Enrollment begins for Sanofi and GSK's Phase 3 efficacy trial of COVID-19 vaccine candidate in Nepal, led by IVI

International Vaccine Institute (IVI) will lead the clinical trial in Nepal of an adjuvanted recombinant-protein COVID-19 vaccine candidate

SEOUL, SOUTH KOREA, September 27, 2021 /EINPresswire.com/ -- Sanofi and GSK received approval for their Phase 3 clinical study in Nepal to assess the safety, efficacy and immunogenicity of their adjuvanted recombinant-protein COVID-19 vaccine candidate. The International Vaccine Institute (IVI), an international organization dedicated to the discovery, development and delivery of safe, effective and affordable vaccines, will conduct the Phase 3 clinical trial in Nepal, expecting to enroll 4,000 volunteers across 3 study sites in the country.

In addition to generating local data to support the global clinical trial, this Phase 3 study led by IVI will continue to build capacity and infrastructure for vaccine research and development in Nepal. As COVID-19 vaccination becomes available, study participants are encouraged to receive an approved COVID-19 vaccine during the study, if they wish to do so. As part of the study design, all participants including the control group will be offered the study vaccine as soon as it is determined to be safe and effective.

"Nepal is participating in Sanofi Pasteur's pivotal Phase 3 study, and we have begun enrollment of study participants in the country. We have partnered with International Vaccine Institute for the study in Nepal." said Annapurna Das, Country Head, Sanofi Pasteur India and South Asia.

"As the virus continues to evolve, we are anticipating what will be needed in the coming months and years, and accordingly, have adapted our vaccine development program. We believe our COVID-19 adjuvanted, recombinant vaccine can make a significant contribution to the ongoing fight against COVID-19 and are committed to initiating our clinical program in Nepal, at the earliest" she added.

"Achieving global immunity to end the COVID-19 pandemic requires an innovative generation of new vaccines that have been tested against circulating variants and that will be accessible to low-resource settings. We are pleased to partner with Sanofi Pasteur on this pivotal Phase 3 study in Nepal, particularly in light of our recent collaboration agreement with the Nepal Health Research Council earlier this year to strengthen public health in the region," said Dr. Anh Wartel, Deputy Director General at IVI.

About the Phase 3 study

The primary endpoint of the study is the prevention of symptomatic COVID-19 in SARS-CoV-2 naïve adults, with secondary endpoints being the prevention of severe COVID-19 disease and prevention of asymptomatic infection.

In a two-stage approach, the study will initially investigate the efficacy of a vaccine formulation targeting the original virus strain (D.614), while a second stage will evaluate a second formulation targeting the Beta variant (B.1.351). Recent scientific evidence shows that antibodies created against the Beta variant may provide broad cross-protection against other more transmissible variants.

The design of the Phase 3 study, conducted across a broad diversity of geographies, also allows evaluation of the efficacy of the candidate against a variety of circulating variants. Sanofi and GSK will also run clinical studies to assess the ability of the adjuvanted recombinant-protein COVID-19 vaccine candidate to generate a strong booster response regardless of the type of vaccine initially received.

The Phase 3 study initiation follows the global interim Phase 2 results which showed that the adjuvanted recombinant COVID-19 vaccine candidate achieved high rates of neutralizing antibody responses in all adult age groups, with 95 to 100% seroconversion rates. After a single injection, high neutralizing antibody levels were also generated in participants with evidence of prior SARS-CoV-2 infection, suggesting strong potential for development as a booster vaccine.

About the Sanofi and GSK partnership

In the partnership between the two Companies, Sanofi provides its recombinant antigen and GSK contributes its pandemic adjuvant, both established vaccine platforms that have proven successful against influenza. The recombinant technology combined with GSK's adjuvant is designed to offer the advantages of stability at temperatures used for routine vaccines, making it easily implementable and easier to distribute at a global scale through existing infrastructures where vaccines are stored at normal refrigerator temperature. It is also designed to offer the potential to generate high and sustained immune responses, and the potential to prevent virus transmission.

Shots on goal in the fight against the COVID-19 pandemic

In addition to the adjuvanted recombinant protein-based vaccine in collaboration with GSK, Sanofi is developing a messenger RNA vaccine in partnership with Translate Bio. In March 2021, Sanofi and Translate Bio initiated a Phase 1/2 clinical trial of their mRNA COVID-19 vaccine candidate, in order to assess safety, immune response and reactogenicity, after preclinical data showed high neutralizing antibody levels. First results are expected in the third quarter of 2021.

Sanofi is also committed to providing manufacturing support to other vaccine producers. The company recently announced it will manufacture up to 200 million doses of Moderna's COVID-19 vaccine for the U.S., starting in September 2021. Earlier this year, Sanofi also announced the company will provide support to BioNTech for 125 million doses for the European Union. In February, Sanofi said it would support Johnson & Johnson for the production of its COVID-19 vaccine at a rate of approximately 12 million doses per month.

In addition to developing its two COVID-19 vaccines, Sanofi is the only company to leverage its manufacturing capacity and expertise for three different COVID-19 vaccines to support the global vaccines supply and help combat the pandemic.

About the International Vaccine Institute
The International Vaccine Institute (IVI) is a nonprofit inter-governmental organization established in 1997 at the initiative of the United Nations Development Programme (UNDP). IVI has 36 countries and the World Health Organization (WHO) on its treaty, including Korea, Sweden, India, and Finland as state funders.

Our mandate is to make vaccines available and accessible for the world's most vulnerable people. We focus on infectious diseases of global health importance such as cholera, typhoid, shigella, salmonella, schistosomiasis, Group A Strep, Hepatitis A, HPV, TB, HIV, MERS, COVID-19, as well as antimicrobial resistance. For more information, please visit https://www.ivi.int

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