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SK bioscience reaches final stage of developing KoreaÃ?Â´s first COVID-19 vaccine

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Advanced Purchase Agreement with Korea CDC signed for supply of 10 million doses of the vaccine



South Korea-based SK bioscience and GSK have announced submission of a biologics license application for SKYCovione a recombinant protein-based COVID-19 vaccine candidate adjuvanted with GSK's pandemic adjuvant, to the Korean Ministry of Food and Drug Safety (KMFDS) following positive Phase III clinical data.

SK bioscience conducted a Phase III clinical trial in 4,037 adults over 18-year-old across 6 countries (Thailand, Vietnam, New Zealand, Ukraine, the Philippines and South Korea). The clinical trial was conducted in cooperation with 16 institutions, including Korea University Guro Hospital and IVI (International Vaccine Institute), a non-profit international organization.

The results of the Phase III clinical trial show a superior neutralizing antibody response of SKYCovione against SARS-CoV-2 parental strain, 2.93 times that of a control vaccine 2 weeks after the second dose.

SKYCovione is a self-assembled nanoparticle vaccine candidate targeting the receptor binding domain of the SARS-CoV-2 Spike protein for the parental SARS-Cov-2, jointly developed with the Institute for Protein Design (IPD) at the University of Washington School of Medicine with combination of GSK's pandemic adjuvant. The development of SKYCovione has been supported by funding from the Coalition for Epidemic Preparedness Innovations (CEPI).

The approval of SKYCovione is through a formal biologics license application procedure, not a conditional approval process.

SK bioscience will apply for emergency use listing (EUL) to the World Health Organization (WHO) and authorizations at individual regulatory agencies around the world. The company is conducting a homologous booster clinical trial of SKYCovione in South Korea and a heterologous booster trial in both South Korea and abroad.