Vaccines and Related Biological Products
Advisory Committee Meeting
October 26, 2021

Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Amendment Request for Use in Children 5 through 11 Years of Age

Applicant: BioNTech Manufacturing GmbH

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Background Outline

- Currently available COVID-19 vaccines (licensed and EUA)
- Overview of the EUA request and the clinical package
- Pfizer-BioNTech COVID-19 Vaccine formulation requested for EUA
- Overview of Today's Agenda
- Voting Question

Pfizer-BioNTech COVID-19 Vaccine and Comirnaty

Pfizer-BioNTech COVID-19 Vaccine (available under EUA)

- 2-dose primary series (3 weeks apart) in individuals ≥12 years of age
- 3rd primary series dose (at least 1 month after the second dose) in individuals ≥12 years of age who have been determined to have certain kinds of immunocompromise
- A single booster dose (at least 6 months after completing a primary series of Pfizer-BioNTech COVID-19 Vaccine in individuals
  - ≥65 years of age
  - 18 through 64 years of age and at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine (heterologous booster)
- Each 0.3 mL dose contains 30 μg of mRNA encoding the viral spike glycoprotein of SARS-CoV-2

COMIRNATY

- FDA-approved (licensed on August 23, 2021) for use in individuals ≥16 years of age
- Each 0.3 mL dose contains 30 μg of mRNA
- Can be used interchangeably with Pfizer-BioNTech COVID-19 Vaccine as currently authorized to provide doses for COVID-19 primary vaccination or a booster dose

Currently Available COVID-19 Vaccines, continued

- **Moderna COVID-19 Vaccine (EUA)**
  - 2-dose primary series (1 month apart), individuals ≥18 years of age
  - 3rd primary series dose, certain immunocompromised individuals
  - A single homologous and heterologous booster dose;
  - Booster use population and interval is the same as for Pfizer-BioNTech COVID-19 Vaccine or Comirnaty

- **Janssen COVID-19 Vaccine (EUA)**
  - Single dose, individuals ≥18 years of age
  - A single booster dose may be administered at least 2 months after primary vaccination to individuals 18 years of age and older
  - A single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine (heterologous booster)

EUA Amendment Request for Children 5 through 11 Years of Age

- Submission Date: October 6, 2021

- Proposed dose and regimen:

  A primary series of 2 doses (0.2 mL each, 10 μg of mRNA), 3 weeks apart, administered intramuscularly in individuals 5 through 11 years of age

- The clinical package includes safety and immunogenicity data
  - ~1,500 vaccine recipients with 2 months or more safety follow-up, post-dose 2
  - ~1,600 vaccine recipients with about 2 weeks safety follow-up, post-dose 2

Pfizer-BioNTech COVID-19 Vaccine Formulations

12 years of age and older:
PBS/Sucrose formulation

- Dilute before use
- Each dose:
  - 0.3 mL
  - 30 μg mRNA
- Must be stored frozen at -80ºC until expiry date or -20°C for up to 2 weeks prior to use

5 through 11 years of age:
Tris/Sucrose formulation

- Dilute before use
- Each dose:
  - 0.2 mL
  - 10 μg mRNA
- Can be stored at refrigerator temperature (2°C to 8°C) for up to 10 weeks prior to use

➢ Tris and PBS are buffering agents that help maintain the pH and stability of the product.

Evaluation of Pfizer-BioNTech COVID-19 Vaccine Formulations

In study C4591007 in children 5 through 11 years of age, the PBS/Sucrose formulation was diluted to adjust the mRNA content to 10 μg per dose (0.2 mL).

Analytical Comparability data were used to demonstrate comparability between PBS/Sucrose and Tris/Sucrose formulations

- In-process tests
- Drug Product release tests
- Product characterization tests
- Ongoing stability studies

Manufacturing consistency established

Overview of Today's Agenda

- **FDA Introduction**
  - **Welcome**
    Peter Marks, M.D., Ph.D., Center Director, CBER, FDA
  - **Introduction of the Topic**
    Doran Fink, M.D., Ph.D., Deputy Director - Clinical, DVRPA, OVRR, CBER, FDA
  - **Background**
    Ramachandra Naik, Ph.D., Review Committee Chair, DVRPA, OVRR, CBER, FDA
- **Epidemiology of COVID-19 in Children**
  Fiona Havers, M.D., Centers for Disease Control and Prevention, Division of Viral Disease, National Center for Immunization and Respiratory Diseases
- **Known safety signals (Myocarditis in adolescents and young adults)**
  Mathew Oster, M.D., M.PH., Centers for Disease Control and Prevention, CDC COVID-19 Response CDC Center on Birth Defects and Developmental Disabilities
- **Break (5 min)**
- **Sponsor Presentation**
  William Gruber, M.D., FAAP, FIDSA, FPIDS, Senior Vice President, Vaccine Clinical Research and Development, Pfizer, Inc.

Overview of Today's Agenda, continued

- **FDA Presentations**
  - **Clinical**
    Leslie Ball, M.D., Medical Officer, DVRPA, OVRR, CBER, FDA
  - **Post-market active surveillance of COVID-19 vaccines in the pediatric population in the FDA BEST System**
    Hui-Lee Wong, Ph.D., M.Sc., Associate Director for Innovation and Development, OBE, CBER, FDA
  - **Benefit-Risk Analysis**
    Hong Yang, Ph.D., Senior Advisor for Benefit-Risk Assessment, OBE, CBER, FDA

- **Lunch (35 min)**
- **Open Public Hearing (60 min)**
- **Break (10 min)**
- **Q & A Session regarding the Applicant and FDA presentations (45 min)**
- **Committee Discussion and Voting (125 min)**
- **Meeting adjourned**

Question to the Committee

1. Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 µg each dose, 3 weeks apart) outweigh its risks for use in children 5 through 11 years of age?

Please vote Yes or No.

Thank you!