Vaccines and Related Biological Products
Advisory Committee meeting
June 7, 2022

Novavax COVID-19 Vaccine, Adjuvanted Request for Emergency Use Authorization

Applicant: Novavax, Inc.

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Outline

- SARS-CoV-2 Pandemic
- Novavax COVID-19 Vaccine, Adjuvanted and EUA request for immunization as a primary series (2 doses, 3 weeks apart)
- Considerations for EUA of a COVID-19 vaccine
- COVID-19 vaccines available for use in the U.S.
- Overview of Today's Agenda
- Voting Question for the Committee

SARS-CoV-2 Pandemic

- Since the beginning of the pandemic in early 2020, SARS-CoV-2 has caused over half a billion confirmed cases of COVID-19, including over 6 million deaths, worldwide*

- In the United States, SARS-CoV-2 has caused over 84 million reported COVID-19 cases and over 1 million deaths**

- Surges in SARS-CoV-2 transmission and COVID-19 cases, hospitalizations, and deaths have been associated with emergence of SARS-CoV-2 variants (e.g., Beta, Delta, Omicron) that are more infectious, more virulent, and/or more resistant to natural or vaccine-elicited immunity than the prototype strain

*WHO COVID-19 Dashboard as of June 2, 2022

** CDC COVID Data Tracker as of June 3, 2022

Novavax COVID-19 Vaccine, Adjuvanted

- Each 0.5 mL dose of Novavax COVID-19 Vaccine, Adjuvanted contains 5 mcg of recombinant viral spike protein from SARS-CoV-2 (Wuhan-Hu-1 strain) expressed in Sf9 cells and 50 mcg of Novavax's saponin-based Matrix-M adjuvant

- Proposed use under EUA: Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older

- Dosing regimen: A series of 2 doses, 0.5 mL each, administered intramuscularly three weeks apart

- Also referred to as NVX-CoV2373 during clinical development

EUA Request for Novavax COVID-19 Vaccine, Adjuvanted

- On February 1, 2022, FDA received Novavax's request for Emergency Use Authorization (EUA) of Novavax COVID-19 Vaccine, Adjuvanted
- EUA of Novavax COVID-19 Vaccine, Adjuvanted would depend on:
  - Clinical data to inform benefits and risks
  - Manufacturing and product information to ensure the vaccine's quality and consistency
- The manufacturing process for Novavax COVID-19 Vaccine, Adjuvanted has changed over time, and submission to FDA of complete manufacturing and product information to support the vaccine product intended for use under EUA is ongoing

EUA Request for Novavax COVID-19 Vaccine, Adjuvanted

The EUA request clinical package includes:

- Safety, immunogenicity and efficacy data from a Phase 3 study (2019nCoV-301) conducted in the US and Mexico with approximately 30,000 participants
  - FDA will be able to determine comparability of the vaccine product evaluated in this study to the vaccine product intended for use under EUA
- Additional safety data from approximately 10,000 NVX-CoV2373 recipients across three clinical studies: 2019nCoV-302 (Phase 3, UK), 2019nCoV-501 (Phase 2, South Africa), and 2019nCoV-101 (Phase 1, Australia/US)
  - Available manufacturing and product information does not allow for a determination of comparability between the vaccine product used in these three studies and the vaccine product intended for use under EUA; therefore, FDA review of these studies was limited to safety evaluation

Criteria for 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
  - There is 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)

COVID-19 Vaccines Available in the U.S. for Use in Individuals 18 years of Age and Older

- Pfizer-BioNTech COVID-19 Vaccine (licensed as COMIRNATY)
- Moderna COVID-19 Vaccine (licensed as SPIKEVAX)
- Janssen COVID-19 Vaccine (not licensed, available only under EUA)
  - Use of Janssen COVID-19 Vaccine is limited to individuals for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and individuals who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine

Overview of Today's Agenda

- **FDA Introduction**
  - **Background/Introduction of the Topic (10 Min)**
    - Goutam Sen, Ph.D., Review Committee Chair, DVRPA, OVRR, CBER, FDA
- **Current Epidemiology of COVID-19 and COVID-19 Vaccination Rates in the United States (20 Min)**
  - CDR. Heather Scobie, Ph.D., Epidemiology Task Force, COVID-19 Emergency Response, Centers for Disease Control and Prevention
- **Overview of COVID-19 Vaccine Associated Myocarditis (15 Min)**
  - CAPT. Tom Shimabukuro, M.D., Immunization Safety Office, Centers for Disease Control and Prevention
- **Sponsor Presentation (60 Min including Q&A)**
  - **Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older (50 min)**
    - Filip Dubovsky, M.D., Executive Vice President and Chief Medical Officer, Novavax, Inc. *Introduction*
    - Raburn Mallory, M.D., Head of Clinical Development, Novavax, Inc. *Immunogenicity and Efficacy*
    - Denny Kim, M.D., Chief Safety Officer, Novavax, Inc. *Safety*
    - Gregory A. Poland, M.D., Mayo Vaccine Research Group. Novavax Consultant, *Clinical Perspective*

Overview of Today's Agenda (2)

- **Break**

- **FDA Presentation**
  - **FDA Review of Effectiveness and Safety of Novavax COVID-19 Vaccine, Adjuvanted in Individuals 18 years of Age and Older (60 Min including Q&A)**
    Lucia Lee, M.D., Lead Medical Officer, DVRPA, OVRR, CBER, FDA

- **Lunch (45 Min)**

- **Open Public Hearing (60 min)**
- **Break (10 min)**
- **Additional Q & A regarding the Sponsor and FDA presentations (50 min)**
- **Committee Discussion and voting (120 min)**
- **Meeting adjourned**

Voting Question for the Committee

- Based on the totality of scientific evidence available, do the benefits of Novavax COVID-19 Vaccine, Adjuvanted, when administered as a 2-dose series, outweigh its risks for use in individuals 18 years of age and older under EUA?

Thank you!