대한민국 대전환 한국판뉴딜

Ministry of Food and Drug Safety

Press Release

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담 당 과	첨단제품허가담당관 바이오생약국 바이오의약품정책과 백신심사반 총괄검토팀 바이오치료제심사반 총괄검토팀 바이오치료제심사반 임상심사팀
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MDFS grants Marketing Authorization for COVID-19 treatment, Regkirona Inj.

- Improving the clinical symptoms in outpatients with mild (high risk group) to moderate cases -

☐ 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 COVID-19 treatment, Regkirona Inj. 960mg (regdanvimab) which Celltrion Inc. submitted the application on December 29, 2020, on condition of submitting results of a Phase Ⅲ clinical trial.

1 Product overview

☐ Regkirona Inj. is a recombinant neutralizing antibody drug. It is a biological product produced after selecting a neutralizing antibody gene expressed in a COVID-19 convalescent patient's blood and inserting the selected gene into a host cell. The host cell is then cultured for the large-scale production of the antibody.

○ The Regkirona Inj. intends to improve clinical symptoms of COVID-19 outpatients with mild (at high risk)* to moderate symptoms (aged 18 or more), and to be administered by intravenous (IV) infusion (40mg of Regkirona Inj. per 1kg body weight) over 90 minutes (±15min.).

* Mild symptoms of high risk group: over 60 years old or a mild symptom patient with more than one underlying disease among cardiovascular risk, chronic respiratory disease, diabetes, high blood pressure.

* 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'

☐ Regkirona Inj is the first approved COVID-19 treatment as a domestically developed drug and the third regulatory-verified COVID-19 antibody treatment all over the world.

○ MFDS expects that use of this drug along with other vaccines can help us combat the pandemic and go back to normal life.

2 Approval Procedure

< Procedure for Approval >

☐ MFDS received marketing authorization application for Regkirona Inj. on December 29, 2020 and then carried out thorough review based on scientific ground, prioritizing s afety.

○ Available data was reviewed during a rolling review before application, and this enabled us to secure enough time 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, and Good Manufacturing Practice (January 4-7) and Good Clinical Practice (January 12-15) inspections.

3 3-Tiered Advisory Review

☐ 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), and 3) the “Final Evaluation Committee” to obtain expertise and maintain objectivity in the market authorization evaluation process for COVID-19 therapeutics.

○ At the Advisory Committee meeting on January 17, whether clinical trial results demonstrates efficacy and safety was discussed, and at the Central Pharmaceutical Advisory Committee on January 27th, discussion was on whether efficacy and safety data is sufficient to grant market authorization on condition of providing the Phase III clinical trial data.

○ On February 5th, the “Final Evaluation Committee” meeting was held to make final decision on marketing authorization of Regkirona 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 other 5 officials from MFDS including Minister of Food and Drug Safety.

4 Review Results of the Final Evaluation Committee

☐ The Final Evaluation Committee considered both regulatory review and the results of two previous committee meetings and recommended marketing authorization of Regkirona Inj. on condition of submitting results of a Phase Ⅲ clinical trial.

○ 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.

○ Based on the opinions of the Advisory Committee and the Central Pharmaceutical Advisory Committee, the Final Evaluation Committee concluded that Regkirona Inj. will be used in adult patients with mild (at high risk) to moderate symptoms.

5 Future Plans

☐ MFDS has made concerted efforts to expedite the approval process while thoroughly evaluating its safety and efficacy and accordingly authorized a COVID-19 neutralizing antibody drug developed for the first time in Korea.

○ MFDS will supervise the implementation of the Phase III clinical trial of Regkirona Inj., closely monitor any side effects during its use, and cooperate with other relevant Ministries to ensure that it is safely used in clinical trial patients.

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