

IVI & SK bioscience confirm SK's COVID-19 vaccine candidate meets coprimary objectives in a 6-country Phase III study

SEOUL, REPUBLIC OF KOREA, May 10, 2022 /EINPresswire.com/ --

- Recombinant protein-based 'SKYCovione™' adjuvanted with GSK's pandemic adjuvant demonstrates superior neutralizing titers compared to a control vaccine and safety
- SK bioscience submits a biologics license application to KMFDS, and will submit license applications to international regulatory agencies
- Company set to supply 10 million doses of the vaccine to Korea under Advance Purchase Agreement with KDCA

The International Vaccine Institute (IVI) and SK bioscience successfully completed their joint six-country Phase

III clinical trial of SK bioscience's COVID-19 vaccine candidate ('GBP510'), which has confirmed that the vaccine meets coprimary objectives and demonstrates superior neutralizing titers compared to a control vaccine and safety. Based on positive Phase III clinical data, SK bioscience recently submitted license application for the recombinant protein-based vaccine adjuvanted with GSK's pandemic adjuvant to the Korean Ministry of Food and Drug Safety (KMFDS).

SK bioscience and IVI jointly conducted the Phase III trial study of the vaccine "SKYCovione™" in 4,037 adults over 18-year-old across 6 countries (Thailand, Vietnam, New Zealand, Ukraine, the Philippines, and South Korea), with IVI coordinating the trial in five countries, excluding Korea. The vaccine candidate demonstrated superior neutralizing antibody titers over AstraZeneca's Vaxzevria™ (control vaccine), a currently authorized COVID-19 vaccine. The vaccine candidate also showed a clinically favorable safety profile.



IVI and SK bioscience successfully completed a joint Phase III clinical trial of SK bioscience's COVID-19 vaccine candidate SKYCovione™ across Thailand, Vietnam, New Zealand, Ukraine, the Philippines, and South Korea. Credit: SK bioscience

The results of the Phase III study dubbed the 'COVID vaccine Clinical and Operational Alliance (COCOA)' 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. In addition, the proportion of participants who seroconverted, (with a greater than four-fold increase in neutralizing antibody titers compared to baseline), was 98.06% in the SKYCovione™ group and 87.30% in the control (Vaxzervia) group.

Even in subjects aged 65 or older, the antibody conversion rate of those vaccinated with SKYCovione™ was over 95%, when compared to the control vaccine (about 79% for the same age group).

In terms of safety, overall, SKYCovione™ showed a clinically acceptable safety profile. Most of the adverse reactions that occurred after injection were mild or moderate. IVI and the Korea Institute of Health under KDCA jointly performed analysis of clinical samples to measure the vaccine's efficacy.

Dr. Sushant Sahastrabuddhe, the Principal Investigator of the study and Director of COCOA, said, "IVI is proud to have successfully completed the global Phase III clinical trial of SK bioscience's new COVID-19 in collaboration with partners in the five countries, despite multiple challenges including the war in Ukraine. We express our profound gratitude to all the study participants, their families, the site staff, CROs, and partners including SK bioscience and CEPI who played critical roles in this success. This study will pave the way for use of this vaccine in our continued fight against COVID-19."

Jae-Yong Ahn, CEO of SK bioscience said, "SK bioscience has reached the final stage of developing Korea's first COVID-19 vaccine for the benefit of Korea and the world. SK bioscience will not settle for the present but will do its best to become an innovative vaccine and biotechnology company in South Korea through continuous cooperation with global organizations and companies."

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 CEPI, and the vaccine was the first COVID-19 vaccine candidate to be selected as a part of Wave 2, a project initiated CEPI in 2020 to support promising vaccine candidate.

SKYCovione™, a recombinant protein-based vaccine, is expected to give a new vaccine option to people around the world in addition to other currently available COVID-19 vaccines.

SKYCovione™ can be refrigerated at 2 to 8 degrees Celsius and stored for a long time, unlike the existing mRNA vaccines that require cryogenic storage. Based on these advantages, the vaccine may play a key role in increasing the vaccination rate in low-income countries, where the supply

of COVID-19 vaccine was insufficient due in part to the lack of expensive cryogenic facilities.

“The clinical development of SK bioscience’s COVID-19 vaccine is an exemplary model of public-private partnership in the quest to develop much-needed vaccines against COVID-19,” said Dr. Jerome Kim, Director General of IVI. “IVI is committed to contributing to the development of additional vaccines against COVID-19 and vaccines against other diseases of global health significance.”

The approval of SKYCovione™ in South Korea is through a formal biologics license application procedure, not a conditional approval process. In March, SK bioscience signed an advance purchase agreement with the Korea Disease Control and Prevention Agency (KDCA) to supply a total of 10 million doses of SKYCovione™.

In addition, SK bioscience will apply for the vaccine’s emergency use listing (EUL) to the World Health Organization (WHO) and authorizations at individual national regulatory agencies around the world. If authorized, the vaccine can be made available to the COVAX Facility for procurement and equitable distribution worldwide, if required.

SK bioscience is conducting a homologous booster clinical trial of SKYCovione™ in South Korea and a heterologous booster (“mix and match”) trial in both South Korea and overseas. A trial for adolescents between 12- to 17-year-old is expected to enter Phase III in the first half of 2022. In addition, an extended clinical trial designed test SKYCovione™’s protection against COVID-19 variants including Omicron is planned.

Aerie Em
International Vaccine Institute
+82 2-881-1386

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