

## Issue Brief

# ASTHO Summary of Emergency Use Authorization Application Materials for Janssen COVID-19 Vaccine

March 2021

### Background

The Janssen Ad26.COVS vaccine is a one-dose, replication-incompetent adenovirus type 26 (Ad26)-vectored vaccine, encoding a stabilized variant of the SARS-CoV-2 S protein. The EUA request includes safety and efficacy data from ongoing Phase 3 clinical trials of approximately 40,000 participants. Study participants were randomized to receive either the vaccine or placebo. The vaccine is disseminated as a multi-dose vial containing approximately five (0.5 mL) doses each. Once punctured, vials can be stored at 2-8°C (36° to 46°F) for up to six hours or at room temperature for up to two hours. It does not contain a preservative.

### Timeline

- **Feb. 4:** Janssen Biotech, Inc. submitted an [Emergency Use Authorization \(EUA\)](#) application to FDA for a COVID-19 vaccine candidate (Ad26.COVS). FDA has provided a [briefing document](#) to the [Vaccines and Related Biological Products Advisory Committee \(VRBPAC\)](#) summarizing the data provided in the EUA application.
- **Feb. 26:** FDA convened a VRBPAC meeting to discuss whether the benefits of the Janssen Ad26.COVS vaccine outweigh its risks for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. FDA [authorized](#) the Janssen COVID-19 vaccine for use among persons 18 years and older.
- **Feb. 28-Mar. 1:** CDC's Advisory Committee on Immunization Practices (ACIP) met to vote on whether to issue an interim recommendation for use of the Janssen COVID-19 vaccine in persons older than 18 years under the FDA emergency use authorization. [ACIP](#) voted 12 to 0, with one recusal, to issue an interim recommendation for use of the Janssen COVID-19 vaccine in persons older than 18 years under the FDA emergency authorization. Rochelle Walensky, director of CDC, approved the recommendations and CDC published an MMWR. The [MMWR](#) includes specific research, including a detailed summary of [safety data](#), a [GRADE review](#) of the evidence for benefits and harms, and information on [administration](#) and use in special populations.

### Safety and Side Effects Summary Extracted from FDA Briefing Document

- The study demonstrates that the Janssen vaccine is safe, effective, and well-tolerated in participants 18 years of age and older.
- Reactogenicity and adverse events were generally milder and less frequent in older participants (≥60 years of age) compared with the younger group (≤59 years of age). Reactogenicity was considered mostly mild to moderate.
- Common side effects include injection site reactions (48.6%), headache (38.9%), fatigue (38.2%), myalgia (33.2%), nausea (14.2%), and fever (9%). Reactions were less commonly reported among participants 60 years of age and older compared to participants aged 18-59. Median onset of symptoms was 0-2 days after vaccination and duration was approximately 1-2 days.

- Seven severe adverse events (SAEs) were reported in the clinical trial, three of which are considered likely related to the vaccine. Of those considered likely related to the vaccine, there was one report of vaccination site hypersensitivity, one report of post vaccination syndrome, and one report of radiculitis brachial (severe shoulder and/or arm pain associated with reduced range of movement). In addition, there were also two SAEs reported that are considered possibly related to the vaccine. Of those possibly related to the vaccine, there was one report of Guillain-Barre Syndrome and one report of pericarditis. In FDA’s assessment, a causal relationship cannot be definitively excluded.
- A total of 25 deaths were reported during the study (five in vaccine group and 20 in placebo group). Of the 25 reported deaths, seven were related to COVID-19 and all occurred in the placebo group.
- Participants were initially excluded if they were pregnant or planned to become pregnant within three months of vaccine administration, however eight participants (four in vaccine group and four in placebo group) reported pregnancies as of mid-January 2021.

### **Efficacy Summary**

- Based on the totality of available scientific evidence, the vaccine demonstrated 100% efficacy against COVID-19-related hospitalizations and deaths in individuals 18 years of age and older.
- Study results show the vaccine provided protection against COVID-19 in participants who had no evidence of prior infection, with more severe cases observed in the placebo group.
- Vaccine efficacy was similar between participants aged 18 to 59 and participants aged ≥60 years of age.
- The vaccine was 66.9% effective in preventing moderate to severe COVID-19 occurring at least 14 days after vaccination. The vaccine was 66.1% effective in preventing moderate to severe COVID-19 occurring at least 28 days after vaccination.
- The vaccine was 76.7% effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination. The vaccine was 85.4% effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination.
- The vaccine is effective across gender, race, and ethnicity demographics, and persons with comorbidities; however, there were not enough racial minorities enrolled in the study to make specific statements about the vaccine effectiveness broken down by race/ethnicity.
- There is limited data surrounding the vaccine efficacy against asymptomatic disease and transmission.

### **Next Steps**

An EUA will authorize use, but not approve the vaccine. The Janssen vaccine will undergo further investigation as part of the Biologics License Application process. Participants will be followed for two years. Please refer to the [FDA briefing document](#) for further information.