SK bioscience and GSK's adjuvanted COVID-19 vaccine candidate meets coprimary objectives in a phase III study; Biologics License Application submitted for SKYCovione™(GBP510/GSK adjuvant) in South Korea

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- Recombinant protein-based 'GBP510' with GSK pandemic adjuvant demonstrates superior neutralising titres compared to a control vaccine and clinically favourable safety profile

- SK submits license application to MFDS to support vaccine sovereignty in South Korea

- Plans for license applications in multiple markets

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

SK bioscience and GSK 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 vaccine candidate demonstrated superior neutralizing antibody titres over AstraZeneca's Vaxzevria™ (control vaccine), a currently authorized COVID-19 vaccine. SKYCovione™ vaccine candidate showed a clinically favorable safety profile.

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.

In addition, the proportion of participants who seroconverted, (with a greater than four-fold increase in neutralizing antibody titres compared to baseline), was 98.06% in the SKYCovione™ group and 87.30% in the control group.

Both immunological superiority and non-inferiority of SKYCovione™ was demonstrated compared to Vaxzevria™ (control vaccine).

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.

Roger Connor, President of GSK Vaccines, said,

> As the COVID-19 pandemic continues to evolve, a variety of vaccines will be needed to meet the health needs across the globe, including temperature stable vaccines like the SK/GSK vaccine candidate. These immunogenicity and safety data confirm the important role that our adjuvant technologies play in vaccine development.

Jae-Yong Ahn, CEO of SK bioscience said, “At this point in time, when countries around the world are developing strategies to respond to the

endemic phase of the COVID-19 global health crisis, 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 the Coalition for Epidemic Preparedness Innovations (CEPI).

The approval of SKYCovione™ 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 Centers for Disease Control and Prevention (KDCA) for a total of 10 million doses of SKYCovione™.

In addition, SK bioscience will apply for emergency use listing (EUL) to the World Health Organization (WHO) and authorizations at individual regulatory agencies around the world. If authorized, GBP510 could be made available to the COVAX Facility for procurement and equitable allocation worldwide, if required.

SK bioscience is conducting a homologous booster clinical trial of SKYCovione™ in South Korea and a heterologous booster trial in both South Korea and abroad. The Adolescents trial between 12 to 17-year-old is expected to enter a Phase III stage in the first half of 2022. In addition, an extended clinical trial seeking to test the preventive effect of SKYCovione™ against COVID-19 variants such as Omicron is planned.

SK bioscience is an innovative biopharmaceutical company, standing committed to global pandemic preparedness in vaccine development and manufacturing to create more equitable access to vaccines. In leveraging strengths on cutting-edge vaccine development technologies, SK bioscience has been dedicated to improving healthcare from prevention to cure across the globe. Under collaborations of domestic and international governments, regulatory agencies, healthcare providers, doctors and medical experts, SKBS

has firmly established globally certified R&D and manufacturing technologies. All of SK colleagues are passionately committed to providing high-quality vaccines to those who need them and better public healthcare solutions.

For further information, please visit https://www.skbioscience.co.kr/en/main.

GSK is a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

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