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SK bioscience seeks European approval for COVID-19 vaccine

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SK bioscience submits conditional marketing authorisation application of COVID-19 vaccine, SKYCovion to the medicines and healthcare products regulatory agency

South Korea-based SK bioscience, a global innovative vaccine and biotech company dedicated to promoting human health from prevention to cure across the globe, has announced that the company applied for a Conditional Marketing Authorization (CMA) of the joint-developed COVID-19 vaccine, 'SKYCovion' to the UK Medicines and Healthcare Products Regulatory Authority (MHRA).

SKYCovion has been submitted to an application for rolling review by the MHRA since March. SK bioscience additionally applied the recently secured Phase III clinical data of SKYCovion for a formal conditional approval.

Following UK submission, SK bioscience has also applied for conditional approval to the European Medicines Agency (EMA). SK bioscience intends to make SKYCovion available through the COVAX Facility for procurement and equitable allocation worldwide should an Emergency Use Listing (EUL) be obtained from the World Health Organization (WHO).

SKYCovion is a self-assembled nanoparticle vaccine 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 SKYCovion has been supported by funding from the Bill & Melinda Gates Foundation and the Coalition for Epidemic Preparedness Innovations (CEPI), with support from the European Union's Horizon 2020 Programme.