대한민국 대전환 한국판뉴딜

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보 도 자 료

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MDFS grants Marketing Authorization for Korea AstraZeneca's COVID-19 Vaccine

Administration to Individuals Aged 18 and Older, Including Older Adults (Aged 65 and Older)

☐ The Ministry of Food and Drug Safety (Minister Kim Ganglip) held the Final Evaluation Committee meeting comprised of internal·external experts and granted a marketing authorization for "Korea AstraZeneca COVID-19 Vaccine Inj." for which AstraZeneca Korea filed application on Jan. 4, 2021 on condition of submitting results of the currently ongoing clinical trial.

1 Product Overview

☐ The AstraZeneca COVID-19 vaccine Inj., is a viral vector vaccine. manufactured by inserting the spike protein gene of a pathogenic virus into the chimpanzee adenovirus template. This AstraZeneca vaccine uses an adenovirus that infects only chimpanzees as the vector to deliver the genetic material of SARS-CoV-2 spike protein to human cells. The genetic material enables the synthesis of antigens that trigger the production of neutralizing antibodies in the human body, leading to the neutralization of the virus for destruction.

○ Proposed recipients of Korea AstraZeneca COVID-19 Vaccine Inj. are those who are aged 18 and older. The vaccine is to be administered as a series of two doses (0.5 mL each) 4 to 12 weeks apart.

* For more information, you can visit the Ministry's drug safety website (e-government service platform, nedrug.mfds.go.kr) → Search 'Pharmaceuticals'→ Search 'product name'

□ Korea AstraZeneca COVID-19 Vaccine Inj. manufactured by contract with SK Bioscience in Korea is the first approved domestic COVID-19 vaccine and is granted with marketing authorization from 50 regulatory authorities including the European Medicines Agency (EMA) and the U.K.

* (Conditional marketing authorization) 27 European countries (EMA), Thailand, and the Republic of Ecuador

(Emergency Use Authorization) 21 countries including the U.K, Argentina, Republic of El Salvador, Dominican Republic, Mexico, Morocco, India and Brazil

2 Approval Procedure

< Procedure for Approval >

□ The MFDS received marketing authorization application for "Korea AstraZeneca COVID-19 Vaccine Inj." on Jan. 4, 2021 and then carried out thorough review based on scientific ground, prioritizing safety.

○ Available data was reviewed during a rolling review even before application, and this enabled us to secure as much time as possible to review safety and efficacy data.

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

- In particular, the comparability of SK Bioscience product (drug substance and drug products) was evaluated. In the process, the company's products was tested and evaluated in comparison with its comparability to that of the European countries.

- Along with the review on submitted data, inspections on Good Manufacturing Practice (GMP) (Jan. 18-20) and Good Clinical Practice (GCP) (Feb. 2-3) on AstraZeneca Korea Co., Ltd were conducted.

3 3-Tiered Advisory Review

□ The MFDS is taking the 3-tiered advisory review : 1) the "Advisory Committee for the Safety and Efficacy Assessment of COVID-19 Therapeutics/Vaccine" (hereinafter Advisory Committee), 2) the "Central Pharmaceutical Advisory Committee" (legal advisory body of MFDS in accordance with the Pharmaceutical Affairs Act, and 3) the "Final Evaluation Committee" to obtain expertise and maintain objectivity in the market authorization evaluation process for COVID-19 vaccine.

○ The MFDS found the advice from the Advisory Committee meeting on January 31 and at the Central Pharmaceutical Advisory Committee on January 27th, concerning dosage, administration interval and efficacy in individuals aged 65 and older based on the submitted data such as clinical trial results.

○ On February 10th, the "Final Evaluation Committee" meeting was held to make final decision on marketing authorization of Korea AstraZeneca's COVID-19 vaccine Inj. at 10am.

- This was the final step for the authorization COVID-19 Therapeutics/Vaccines. The meeting was attended by 3 experts including chairman Oh Il-hwan of the Subcommittee on Biologics of the Central Pharmaceutical Advisory Committee and five other officials from the MFDS including Minister of Food and Drug Safety.

4 Review Results of the Final Evaluation Committee

☐ Based on regulatory review and the results of two previous committee meetings, the Final Evaluation Committee decided to grant marketing authorization for Korea AstraZeneca's COVID-19 vaccine Inj. on condition of submitting results of Phase III clinical trial that is ongoing in countries including the U.S.

○ The Final Evaluation Committee determined that it is reasonable to allow authorization based on the submission of required clinical, non-clinical, quality, risk management plan, and GMP data to make regulatory decision, and desk-review and on-site inspections results for safety and efficacy.

○ (Safety) The Final Evaluation Committee concluded that most of the reported adverse reactions are predicted adverse reactions following administration of a vaccine and that they are in a range of acceptable level.

- Until now, four safety evaluation were conducted in states including the U.K (phase I/II, phase II/III), Brazil (phase III) on 23,745 subjects aged 18 and older (12,021 in the vaccinated group and 11,724 in the control group) and 8.9% (2,109) of the subjects were individuals aged 65 and older.

- Most common adverse reactions were pain and/or bruising at the injection site, tenderness, fatigue, flare, a sense of heat, fever, headache and muscle pain. These were mild to moderate symptoms and disappeared within a few days after the administration.

  * most common: adverse reaction found in more than 10% of the subjects.

- No adverse reactions, such as anaphylaxis or exacerbated the COVID-19 symptoms occurred, which can arise as hypersensitivity reactions after vaccination.

  * anaphylaxis: rapid systemic reaction caused by an antigen-antibody immune response

- There was no serious adverse reaction in individuals aged 65 and older and the rate of predicted or unpredicted adverse reaction was similar to or lower than the adult group.

  * Predicted adverse reaction: adults (87.7%) v. older adults (82.4%)
  * Unpredicted adverse reaction: adults (39.2%) v. older adults (24.6%)

○ Based on these findings, the Final Evaluation Committee came to a conclusion that in overall scope, the vaccine is safe. Meanwhile, continuous monitoring is needed even after the authorization regarding neuroinflammatory adverse reactions such as transverse myelitis. Further reports on adverse reactions will be added to the authorization clauses.

  * ransverse myelitis: a general term that includes various symptoms caused by immune mediated reaction.

○ (Efficacy) Preventive effect was 62% as among the vaccinated group and the control group, 27 and 71 subjects were tested positive reciprocally. This result satisfies domestic and global standard on COVID-19 vaccines effectiveness (more than 50% of preventive effect), including that of the WHO.

  * Vaccine Efficacy (VE) % = 100 x (1 - (Attack $Rate_{vaccinated}$) / (Attack $Rate_{unvaccinated}$))

- This is the result of clinical trials conducted in the U.K (Phase II/III) and Brazil (Phase III) on 8,895 subject (4,440 in the vaccinated group and 4,455 in the control group) aged 18 and older who are tested negative of COVID-19 virus.

○ The Final Evaluation decided that the vaccine should be authorized under the condition of administering with the right dosage and interval that was proven to be effective in the clinical trial, accepting the recommendation results from Committee and the Central Pharmaceutical Advisory Committee.

  * Dosage instruction: Administer two separate doses of 0.5mL each. The second dose should be administered between 4 and 12 weeks after the first dose.
  * Standard dose: 5*1010 virus particle (vp) (approval application dose)

○ (Administration to Individuals Aged 65 and Older) The Final Evaluation Committee concluded that as the CPAC advised, the vaccine is authorized on condition of administering to individuals aged 18 and older, including older adults (aged 65 and older). Meanwhile, the committee decided to include comments in drug description: “Be attentive when administering to individuals aged 65 and older.”

- This means, safety and immune response in older adults are proven to be in normal range but additional test results are needed as only 660 (7.4%) of individuals aged 65 and older participated the clinical trial. Physicians should weigh possible benefits considering patients’ condition prior to administering the vaccine to older adults.

- The CPAC recommended consultation with the Vaccination Expert Committee about administration of the vaccine to older adults.

○ (Administration to Pregnant or Breast-Feeding Women) The Final Evaluation Committee decided that as the CPAC and the Advisory Committee advised, administration of the vaccine to pregnant or breast-feeding women should only be considered when the potential benefits outweigh any potential risks, but it is not recommended for the purpose of prevention during pregnancy.

- The committee also decided to include a comment in drug description: “It is unknown whether this vaccine is excreted in human milk.”

5 Future Plans

□ The MFDS has made concerted efforts to thoroughly evaluate the safety and efficacy and accordingly authorized a COVID-19 vaccine for the first time in Korea.

○ The MFDS will make sure that the ongoing clinical trial result is submitted expeditely after the marketing authorization of Korea AstraZeneca COVID-19 Vaccine Inj.

- In close cooperation with relevant ministries, the MFDS will thoroughly monitor adverse reaction after vaccine administration and establish a system to swiftly respond to any possible adverse reaction in order to ensure a safe use of the vaccine for the people.