COVID-19 Vaccine (BNT162, PF-07302048)

Request for Comments and Advice

sBLA Booster Dose for Children 12 Through 15 Years of Age

March 2022

1. INTRODUCTION

Reference is made to BB-IND 19736 for the COVID-19 Vaccine (BNT162; PF-07302048), which Pfizer and BioNTech are developing for the indication of active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Reference is also made to the Emergency Use Authorization (EUA 27034) for Pfizer-BioNTech COVID-19 Vaccine most recently re-issued on 3 January 2022 extending the licensure to include: 1) booster dose for adolescents 12 through 15 years of age; 2) reduced interval between the completion of primary vaccination and a booster dose to at least 5 months; 3) a third primary series dose for certain immunocompromised children 5 through 11 years of age.

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 (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.

As communicated with the United States (US) Food and Drug Administration (FDA), Pfizer/BioNTech plan to submit the sBLA to add a booster dose for individuals ≥16 years old with 6 months safety data post-Dose 3 and FDA agreement has been reached on the data requirements to support review of the application in an email correspondence from Dr. Ramachandra Naik (CBER) to Ms. Elisa Harkins Tull (Pfizer Inc.) on 20 January 2022.

The purpose of this communication is to request feedback from FDA on the acceptability of applying for licensure of a booster dose for adolescents 12 through 15 years of age in the same sBLA planned to apply for licensure of a booster dose for individuals 16 years of age and older as a single submission.

Specifically, we intend to submit the following to support approval of a booster dose for adolescents 12 through 15 years of age:

- A summary of real-world safety and effectiveness data available for this age group, including recent data from the Centers for Disease Control and Prevention and our site at Kaiser Permanente Southern California. These data will be used to inform a benefit-risk assessment for use of a booster dose among children 12 through 15 years of age.
- A cumulative review of post-authorization adverse event reports following administration of a booster dose in adolescents 12 through 15 years of age will be included, to be provided together with the cumulative review already agreed covering the individuals ≥16 years who received a booster dose.

A booster dose of BNT162b2 is currently being studied in individuals 12 through 17 years of age (randomized to receive either 10 µg or 30 µg) in Substudy C of Study C4591031. It is planned to randomize approximately 600 participants in this age group but due to emergency use authorization of a booster dose for adolescents 12 through 15 years of age being granted

in January 2022, enrollment (which started in December 2021) is lagging significantly. As of 11 March 2022, 132 participants have been randomized (about half of whom will have received 30 µg).

Since the immune response after the first 2 doses of BNT162b2 30 µg in adolescents 12 through 15 years of age was greater than in individuals 16 through 25 years of age, there is no reason to expect that the immune response to a booster dose would be any different. In light of the widespread availability of the booster dose under the EUA, and the resultant challenges to enrolling such individuals into a clinical study, Pfizer/BioNTech propose to submit descriptive safety and immunogenicity data from approximately 200 randomized participants from Substudy C of Study C4591031 as a post approval commitment. The protocol allows for conduct of non-prespecified analyses if required for regulatory purposes.

We respectfully request Agency's feedback by 22 March 2022.

2. QUESTIONS FOR THE AGENCY

2.1. Sponsor Question 1

Does CBER agree that Pfizer/BioNTech submit a single sBLA supported by clinical trial data for individuals 16 years and older and supplemented with real world data for adolescents 12 through 15 years of age to obtain approval of a booster dose for individuals 12 years of age and older?

Document Approval Record

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