

Listing of Severe, Serious, Life threatening, or Leading to Withdrawal Adverse Events From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

| Treatment Group/ Age Group (Years)/ Subject | System Organ Class | Preferred Term/ AE Investigator Text | Dose No. | Onset Date | Rel Day ^a / Dur (Days) ^b | Toxicity Grade | Vax Rel ^c | Cause of AE | Action: Investigational Vaccine Dose/ Subject | Outcome (End Date) | SAE/Imm AE (Yes/No) |
|--|--------------------------|---|-------------|---------------|---|-------------------|-------------------------|-------------------|--|-----------------------|---------------------------|
| BNT162b2 (30 µg)/ 16-55/ C4591001 1226 12262255 | MUSC | Myalgia/ muscle pain | 1 | 19OCT2020 | 4/4 | 2 | Yes | | NA/TC | R (22OCT2020) | N/N |
| | GASTR | Nausea/ Nauseas | 2 | 06NOV2020 | 1/3 | 3 | Yes | | NA | R (08NOV2020) | N/N |
| | | Vomiting/ Vomiting | 2 | 06NOV2020 | 1/3 | 3 | Yes | | NA/TC | R (08NOV2020) | N/N |
| | GENRL | Chills/ Chills | 2 | 06NOV2020 | 1/3 | 3 | Yes | | NA | R (08NOV2020) | N/N |
| | | Injection site pain/ Pain at the injection site | 2 | 06NOV2020 | 1/3 | 3 | Yes | | NA | R (08NOV2020) | N/N |
| | | Pyrexia/ Fever 39 C | 2 | 06NOV2020 | 1/3 | 3 | Yes | | NA/TC | R (08NOV2020) | N/N |
| | MUSC | Myalgia/ Muscle pain | 2 | 06NOV2020 | 1/3 | 3 | Yes | | NA/TC | R (08NOV2020) | N/N |
| BNT162b2 (30 µg)/ 16-55/ C4591001 1230 12301045 | INJ&P | Exposure during pregnancy/ Exposure during Pregnancy | 1 | 20OCT2020 | 22/C | | No | O | P | UNK | N/N |
| Placebo/ 16-55/ C4591001 1229 12291083 | METAB | Diabetes mellitus/ Diabetes Mellitus | 2 | 28DEC2020 | 68/C | 4 | No | O | NA | N | Y/N |
| | INFEC | COVID-19 pneumonia/ Covid 19 Pneumonia | 2 | 01JAN2021 | 72/5 | 4 | No | O | NA/W | F (05JAN2021) | Y/N |
| BNT162b2 (30 µg)/ >55/ C4591001 1015 10151238 | INFEC | Pneumonia/ Pneumonia | 2 | 20JAN2021 | 86/8 | 3 | No | O | NA/TC | R (27JAN2021) | Y/N |

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|--|--------------------------|---|-------------|---------------|---|-------------------|-------------------------|-------------------|--|-----------------------|---------------------------|
| | | | | | | | | | | | |
| | GENRL | Oedema peripheral/ Peripheral edema | 2 | 03FEB2021 | 100/31 | 2 | No | O | NA | R (05MAR2021) | N/N |
| BNT162b2 (30 µg)/ >55/ C4591001 1156 11561160 | INJ&P | Road traffic accident/ MOTOR VEHICLE ACCIDENT | 2 | 24DEC2020 | 74/1 | 4 | No | O | NA/W | F (24DEC2020) | Y/N |

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA_RR/adae_1002_fda_hiv