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Korea's SK bioscience plans Ph III COVID-19 vaccine trial in multiple countries

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IVI to conduct Phase 3 clinical trials of SK bioscience's recombinant protein vaccine candidate (GBP510) in Europe and Southeast Asia

The International Vaccine Institute (IVI) is partnering with SK bioscience of South Korea to conduct Phase III clinical trials of SK bioscience's COVID-19 vaccine candidate in multiple countries in an effort to accelerate the development of much-needed "Wave 2" vaccines. This is the first Phase III IND approval by the MFDS for a COVID-19 vaccine developed domestically in Korea.

Funding for this Phase III study has been provided by the Coalition for Epidemic Preparedness Innovations (CEPI). Additionally, IVI, SK, and the Korea National Institute of Health (KNIH) under the Korea Disease Control and Prevention Agency (KDCA) signed an agreement to jointly conduct antibody testing for the global Phase III trials.

These moves follow SK bioscience's announcement on August 10 confirming the safety and robust immunogenic response of its GBP510 vaccine candidate, co-developed with the Institute for Protein Design (IPD) at the University of Washington and adjuvanted with GlaxoSmithKline's (GSK) AS03, in an interim analysis of the stage 1 segment in a Phase I/II study.

Based on the promising interim data from Phase I/II clinical trials, SK bioscience has formed the COVID vaccine Clinical and Operational Alliance (COCOA) and is working with IVI on global Phase 3 trials of the vaccine. The aim of this consortium is to make the GBP510 vaccine available worldwide with WHO prequalification (PQ) / WHO Emergency Use Listing (EUL).

IVI and SK will aim to complete the Phase 3 trial of GBP510 in Europe and Southeast Asia and bring the vaccine to market by the first half of 2022.