



**BNT162b2**

**BLA STN 125842/0**

**Response to CBER 08 June 2021 Clinical Information Request**

**June 2021**

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## 1. INTRODUCTION

On 08 June 2021, Pfizer/BioNTech received the following Clinical Information Request from the FDA regarding the Study BNT162-01 and Study C4591001 submitted to STN 125742/0 on 18 May 2021 (STN 125742/0/1). Pfizer/BioNTech's response to the Clinical Information Request is provided below.

## 2. CLINICAL INFORMATION REQUEST

### 2.1. FDA Information Request Item 1

*For Study BNT162-01:*

1. *In the IS dataset, there is missing immunogenicity data for at least 12 subjects who received the 30 µg dose of BNT162b2. Please submit all immunogenicity data for participants who received 30 µg dose of BNT162b2 to the BLA.*
2. *Please submit fully functional pdf documents (e.g., that can be searched to locate information) for the following reports that are hyperlinked from the BLA submission (document bnt162-01-interim3-report body):*
  - a. *R&D Report R-20-0253 (28 November 2020)*
  - b. *R&D Report R-20-0235 (27 Nov 2020)*
  - c. *Interim report GA-RB-02201A (19 March 2021)*
  - d. *R-20-0244 (19 March 2021)*
  - e. *Interim Clinical Study Report R-20-0241 (20 March 2021)*

### **Response**

#### **1. Immunogenicity data for participants who received 30 µg dose of BNT162b2**

These data were not available at the time of immunogenicity cut-off for this report because the samples were put on hold due to necessary testing prioritizations at the Pfizer labs (eg C4591001 6-month stability and booster; C4591007). Pfizer has now resumed testing of these samples and an updated BNT162-01 study report will be provided once it is available. Pfizer/BioNTech do not believe these data to be material to the review of the Biologics License Application.

#### **2. Fully functional pdf documents (e.g., that can be searched to locate information) for the following reports**

The following pdf documents have been corrected for functionality and can be accessed through the individual links provided below:

- a) [R&D Report R-20-0253](#) (28 November 2020)
- b) [R&D Report R-20-0235](#) (27 Nov 2020)
- c) [Interim report GA-RB-02201A](#) (19 March 2021)
- d) [R-20-0244](#) (19 March 2021)
- e) [Interim Clinical Study Report R-20-0241](#) (20 March 2021)

## 2.2. FDA Information Request Item 2

*For Study C4591001:*

- 1. Please provide a rationale for the differences in the number of participants described in the reactogenicity subset of the safety population as presented in Tables 1 through 4 in (1) the proposed Prescribing Information (PI), submitted in STN 125742/0/1 (dated May 18, 2021) and (2) the most recent version of the Fact Sheet for Healthcare Providers/Full EUA PI, submitted with EUA 27034/181 (dated May 20, 2021). The descriptions for the safety population in Section 6 of each of the PI documents are similar, with an enrollment by date of October 9, 2020 and differing data cut off dates, as expected. However, we would expect that the entire reactogenicity subset would be included in the BLA submission, without a specified “enrollment by date.” If this is the rationale for the differences in the number of participants described in the reactogenicity subset, please provide a revised PI to STN 125742 that accurately describes the safety population in Section 6, in tracked changes.*

### **Response**

The current effective Fact Sheet for Healthcare Providers/Full EUA Prescribing Information (EUA PI) submitted 20 May 2021 does not contain the 6-month post-dose 2 update. This is the rationale for the differences in the number of participants described in the reactogenicity subset of the safety population as presented in Tables 1 through 4 in the proposed BLA PI, submitted 18 May 2021 (STN 125742/0/1) and the most recent version of the EUA PI, submitted 20 May 2021 (EUA 27034/181). Please refer to the EUA PI submitted 14 May 2021, currently under review, which includes the 6-month post-dose 2 update.