SANOFI

Press Release

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

Sanofi and GSK initiate Phase 1/2 clinical trial of COVID-19 adjuvanted recombinant protein-based vaccine candidate

- Pre-clinical studies show promising safety and immunogenicity.
- Over 400 participants being enrolled in Phase 1/2 study
- Pending positive Phase 1/2 data, companies aim to move into Phase 3 by end of 2020
- Sanofi and GSK are scaling up manufacturing of the antigen and adjuvant with the target of producing up to one billion doses in 2021

PARIS and LONDON – Sept. 3, 2020 – Sanofi and GSK today started the Phase 1/2 clinical trial for their adjuvanted COVID-19 vaccine. The vaccine candidate, developed in partnership by Sanofi and GSK, uses the same recombinant protein-based technology as one of Sanofi's seasonal influenza vaccines with GSK's established pandemic adjuvant technology.

The Phase 1/2 clinical trial is a randomized, double blind and placebo-controlled trial designed to evaluate the safety, reactogenicity (tolerability) and immunogenicity (immune response) of the COVID-19 vaccine candidate. A total of 440 healthy adults are being enrolled in the trial across 11 investigational sites in the United States.

The companies anticipate first results early December 2020 which will support the initiation of a Phase 3 trial in December 2020. If data are sufficient for licensure application, the plan is to request regulatory approval in the first half of 2021.

Sanofi is leading the clinical development and registration of the COVID-19 vaccine. Preclinical data showed an acceptable reactogenicity profile and data based on two injections of the adjuvanted recombinant vaccine showed high levels of neutralizing antibodies that are comparable to levels in humans who recovered from the COVID-19 infection. Pre-clinical results will be published later this year. In parallel, Sanofi and GSK are scaling up manufacturing of the antigen and adjuvant with the target of producing up to one billion doses in 2021.

"Sanofi and GSK bring proven science and technology to the fight against the global COVID-19 pandemic, with the shared objective of delivering a safe and effective vaccine," said Thomas Triomphe, Executive Vice President and Global

Head of Sanofi Pasteur. *"The initiation of our clinical study is an important step and brings us closer to a potential vaccine which could help defeat COVID-19. Our dedicated teams and partner continue to work around the clock as we aim to deliver the first results in early December. Positive data will enable a prompt start of the pivotal phase 3 trial by the end of this year."*

Roger Connor, President of GSK Vaccines added, *"Moving this vaccine candidate into clinical development is an important moment in the progress towards addressing the global pandemic we are all facing. This builds on the confidence shown by governments already in the potential of this protein-based adjuvanted vaccine candidate, which utilizes established technology from both companies, and can be produced at scale by two of the leading vaccine manufacturers globally. We now look forward to the data from the study, and if positive, beginning Phase 3 by the end of the year."*

The development of the adjuvanted COVID-19 vaccine candidate is being supported through funding and a collaboration with 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.

Sanofi and GSK are committed to making the vaccine available globally

In July 2020, Sanofi and GSK announced a collaborative effort with the U.S. government to supply up to 100 million doses of their COVID-19 recombinant protein-based vaccine to meet the U.S. government's Operation Warp Speed goal of making hundreds of millions of doses of safe and effective COVID-19 vaccines available in the United States as quickly as possible. The U.S. government has a further option to discuss the purchase of up to 500 million doses longer term. Both companies also agreed (subject to final contract) with the UK government to supply up to 60 million doses of recombinant protein-based COVID-19 vaccine.

The partners plan to supply a significant portion of total worldwide available supply in 2021/2022 to COVAX, the vaccines pillar of the ACT-Accelerator (Access to COVID-19 Tools), a global collaboration of leaders of governments, global health organizations, businesses and philanthropies to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

On the front lines in the fight against COVID-19

In addition to the recombinant protein-based vaccine in collaboration with GSK, Sanofi is developing a messenger RNA vaccine in partnership with Translate Bio. With several innovative vaccine platforms currently being investigated across the industry, mRNA is

considered among the most promising. Preclinical data shows that two immunizations of the mRNA vaccine induced high neutralizing antibody levels that are comparable to the upper range of those observed in infected humans. Sanofi expects the Phase 1/2 study to start in November, with earliest potential approval in the second half of 2021. Translate Bio has established mRNA manufacturing capacity and Sanofi expects to be able to supply annual capacity of 90 to 360 million doses.

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.