Vaccines and Related Biological Products
Advisory Committee meeting
June 14, 2022

Moderna COVID-19 Vaccine Request for Emergency Use Authorization (EUA) Amendments, for Use of a 2-Dose Primary Series in Children and Adolescents 6 through 17 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

- Moderna COVID-19 Vaccine and SPIKEVAX
- Currently available COVID-19 vaccines for primary vaccination in pediatric population
- Overview of the EUA requests and the clinical package
- Emergency Use Authorization – statutory requirements
- Overview of Today's Agenda
- Voting Questions for the committee

Moderna COVID-19 Vaccine and Spikevax: Primary Series Vaccination

- **Moderna COVID-19 Vaccine (available under EUA)**
  - 2-dose primary series (1 month apart) in individuals 18 years of age and older
  - 3rd primary series dose (at least 1 month after the second dose) in individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise

- **SPIKEVAX**
  - FDA approved for use as a 2-dose primary series in individuals 18 years of age and older
  - Can be used interchangeably with Moderna COVID-19 Vaccine to provide doses for COVID-19 primary vaccination

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),in 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 2-dose primary series in individuals 16 years of age and older
  - Can be used interchangeably with Pfizer-BioNTech COVID-19 Vaccine to provide doses for COVID-19 primary vaccination

EUA Amendment Request for Individuals 12 through 17 Years of Age

- Submission Date:
  - June 9, 2021, included blinded-follow up through the data cutoff of May 8, 2021
  - March 24, 2022, included blinded-follow up through the data cutoff of January 31, 2022

- Proposed dose and regimen:

  A primary series of 2 doses (0.5 mL each, 100 mcg of mRNA), 1 month apart, administered intramuscularly in individuals 12 through 17 years of age

- The clinical package includes safety, immunogenicity and efficacy data from ~2,500 vaccine recipients

EUA Amendment Request for Individuals 6 through 11 Years of Age

- Submission Date: March 8, 2022

- Proposed dose and regimen:

  A primary series of 2 doses (0.5 mL each, 50 mcg of mRNA), 1 month apart, administered intramuscularly in individuals 6 through 11 years of age

- The clinical package includes safety, immunogenicity and efficacy 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 (30 min)**
  Welcome(10 min)
  Peter Marks, M.D., Ph.D., Center Director, CBER, FDA

  Introduction to Topic 1: Moderna COVID-19 Vaccine: Request for Emergency Use Authorization (EUA) Amendments, Use of a 2-Dose Primary Series in Children and Adolescents 6 years through 17 Years of Age (10 min)
  Sudhakar Agnihothram, Ph.D., Review Committee Chair, DVRPA, OVRR, CBER, FDA

Q/A - 5 min

- **Centers for Disease Control and Prevention (CDC) Presentations (55 Min)**
  COVID-19 Epidemiology and Disease Burden in Infants, Children and Adolescents (15 Min)
  Katherine E. Fleming-Dutra, M.D.
  Medical Officer
  COVID-19 Vaccine Policy Unit
  National Center for Immunization and Respiratory Diseases, CDC

Overview of Today's Agenda - Continued

- **Centers for Disease Control and Prevention (CDC) Presentations (55 Min) – Contd.**
  Update on mRNA COVID-19 Vaccine Effectiveness (15 min)
  Ruth Link-Gelles, Ph.D., M.P.H.
  LCDR, U.S. Public Health Service
  COVID-19 Vaccine Effectiveness Program Lead
  Division of Viral Diseases, CDC

- **Update on mRNA COVID-19 Vaccine Post Authorization Safety Assessment in Pediatric Age Groups (15 Min)**
  Tom Shimabukuro, M.D., M.P.H., M.B.A.
  Captain, U.S. Public Health Service
  Director
  Immunization Safety Office, CDC

Q/A - 10 min

Overview of Today's Agenda - Continued

- **FDA Presentation (15 min)**
  Safety Surveillance of COVID-19 Vaccines in Children and Adolescents (15 min)
  Hui-Lee Wong, Ph.D.
  Associate Director for Innovation and Development
  Office of Biostatistics and Pharmacovigilance (OBPV), CBER

Q/A 5 min
Break (10 min)

- **Sponsor Presentation (60 min including Q & A)**
  mRNA-1273 (Moderna COVID-19 Vaccine) – Request for Emergency Use Authorization for Use in Children and Adolescents 6 through 17 Years of Age (50 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.

Q/A 10 min

Overview of Today's Agenda - Continued

- **FDA Presentation (50 min)**
  FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine in Children and Adolescents 6 through 17 Years of Age
  Rachel Zhang, M.D.
  Medical Officer
  Clinical Review Staff, Immediate Office of Director
  DVRPA, OVRR, CBER, FDA

Lunch 30 Min

- Open Public Hearing (60 Min)
- Additional Q & A for CDC, FDA and Sponsor Presenters (60 min)
- Break (10 min)
- Committee Discussion and Voting (110 min)
- Meeting Adjourned - DFO

Voting Questions for the Committee

1. Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (100 mcg each dose) outweigh its risks for use in adolescents 12 through 17 years of age?

2. Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (50 mcg each dose) outweigh its risks for use in children 6 through 11 years of age?

Acknowledgements

Moderna COVID-19 Vaccine
Review Team and Leadership

Thank you!