SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Sanofi and GSK initiate global Phase 3 clinical efficacy study of COVID-19 vaccine candidate

- Two-stage design will evaluate vaccine formulations targeting original D.614 virus as well as B.1.351 variant, in diverse geographies with multiple circulating variants
- A booster study program will begin in the coming weeks to complement Phase 3 trial
- Pending positive Phase 3 outcomes and regulatory reviews, the vaccine could be approved in Q4 2021

PARIS and LONDON – May 27, 2021 – Today, Sanofi and GSK started enrollment in their Phase 3 clinical study to assess the safety, efficacy, and immunogenicity of their adjuvanted recombinant-protein COVID-19 vaccine candidate. The global, randomized, double-blind placebo-controlled Phase 3 study will include more than 35,000 volunteers aged 18 and older from several countries, including sites in the US, Asia, Africa, and Latin America.

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 D.614 virus (Wuhan), while a second stage will evaluate a second formulation targeting the B.1.351 (South African) variant. Recent scientific evidence[1] shows that antibodies created against the B.1.351 variant may provide broad cross-protection against other more transmissible variants. The design of the Phase 3, conducted across a broad diversity of geographies, also allows evaluation of the efficacy of the candidate against a variety of circulating variants.

Following encouraging interim results from the recent Phase 2 study, the companies will also begin clinical studies in the coming weeks to assess the ability of the adjuvanted recombinant-protein COVID-19 vaccine candidate to generate a strong booster response regardless of initial vaccine platform received.

> *"We are encouraged to see first vaccinations starting to take place in such an important, pivotal Phase 3 study, as we believe that our unique technology platform will provide a clinically-relevant vaccine option"* said Thomas Triomphe, Executive Vice President, Global Head of Sanofi Pasteur. *"We have adapted our vaccine*

[1] Moyo-Gwete, T. et al. SARS-CoV-2 501Y.V2 (B.1.351) elicits cross-reactive neutralizing antibodies. bioRxiv (2021)

development strategy based on forward-looking considerations as the virus continues to evolve, as well as anticipating what may be needed in a post-pandemic setting. This trial is testament to the urgency and agility in our approach to help overcome the ongoing impact of this pandemic.

Roger Connor, President of GSK Vaccines added, *"We believe further solutions for COVID-19 are very much needed to help reach people around the world, especially as the pandemic evolves and variants continue to emerge. Adjusting our technology and study designs reflects this need and will further build the potential of this adjuvanted protein-based vaccine. We are grateful to the volunteers who will take part in the trials and hope the results will add to the encouraging data we've seen so far so we can make the vaccine available as quickly as possible."*

The Phase 3 study follows the 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.

Pending positive Phase 3 outcomes and regulatory reviews, the vaccine could be approved / authorized in Q4 2021. Manufacturing will begin in the coming weeks to enable rapid access to the vaccine should it be approved.

This effort is supported by federal funds from the Biomedical Advanced Research and Development Authority, part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services in collaboration with the U.S. Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense under Contract # W15QKN-16-9-1002.

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.

Find out more about our COVID-19 vaccine candidates.

About GSK
GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. GSK is the leading manufacturer of vaccines globally. For further information please visit www.gsk.com.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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Sanofi Forward-Looking Statements
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends",

"estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly, and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.