Vaccines and Related Biological Products
Advisory Committee meeting
October 15, 2021

Janssen COVID-19 Vaccine
Application for Emergency Use Authorization of a booster dose

Applicant: Janssen Biotech Inc.,

Sudhakar Agnihothram, B. Pharm., Ph.D.
Division of Vaccines and Related Products Applications
Office of Vaccines Research and Review/CBER/FDA

Background Outline

- Janssen COVID-19 Vaccine and EUA Request for Booster Dose
- Overview of Today's Agenda
- Voting and Discussion Questions for the Committee

Janssen COVID-19 Vaccine

- Emergency Use Authorization: February 27, 2021
- Indication and Usage: Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older
- Dosing Regimen: Administered as a single dose (0.5 mL)
- Each dose of Janssen COVID-19 Vaccine contains $5*10^{10}$ viral particles (vp) of a replication-incompetent recombinant adenovirus type 26 (Ad26) vector expressing the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike (S) protein (from the isolate Wuhan-Hu-1) in a stabilized confirmation.

Janssen COVID-19 Vaccine Booster Dose Amendment

- Submission Date: October 4, 2021
- Proposed use of booster dose ($5*10^{10}$ vp) under EUA:
  - A booster dose is recommended at 6 months or later, based on the strength of the immune responses, although a booster dose may be administered as early as 2 months. The need for a booster dose and/or its timing will depend on the local/epidemiological situation and the needs of individuals/specific populations.
- Clinical package includes information from:
  - Phase 1/2 studies evaluating safety and immunogenicity of a second dose or booster dose of $5*10^{10}$ vp administered at various intervals (2 – 6 months) following primary vaccination
  - Phase 3 studies evaluating safety and efficacy of a single dose of $5*10^{10}$ vp and a two-dose regimen ($5*10^{10}$ vp each dose), administered 2 months apart
  - Observational effectiveness study of Janssen COVID-19 Vaccine in the U.S.

Overview of Today's Agenda

- **FDA Introduction (15 min)**
  Introduction of the Topic (5 min)
  Peter Marks, M.D., Ph.D., Center Director, CBER, FDA
  Background (5 min)
  Sudhakar Agnihothram, Ph.D., Review Committee Chair, DVRPA, OVRR, CBER, FDA

  Q/A - 5 min

- **Sponsor Presentation (45 min)**
  Efficacy, Safety and Immunogenicity data for Booster Dose of Janssen COVID-19 Vaccine (Ad26.COV2.S) Janssen/Johnson & Johnson
  Penny Heaton, M.D., Global Therapeutic Area Head, Vaccines, Janssen Research & Development, Johnson & Johnson
  Johan Van Hoof, M.D., Managing Director, Janssen Vaccines & Prevention B.V., Johnson & Johnson
  Dan Barouch, M.D., Ph.D., William Bosworth Castle Professor of Medicine, Harvard Medical School; Ragon Institute of MGH, MIT, and Harvard; Director, Center for Virology and Vaccine Research, Beth Israel Deaconess Medical Center

Overview of Today's Agenda, cont.

- **Sponsor Presentation (45 min)**
  Efficacy, Safety and Immunogenicity data for Booster Dose of Janssen COVID-19 Vaccine (Ad26.COV2.S) Janssen/Johnson & Johnson
  Sebastian Schneeweiss, M.D., Sc.D., Co-founder and Science Lead, Aetion Inc.
  Macaya Douoguih, M.D., M.P.H. Head, Janssen Clinical Development and Medical Affairs, Janssen Vaccines & Prevention B.V., Johnson & Johnson

- **FDA Presentations (50 min)**
  Rachel Zhang, M.D., & Timothy Brennan, M.D., Medical Officers, OVRR, CBER, FDA (30 mins)
  Artur Belov, Ph.D., Office of Biostatistics and Epidemiology, CBER, FDA (10 mins)
  Narayan Nair, MD, Director, Division of Epidemiology, CBER, FDA (10 min)

  Q/A 10 min

Overview of Today's Agenda, cont.

- **Break (10 min)**

- **Open Public Hearing (60 min)**
- **Lunch (30 min)**
- **Additional Q & A Session regarding the Sponsor and FDA presentations (45 mins)**
- **Committee Discussion and Voting (120 min)**

- **Break (15 min)**

- **NIH Mix and Match Booster Study Presentation (45 min)**
  Kristen Lyke, M.D., Professor of Medicine, University of Maryland
  Q/A – 10 min

- **Committee Discussion of FDA Questions (45 mins)**

Voting Questions for the Committee

1. Do available data support the safety and effectiveness of Janssen COVID-19 Vaccine for use under EUA as a booster dose in individuals 18 years and older at least 2 months after a single dose primary vaccination?

    a. If yes to # 1, do available data support that an interval of at least 6 months between a single primary dose and a booster dose may result in a more robust booster response?

    b. If no to # 1, do available data support the safety and effectiveness of Janssen COVID-19 Vaccine for use under EUA as a booster dose in individuals 18 years and older at least 6 months after a single dose primary vaccination?

Non-Voting Discussion Question

Taking into consideration the limitations of the study design and sample size, please discuss any general observations that can be made regarding the data on heterologous boosters presented by NIH from their Mix and Match Booster Study.

Thank you!