대한민국 대전환 한국판뉴딜

Ministry of Food and Drug Safety

Press Release

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MFDS Grants Marketing Authorization for Janssen COVID-19 Vaccine

☐ Following the Janssen Korea's application for the marketing authorization of the Janssen COVID-19 vaccine on February 27, 2021, the Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) granted a marketing authorization to the vaccine after a Final Evaluation Committee meeting with external experts on condition that the final results of the clinical trials be submitted.

1 Overview

☐ The Janssen COVID-19 vaccine, developed by Janssen Korea Ltd., is a

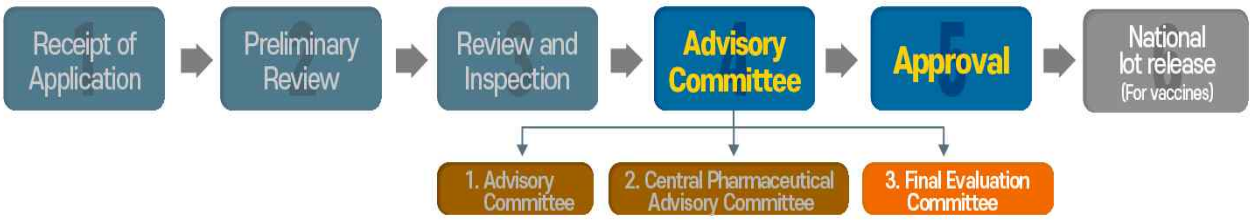
viral vector vaccine manufactured with a recombinant adenovirus to enable the synthesis of antigens which induce the formation of neutralizing antibodies against SARS-CoV-2 in the human body.

○ The Janssen COVID-19 vaccine is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. It should be administered as a single-dose of 0.5 mL and stored at －25℃ to －15℃ for maximum 24 months.

□ The Ministry's approval makes the Janssen vaccine the third COVID-19 vaccine authorized in Korea. The Janssen COVID-19 vaccine received conditional or emergency use authorizations in 35 countries including Switzerland and the United States as well as the EMA and WHO.

* **(Conditional Marketing Authorization)** 30 countries including Canada, Saudi Arabia and Switzerland, and the EMA including 27 European states
(Emergency Use Authorization) 5 countries including Bahrain, Jordan, the United States and Qatar, and the African Union

2 Current Marketing Authorization Review Status



□ With safety as a top priority, the MFDS is committed to conducting rigorous review on vaccines and treatments based on scientific evidence.

○ The Ministry carried out a rolling review to speed up the assessment of the vaccine by reviewing available data from ongoing studies before the application was filed.

○ The COVID-19 Vaccines and Treatments Review Team consisting of multidisciplinary experts at the Ministry reviewed the nonclinical, clinical and quality data submitted by Janssen Korea.

- For nonclinical evaluation, the vaccine was tested for effectiveness (e.g. neutralization potency, immune response or symptoms), pharmacokinetics and toxicity (e.g. repeated dose toxicity or reproductive and developmental toxicity).

- For clinical evaluation, the results of four (4) clinical trials have been reviewed, including one (1) phase I·II clinical trial conducted in the United States and Belgium, one (1) phase I clinical trial in Japan, one (1) phase II multinational clinical trial in countries including Germany, and one (1) phase III clinical trial conducted in *eight countries** including the United States.

  * *eight countries*: Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa and the U.S.

- For quality review, documents regarding manufacturing methods and standards and test methods were examined.

3 Three-tiered Advisory Review Process

□ At the MFDS, a three-tiered advisory review is carried out by the COVID-19 Treatment and Vaccine Safety and Efficacy Assessment Advisory Committee (or the Advisory Committee), the Central Pharmaceutical Advisory Committee and the Final Evaluation Committee to ensure accuracy and objectivity throughout the review and approval processes for COVID-19 vaccines.

○ Based on the Janssen COVID-19 vaccine's submitted data such as clinical data, the Ministry held advisory meetings with the Advisory Committee and the Central Pharmaceutical Advisory Committee on March 28 and April 7, respectively, to review the vaccine's efficacy, effect, safety and effectiveness as well as post-authorization safety management plans.

○ Following these meetings, the MFDS held a Final Evaluation Committee meeting on April 7, 2021, to make a final decision on the Janssen

COVID-19 vaccine's marketing authorization.

- The final advisory meeting was attended by three external experts including the chairman of the Central Pharmaceutical Advisory Committee and five internal experts including the Minister of Food and Drug Safety.

4 Final Evaluation Committee Meeting Outcomes

□ Following the overall examination on the results of the Ministry's review and the outcomes of two advisory meetings, the Final Evaluation Committee concluded that the Janssen COVID-19 vaccine may be granted a marketing authorization on condition that the final results of the clinical trials be submitted after the authorization.

○ The authorization came after assessing the submitted documents including clinical results under in-depth review and GMP inspection.

○ **(Safety)** In terms of safety, the Final Evaluation Committee concluded that most of the reported adverse events were solicited adverse events related to vaccine administration and that they were deemed to be within the acceptable level.

- Of the reported cases, *very common** adverse reactions were pain at the injection site, headache, fatigue and myalgia (muscle pains), which were usually mild or moderate and resolved within two to three days after vaccination.

  * Very common: more than one in ten people reported the adverse reaction

- Of the total 43,783 participants, serious adverse events were reported in 0.4 percent (83 participants) of the vaccinated group and 0.4 percent (96 participants) of the control group; and there were seven serious drug adverse reactions of which a causal relation with vaccination cannot be excluded, with most of the patients recovering at the time of clinical data submission.

- Based on these results, the Final Evaluation Committee concluded that the vaccine's safety profile is generally acceptable.

○ **(Efficacy)** After reviewing the submitted clinical data, the Final Evaluation Committee came to the same conclusion as the two previous advisory meetings that the vaccine had an acceptable level of preventive effect, advising to monitor long-term immunogenicity.

- The clinical trial results showed that the vaccine was 66.9% effective 14 days after vaccination, with 116 participants in the vaccinated group and 348 in the control group tested positive for COVID-19; and 66.1% effective 28 days after vaccination, with 66 in the vaccinated group and 193 in the control group tested positive.

- This was based on the results of the multinational clinical trial in 39,321 participants 18 years and older (19,630 in the vaccinated group and 19,691 in the control group) who had not been tested positive for COVID-19.

○ **(Post-authorization Safety Management Plans)** The Final Evaluation Committee concluded that the overall safety management plan was appropriate, advising that cases such as tinnitus and cerebral venous sinus thrombosis should be monitored by a post-authorization Risk Management Plan (RMP) to ensure safety of the vaccine and that data should continue to be collected to follow up on adverse events that occur in ongoing clinical trials and post-authorization use.

5 Future Plans

□ The MFDS has granted a marketing authorization to Janssen Korea's Janssen COVID-19 vaccine after rigorous review of vaccine's safety and efficacy through the three-tiered advisory review process.

○ The MFDS will continue to do its utmost to strengthen the post-authorization adverse event monitoring system and to ensure safe

vaccination for the people through rigorous monitoring and timely response while coordinating with other organizations such as the KDCA.