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Ministry of Food and Drug Safety

Press Release

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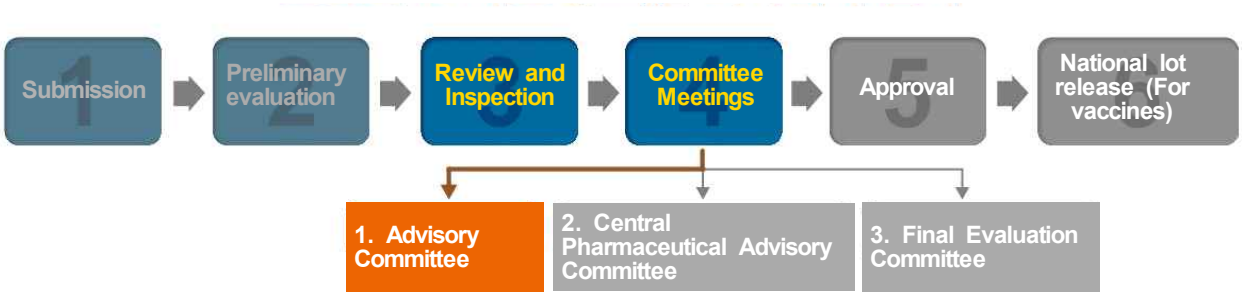
Advisory Committee Meeting Outcomes on Janssen COVID-19 Vaccine

1 Current Marketing Authorization Review Status



□ On March 28, the Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) held a meeting of the COVID-19 Vaccine Safety and Clinical Efficacy Advisory Committee (hereinafter Advisory Committee) to review the clinical trial results on the Janssen COVID-19 vaccine of Janssen Korea Ltd.

○ The Advisory Committee meeting is a mandatory procedure within the Ministry to seek advice on clinical, nonclinical, and quality data from various experts prior to the consultation with the Central

Pharmaceutical Advisory Committee.

- The Advisory Committee meeting was attended by six experts including an infectious disease specialist as well as vaccine and clinical data experts.

2 Clinical Trial Results

<< Overview >>

□ Submitted clinical trial data included the results of four (4) clinical trials 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 such as Germany and one (1) phase III clinical trial conducted in *eight countries** including the U.S.

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

○ In the multinational clinical trial conducted in eight countries, 43,783 participants with an average age of 50.7 were administered with either the test vaccine or placebo. Among the participants, 45 percent (or 19,722 participants) were women; 40.8 percent (or 17,858 participants) had underlying diseases such as obesity, hypertension or diabetes; and 19.6 percent (or 8,561 participants) were aged 65 and older.

<< Efficacy >>

□ (Preventive Effect) The effectiveness in prevention was evaluated by giving an injection of either the test vaccine or placebo (0.9

percent saline solution) to 39,321 participants (19,630 in the vaccinated group and 16,915 in the control group) who had not been tested positive for COVID-19.

○ The preventive effect was evaluated based on the comparison and analysis of the percentage of COVID-19 cases in each group at 14 and 28 days after one dose of vaccination. Participants were considered infected when they showed clinical symptoms for COVID-19 and were tested positive following the *RT-PCR** test for SARS-CoV-2.

* RT-PCR (Reverse Transcription Polymerase Chain Reaction): Abbott Real Time SARS-CoV-2 RT- PCR assay

○ According to the evaluation, the vaccine showed an approximately 66.9 percent *efficacy rate** with 116 confirmed cases in the vaccinated group and 348 in the placebo group at 14 days after vaccination; 66 confirmed cases in the vaccinated group and 193 in the control group at 28 days after vaccination. Regardless of participants' age[1] or underlying disease[2], the vaccine demonstrated a 60 percent or more efficacy rate at 14 days after vaccination.

* Efficacy rate (percent) = 100 x (1 - (percentage of confirmed cases in the vaccinated group) / (percentage of confirmed cases in the control group))

Category		efficacy rate (%)	
		14 days after vaccination	28 days after vaccination
Age[1]	between 18-64	64.2	65.1
	65 or more	82.4	74.0
Underlying Disease[2]	existent	62.9	48.6
	non-existent	69.1	72.6

○ In terms of efficacy against severe COVID-19 cases, the vaccine was 76.7 percent effective with 14 severe cases in the vaccinated group and 60 in the control group at 14 days after vaccination; 85.4 percent with 5 severe cases in the vaccinated group and 34 in the control group at 28 days after vaccination.

□ **(Immunogenicity Evaluation)** As an indirect indicator of the vaccine's effectiveness, immunogenicity was evaluated by examining the kinds and amount of antibodies generated in the body after vaccination.

* Immunogenicity evaluation: three clinical trials have been conducted in: Belgium and the US (phase I·II clinical trial); Japan (phase I clinical trial); and Germany, the Netherlands and Spain (phase II clinical trial)

○ In terms of binding antibodies which bind only to SARS-CoV-2 antigens, the seroconversion rate – the percentage of participants whose antibody titer increased fourfold or more 4 weeks after vaccination – was 95 percent or more.

○ Also, in terms of neutralizing antibodies which affect efficacy by attaching to a viral particle surface and thereby neutralizing viral infectivity, the seroconversion rate was 90 percent or more after one dose of vaccination.

<< Safety >>

□ After vaccination, 6,736 participants (3,356 in the vaccinated group; 3,380 in the control group) were monitored for *Solicited adverse events** (local and systemic) in the first seven days after vaccination.

* (local) pain at the injection site, redness and swelling (systemic) headache,

fatigue, muscle pain, nausea and fever

* solicited adverse events: during the early days (in the first seven days) after vaccination, adverse events are aggressively monitored using electronic record system.

○ The reported local symptoms included pain at the injection site (48.7 percent), redness (7.3 percent) and swelling (5.3 percent), which were mostly mild to moderate symptoms and disappeared within two to three days from the onset.

○ The reported systemic symptoms included headache (39.0 percent), fatigue (38.3 percent), muscle pain (33.2 percent), nausea (14.2 percent) and fever (9.0 percent) – mostly mild to moderate symptoms – appeared within one to two days from vaccination and disappeared within one to two days from the onset.

○ Both local and systemic symptoms were mostly lower in frequency and severity among the people aged 65 or more compared to other age groups.

* (**Local · Systemic Symptoms** (%)) younger age group (aged between 18 and 64): 55.7 · 59.6 | older age group (aged 65 or more): 31.8 · 40.2

□ Vaccination-related unsolicited adverse events (according to a 4-week follow-up after vaccination) were reported in 7.2 percent (242/3,356 participants) of the vaccine recipients and the major symptoms included chills (1.7 percent), nasal congestion (0.3 percent), joint pain (0.5 percent), cough (0.4 percent) and diarrhea (0.3 percent).

* Unsolicited adverse events: clinical trial cases self-reported by participants during a medical check-up or by telephone during the four weeks from vaccination

○ Adverse events among older participants were less frequently reported compared to other age groups, demonstrating no significant difference in post-vaccination adverse events according to age, race or underlying disease.

* younger age group (aged between 18 and 64): 7.8 percent (202/2,593 participants) vs. older age group (aged 65 or more): 5.2 percent (40/763 participants)

○ Among the 43,783 participants registered in the clinical trial, 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.

3 Advisory Committee Meeting Outcomes

□ Based on the clinical trial data of the Janssen COVID-19 vaccine, the Advisory Committee held a meeting to discuss the vaccine's safety and efficacy and ways to guarantee post-authorization safety.

<< Conclusion on the Vaccine's Effectiveness >>

○ Regarding the preventive effect of the vaccine, the Advisory Committee concluded that the vaccine had an acceptable level of preventive effect to be granted a marketing authorization with its efficacy demonstrated among the participants aged 18 or more at 14 and 28 days after one dose of vaccination and its immune response (binding and neutralizing antibodies) effective in at least

the first 12 weeks from vaccination.

<< Conclusion on Safety >>

○ Regarding the adverse events reported during the clinical trials, the Advisory Committee concluded that the vaccine had an acceptable safety profile (tendency) in the clinical trials.

<< Advice on Post-Authorization Safety >>

○ The Committee also advised that there should be a Risk Management Plan (RMP) following the authorization to monitor and follow up on the adverse events reported during the clinical trials.

4 Future Plan for Review and Approval

□ The MFDS will continue to do its utmost to ensure rigorous review and approval processes for COVID-19 vaccines and treatments while at the same time guaranteeing objectivity and transparency across all approval and review processes by taking into account multidisciplinary advice from experts.