Vaccines and Related Biological Products
Advisory Committee meeting
June 15, 2022

Moderna COVID-19 Vaccine
Request for Emergency Use Authorization (EUA)
Amendment, Use of a 2-Dose Primary Series in Children 6 months through 5 Years of Age

Applicant: ModernaTX Inc.,
Sudhakar Agnihothram, B. Pharm., Ph.D.
Division of Vaccines and Related Products Applications
Office of Vaccines Research and Review/CBER/FDA
Background Outline

- Currently available COVID-19 vaccines (licensed and EUA)
- Overview of the EUA request and the clinical package from ModernaTX, Inc.
- Overview of the EUA request and the clinical package from BioNTech Manufacturing GmbH
- Emergency Use Authorization
- Overview of Today’s Agenda
- Voting Questions
Currently Available COVID-19 Vaccines for Primary Vaccination in Pediatric Population

- **Pfizer-BioNTech COVID-19 Vaccine (available under EUA)**
  - 2-dose primary series (3 weeks apart), individuals 5 years of age and older
  - 3rd primary series dose, (at least 28 days after the second dose) in individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise

- **COMIRNATY**
  - FDA-approved for use as a two dose primary series in individuals 16 years of age and older and can be used interchangeably with Pfizer-BioNTech COVID-19 Vaccine as currently authorized
EUA Amendment Request for Individuals 6 months through 5 Years of Age

- Submission Date: April 28, 2022

- Proposed dose and regimen:
  A primary series of 2 doses (0.25 mL each, 25 mcg of mRNA), 1 month apart, administered intramuscularly in individuals 6 months through 5 years of age

- The clinical package includes safety, efficacy and immunogenicity data
  - ~1,800 vaccine recipients (6-23 months of age)
  - ~3,000 vaccine recipients (2-5 years of age)
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Pfizer-BioNTech COVID-19 Vaccine
Emergency Use Authorization Amendment Request
for Use in Children 6 months through 4 Years of Age

Applicant: BioNTech Manufacturing GmbH

Ramachandra Naik, Ph.D.
Division of Vaccines and Related Products Applications
Office of Vaccines Research and Review/CBER/FDA
EUA Amendment Request for Children 6 months through 4 Years of Age

- Submission Date: May 27, 2022

- Current proposed dose and regimen:
  A primary series of 3 doses (0.2 mL each, 3 mcg of mRNA), first two doses administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose, intramuscularly, in individuals 6 months through 4 years of age

- The clinical package includes safety and effectiveness data from ~3,000 vaccine recipients
Emergency Use Authorization

FDA may issue an Emergency Use Authorization (EUA) of an unapproved medical product following an EUA declaration, if the following statutory requirements* are met:

- The agent referred to in the EUA declaration can cause a serious or life-threatening disease or condition
- The medical product may be effective to prevent, diagnose, or treat the serious or life-threatening condition caused by the agent
- The known and potential benefits of the product outweigh the known and potential risks of the product
- No adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition

*Section 564 of the FD&C Act (21 U.S.C. 360bbb-2)
Overview of Today’s Agenda

FDA Introduction (20 min)

- Welcome
  Peter Marks, M.D., Ph.D., Center Director, CBER, FDA
- Background for the EUA Amendment Requests
  - Moderna COVID-19 Vaccine: Use of a 2-Dose Primary Series in Infants and Children 6 Months through 5 Years of Age
    Sudhakar Agnihothram, Ph.D., Review Committee Chair, DVRPA, OVRR, CBER, FDA
  - Pfizer-BioNTech COVID-19 Vaccine: Use of a 3-Dose Primary Series in Infants and Children 6 Months through 4 Years of Age
    Ramachandra Naik, Ph.D., Review Committee Chair, DVRPA, OVRR, CBER, FDA

Sponsor Presentation (ModernaTX, Inc.) (45 min)

- Carla Vinals, Ph.D., Vice President, Regulatory Affairs Strategy, Infectious Diseases, ModernaTX, Inc.
- Evan Anderson, M.D., FAAP, Associate Professor, Pediatrics and Medicine, Emory University School of Medicine
- Jacqueline Miller, M.D., FAAP, Senior Vice President, Therapeutic Area Head, Infectious Diseases, ModernaTX, Inc.
- Rituparna Das, M.D., Ph.D., Vice President, Clinical Development, COVID-19 Vaccines, ModernaTX, Inc.

FDA Presentation (45 min)

FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine in Infants and Children 6 Months through 5 Years of Age
Robin Wisch, M.D., Medical Officer, Clinical Review Staff, Immediate Office of Director, DVRPA, OVRR, CBER
Overview of Today’s Agenda, continued

- Break (15 min)
- Sponsor Presentation (Pfizer, Inc.) (45 min)
  William C. Gruber, M.D., FAAP, FIDSA, FPIDS
  Senior Vice President, Vaccine Clinical Research and Development, Pfizer Inc.
- FDA Presentation (45 min)
  FDA Review of Effectiveness and Safety of Pfizer-BioNTech COVID-19 Vaccine in Infants and Children 6 Months through 4 Years of Age
  Susan Wollersheim, M.D., Medical Officer, Clinical Review Branch 1, DVRPA, OVRR, CBER
- Lunch (30 min)
- Open Public Hearing (60 min)
- Additional Q & A for FDA and Sponsor Presenters – Moderna COVID-19 Vaccine (25 Min)
- Committee Discussion and Voting – Moderna COVID-19 Vaccine (60 Min)
- Break (10 min)
- Additional Q & A for FDA and Sponsor Presenters – Pfizer-BioNTech COVID-19 Vaccine (25 Min)
- Committee Discussion and Voting – Pfizer-BioNTech COVID-19 Vaccine (60 min)
- Meeting adjourned - DFO
Question to the Committee - Moderna COVID-19 Vaccine

Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (25 mcg each dose) outweigh its risks for use in children 6 months through 5 years of age?

Please vote Yes or No.
Question to the Committee – BioNTech Manufacturing GmBH

Based on the totality of the scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine, when administered as a 3-dose series (3 mcg each dose), outweigh its risks for use in infants and children 6 months through 4 years of age?

Please vote Yes or No.
Thank you!