대한민국 대전환 한국판뉴딜

Ministry of Food and Drug Safety

Press Release

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MFDS Grants Marketing Authorization for Pfizer Korea's COVID-19 Vaccine, COMIRNATY Inj.

☐ On March 5, at the Final Evaluation Committee meeting involving internal and external experts, the Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) granted marketing authorization to Pfizer Korea for its COVID-19 vaccine, COMIRNATY Inj., on condition that the final report of the currently ongoing clinical study be submitted. The pharmaceutical company filed for marketing authorization on Jan. 25, 2021.

1 Product Overview

☐ COMIRNATY Inj. is a COVID-19 vaccine jointly developed by U.S. pharmaceutical firm Pfizer and Germany's BioNTech. It is a messenger RNA (mRNA) vaccine which induces immune response by inserting the antigen genes of SARS-CoV-2 into human cells in the form of mRNA for antigen protein synthesis. This triggers the production of neutralizing antibodies in the human body, leading to the neutralization of SARS-CoV-2 for destruction.

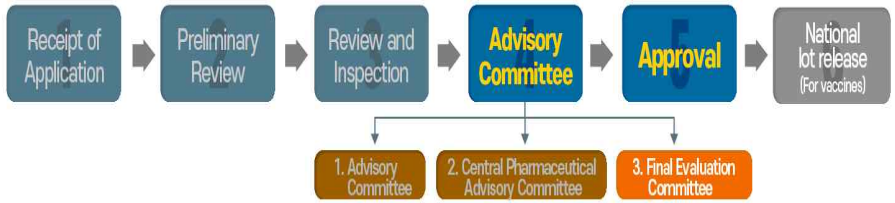
○ mRNA vaccines can be produced much faster in a larger scale than conventional vaccines. However, mRNA vaccines require ultra-cold chain storage to maintain its stability since mRNA, the major substance of the vaccine, can easily be degraded by RNase.

○ The Pfizer Korea COVID-19 vaccine is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is administered as a series of two doses (0.3 mL each after dilution*) 3 weeks apart. The vaccine can be stored for 6 months in a temperature between −60˚C to −90˚C.

*Each vial (0.45mL) is diluted with 1.8mL of 0.9% Sodium Chloride Injection.

☐ COMIRNATY Inj. is the first mRNA vaccine authorized in Korea and has been granted conditional marketing authorization or emergency use authorization by the WHO and 59 states and authorities including the EU (EMA), the U.S. and Japan.

2 Approval Procedure



○ The MFDS has secured as much time as possible to evaluate safety and efficacy data by starting a rolling review on available data even before the application is filed.

○ The COVID-19 Vaccine/Treatment Review Task Force, composed of competent reviewers from the MFDS, was established to focus on review of non-clinical, clinical and quality data required for the approval.

- Reviewed non-clinical data include the vaccine's pharmacology (virus

neutralizing titer, immune response and symptom, among others) in animal testing, pharmacokinetics and toxicity (repeated dose toxicity and reproductive toxicity, among others).

- There have been submissions of data from two clinical studies including a clinical study conducted in Germany (phase I·II) and a multi-national clinical study carried out in *six countries** (phase I·I·III) including the U.S. The safety and efficacy evaluation was based on the multi-national clinical study.

* The U.S., Argentina, Brazil, Germany, South Africa and Turkey

• Immunogenicity Evaluation was carried out based on the phase I·II clinical studies conducted in Germany and the U.S.

- Quality evaluation included a review on the submitted application, which comprises information such as manufacturing methods and standards, and test methods. The evaluation was also conducted on documents on foreign manufacturers' compliance of Good Manufacturing Practice (GMP), which demonstrate whether the manufacturers have the facilities or management system that can guarantee the consistency of product quality.

3 3-Tier Advisory Review

☐ In order to obtain expertise and maintain objectivity in the marketing authorization evaluation process for COVID-19 vaccines, the MFDS carries out the 3-tier advisory review composed of the meetings of the following advisory committees: 1) the COVID-19 Treatment and Vaccine Safety and Efficacy Assessment Advisory Committee (hereinafter the Advisory Committee); 2) the Central Pharmaceutical Advisory Committee, a legal advisory body of the MFDS in accordance with the Pharmaceutical Affairs Act; and 3) the Final Evaluation Committee.

○ The MFDS sought expert advice at the meetings of the Advisory Committee on February 22 and of the Central Pharmaceutical Advisory Committee on February 25, regarding the vaccine's indications, safety, efficacy and post-authorization safety management plans based on the submissions from Pfizer Korea including the clinical data.

○ The Final Evaluation Committee meeting was held at the MFDS at 10 am on March 5, to make a final decision on the vaccine's marketing authorization.

- The meeting, which is the final step of marketing authorization of COVID-19 vaccines, was attended by three external experts including Chairman Oh Il-hwan of the Subcommittee on Biologics of the Central Pharmaceutical Advisory Committee and five members of the MFDS including the Minister of Food and Drug Safety.

4 Review Results of the Final Evaluation Committee

☐ Based on the results of the MFDS's review on the application and the previous two committee meetings, the Final Evaluation Committee recommended granting marketing authorization to COMIRNATY Inj. on condition of submitting final results of clinical studies.

○ **(Safety)** The Final Evaluation Committee viewed that most of the reported adverse events were solicited adverse events following the vaccine administration and that they are in a range of acceptable level.

- Most common adverse events were pain at the injection site, tenderness, fatigue, fever, chills, headache and muscle pain. These were mild to moderate symptoms and disappeared within a few days after the administration.

- There was one report of drug-related hypersensitivity (urticaria) in vaccine recipients and no vaccine-related anaphylaxis reported during clinical studies.

- Among a total of 43,448 participants enrolled in the study, serious adverse events have been reported in 0.6% (126 cases) of vaccine recipients and in 0.5% (111 cases) of placebo recipients. Among them, four serious adverse

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events were considered to be related to vaccine administration: lymphadenopathy, ventricular arrhythmia, shoulder injury and low back pain and bilateral lower extremity pain with radicular paresthesia. Patients with lymphadenopathy and ventricular arrhythmia have made recovery and the rest are currently recovering.

- Based on the data, the Final Evaluation Committee concluded that the vaccine has met the safety standard for granting marketing authorization. Meanwhile, continuous monitoring is required even after the authorization regarding hypersensitivity including anaphylaxis. Further reports on adverse reactions will be reflected in relevant notifications including conditions of authorization.

○ **(Efficacy)** As the result of the previous two committee meetings, the Final Evaluation Committee concluded that the available data provides clear evidence of the Pfizer Korea COVID-19 vaccine's effectiveness in preventing COVID-19.

- Clinical study data showed that the vaccine is 95% effective in preventing COVID-19 among the participants with eight cases in the vaccinated group and 162 in the placebo group.

- The effectiveness data is based on an analysis of the multi-national clinical study carried out in six countries including the U.S. on 36,523 participants (18,198 vaccine, 18,325 placebo) who had not been tested positive to SARS-CoV-2.

○ **(Appropriateness for Use in Persons Aged 16 and Older)** As the results of the previous two advisory committee meetings, the Final Evaluation Committee recommended granting marketing authorization for the vaccine to be used in persons 16 years of age and older considering the following:

▲ The vaccine has demonstrated meaningful preventive effect in individuals 16 years of age and older in clinical studies designed to evaluate its safety and efficacy in the age groups.

▲ Immune response in adolescents aged 16 and 17 is deemed to be similar to that of adults.

▲ Results from the clinical studies in adults can be used as reference.

▲ In multiple countries including the U.S., E.U. countries, the U.K. and Japan, the vaccine has been approved for use in individuals 16 years of age and older.

○ **(Safety Management after Marketing Authorization)** The advisory panel of the Final Evaluation Committee viewed that the overall plan on safety management is acceptable. The panel requested a continued follow-up on adverse events such as anaphylaxis and lymphadenopathy based on the submitted risk management plan. The plan includes continued monitoring on the safety profile of the Pfizer Korea COVID-19 vaccine to identify and evaluate safety concerns that may occur in the ongoing clinical study and in the post-authorization use.

5 Future Plans

□ The MFDS has granted marketing authorization for Pfizer Korea's COMIRNATY Inj. after meticulously reviewing its safety and efficacy through the three-tier advisory committee meetings.

- In close cooperation with the Korea Disease Control and Prevention Agency, the MFDS will thoroughly monitor adverse reactions following vaccine administration and establish a system to swiftly respond to possible safety concerns in order to ensure safe vaccination for the people.

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