin G; SARS-CoV-2 – severe acute respiratory syndrome coronavirus 2; NA – not applicable; PWRD – Pfizer Worldwide Research & Development; IM - intramuscular; SNPRC – Southwest National Primate Research Center.