COMIRNATY (COVID-19 VACCINE, mRNA)

Response to CBER 22 April 2022 Information Request to Pfizer/BioNTech Regarding Study Protocol for Study C4591022 (A Non- Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/Mother To Baby Pregnancy Registry)

02 May 2022

1. INTRODUCTION

Reference is made to the Biologics License Application (BLA) 125742 for COMIRNATY (COVID-19 Vaccine, mRNA) approved 23 August 2021 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. Additional reference is made to the supplemental BLA (sBLA) to extend licensure of COMIRNATY to adolescents 12 through 15 years of age submitted on 16 December 2021 (sBLA 125742/45; Sequence 0211) with a proposed indication of active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

Reference is also made to CBER's information request (received 22 April 2022) regarding a request to revise study protocol for Study C4591022 - pregnancy registry study (postmarketing commitment (PMC) #10 as described in the STN 125742/0 approval letter)

The FDA's requests in ***bold italics*** are followed by Pfizer/BioNTech's responses below.

2. FDA REQUEST

The review team has the below Information Request regarding Study C4591022, the pregnancy registry study.

The current version (version 3.0, dated November 29, 2021) of your protocol for the pregnancy registry study (postmarketing commitment (PMC) #10 as described in the STN 125742/0 approval letter, dated August 23, 2021) includes individuals aged 18 years and older. In the context of the Pharmacovigilance Plan (PVP, version 1.4) submitted with sBLA 125742/45 to extend the use of COMIRNATY to individuals 12 years of age and older, please revise the study protocol for C4591022 to include pregnant individuals of all ages. Please respond to this Information Request under sBLA 125742/45 and submit a revised final study protocol and statistical analysis plan (both tracked changes and clean running versions) to IND 19736 by May 6, 2022.

Response

As per CBER's request, Pfizer/BioNTech will revise the study protocol for study C4591022 to include pregnant individuals of all ages. Please note, while we have reached the target enrollment sample size in the exposed group of pregnant individuals who received the Pfizer-BioNTech COVID-19 Vaccine during pregnancy, we will attempt to enroll individuals <18 years of age who may qualify for this group. An amended study protocol and statistical analysis plan (both tracked changes and clean running versions) will be submitted by 20 May 2022.

Document Approval Record

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