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MFDS Begins Rolling Review of Novavax COVID-19 Vaccine

☐ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) announced that SK Bioscience filed for a *rolling review** of the Novavax COVID-19 vaccine on April 29 before submitting an application for marketing authorization.

* Rolling review: a system (underway in the U.S. and Europe) where data is reviewed as it becomes available from ongoing studies before an application for marketing authorization is submitted

○ The Novavax vaccine is a synthetic antigen vaccine manufactured based on recombinant DNA technology. The data submitted for the rolling review are nonclinical data (from toxicity and efficacy tests) and *early phase clinical trial data**.

* Early phase clinical trial data: phase I/II clinical trial results

☐ To ensure a speedy approval process, MFDS had prior consultations with the regulatory team of Novavax when Novavax CEO Stanley Erck visited Korea.

* Hybrid meetings were held between the Ministry of Health and Welfare (MoHW), MFDS and Novavax on April 9, April 23 and April 27, 2021

* Working-level discussions between MFDS and Novavax were held on April 27, 2021

○ Based on the submitted data, the Vaccine Review Team of specialized experts in nonclinical and clinical areas will thoroughly review the safety and efficacy of the vaccine.

○ The Novavax vaccine is currently under rolling review by the Medicines and Healthcare products Regulatory Authority (MHRA) and European Medicines Agency (EMA) among others. With the initiation of the rolling review by MFDS, the vaccine will go through approval processes in Korea in line with other regulatory authorities.

□ MFDS is fully committed to ensuring a swift supply of safe and effective vaccines to the people.