



**BNT162b2**

**BLA STN 125742/0**

**Response to CBER 06 July 2021 Clinical Information Request**

**July 2021**

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## 1. INTRODUCTION

On 06 July 2021, Pfizer/BioNTech received the following Clinical Information Request from the FDA regarding Study C4591001 submitted to STN 125742/0.

The FDA's request in ***bold italics*** is followed by Pfizer/BioNTech's response below.

## 2. CLINICAL INFORMATION REQUEST

### 2.1. FDA Information Request Item 1

***Please provide a description of the nature of the severe AEs and the AEs which lead to withdrawal from the stable HIV cohort at any time during the study. (e.g., in section 12.2.3.1.1.1. Participants with Confirmed Stable HIV Disease – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 and 12.2.3.2.1.1. Participants with Confirmed Stable HIV Disease – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date. There were 2 SAEs in the BNT162b2 group (1 severe and 1 life-threatening) and 2 SAEs in the placebo group (1 life-threatening). There were 2 AEs leading to withdrawal in the BNT162b2 group (1 life-threatening) and 1 AE (life-threatening) leading to withdrawal in the placebo group). Or if this information is available in the submission, please provide a reference to the location of the requested information.***

### Response

There were 5 participants in the stable HIV cohort who reported severe, serious, life-threatening, or leading to withdrawal AEs from Dose 1 to the unblinding date (inclusive of Dose 1 to 1 month after Dose 2) ([Appendix 1](#)). Narratives describing the events for 4 of these participants are available in the submission and also provided in the appendix:

- C4591001 1015 10151238: BNT162b2 group, SAE (severe) of pneumonia ([Appendix 2](#)),
- C4591001 1156 11561160: BNT162b2 group, SAE (life-threatening) of road traffic accident; participant was withdrawn ([Appendix 3](#))
- C4591001 1230 12301045: BNT162b2 group, AE of exposure during pregnancy; participant was withdrawn ([Appendix 4](#))
- C4591001 1229 12291083: Placebo group, 2 SAEs (both life-threatening) of diabetes mellitus and COVID-19 pneumonia; participant was withdrawn ([Appendix 5](#))

A narrative that was not included in the submission is provided in [Appendix 6](#) for the following participant:

- C4591001 1226 12262255: BNT162b2 group, AEs of nausea, vomiting, chills, injection site pain, pyrexia, and myalgia (all severe)

### 3. APPENDIX

Appendix 1. [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  \$\geq\$ 16 Years of Age – Safety Population](#)

Appendix 2. [Narrative for Subject ID: C4591001 1015 10151238](#)

Appendix 3. [Narrative for Subject ID: C4591001 1156 11561160](#)

Appendix 4. [Narrative for Subject ID: C4591001 1230 12301045](#)

Appendix 5. [Narrative for Subject ID: C4591001 1229 12291083:](#)

Appendix 6. [Narrative for Subject ID: C4591001 1226 12262255](#)

## Document Approval Record

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