# COVID-19 Vaccine (BNT162, PF-07302048; COMIRNATY)

## BLA STN 125742/45

## Response to CBER Information Request of 07 March Regarding Immunobridging Data and Updated Safety Data for Adolescents 12 Through 15 Years of Age

**11 March 2022**

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FDA-CBER-2022-5812-0235605

# 1. INTRODUCTION

Reference is made to the sBLA to extend licensure of COMIRNATY to adolescents 12 through 15 years of age submitted to FDA on 16 Dec 2021 (Sequence number 0211).

Reference is also made to the Information Request received from CBER on 07 March 2022.

Below, the requests are shown in ***bold italics*** followed by Pfizer/BioNTech's response in plain text.

# 2. REQUESTS

## 2.1. Request 1

***The submitted immunobridging data (adolescents 12 through 15 years of age vs. young adults 16 through 25 years of age in Study C4591001) with an estimated geometric mean titer ratio of 1.76 and a seroresponse rate difference of -2.1% appear to be based on an LLOQ of 20. Please confirm whether the assay LLOQ has been revised to 41. Please provide updated immunobridging analysis results (i.e., geometric mean titer ratio and seroresponse rate difference) as appropriate.***

**Response**

The previously submitted immunobridging analyses were based on an LLOQ of 20. New analyses using the updated LLOQ of 41 have been completed and are included with this response (see Appendix 1). A track changes version of the table is also provided, which shows the changes to the data that resulted from using a different LLOQ (see Appendix 2).

The geometric mean ratio (GMR), previously 1.76 (95% CI: 1.47, 2.10) is now 1.77 (95% CI: 1.50, 2.09), and the seroresponse rate difference, previously -2.1% (95% CI: -6.0%, 0.9%), is now 0.4% (95% CI: -4.2%, 5.5%). The changes to these values are not clinically significant and do not alter the conclusions of the respective analyses.

Appendix 1. Immunobridging data – Adolescents 12 through 15 years of age vs. young adults 16 through 25 years of age in Study C4591001 – Analyses based on an LLOQ of 41

Appendix 2. TRACKED CHANGES VERSION - Immunobridging data – Adolescents 12 through 15 years of age vs. young adults 16 through 25 years of age in Study C4591001 – Analyses based on an LLOQ of 41

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### 2.2. Request 2

***Please clarify whether additional solicited adverse reaction data for adolescents 12 through 15 years of age in Study C4591001 have been collected up to the September 2, 2021 data cutoff since EUA issuance. Please submit updated solicited adverse reaction frequencies as appropriate, annotating any changes to the results.***

***On 08 March 2022, Captain Michael Smith clarified that the comment pertains to reactogenicity data collected in the e-diary, as presented in Tables 5 and 6 of the draft package insert.***

**Response**

No additional reactogenicity data (e-diary data) have been collected for adolescents 12 through 15 years of age beyond those provided in the EUA amendment. Per protocol, participants 12 through 15 years of age who had been randomized to placebo and crossed over to receive open-label BNT162b2 did not complete the e-diary. For these participants, any reactogenicity events were to be reported as adverse events.

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# Document Approval Record

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