

Sanofi and GSK initiate new Phase 2 study of their adjuvanted recombinant protein-based COVID-19 vaccine candidate

- * New Phase 2 study assesses potential for refined antigen formulation to achieve optimal immune response, including in older adults
- * If results are positive, Phase 3 study to start in Q2 2021, with vaccine expected to be available in Q4 2021
- * In parallel, development work on new SARS-CoV-2 variants underway

PARIS and LONDON – February 22, 2021 – Sanofi and GSK announced today the initiation of a new Phase 2 study with 720 volunteers aged 18 and over to select the most appropriate antigen dosage for Phase 3 evaluation of their adjuvanted recombinant protein COVID-19 vaccine candidate.

“Over the past few weeks, our teams have worked to refine the antigen formulation of our recombinant-protein vaccine, based on learnings from our initial Phase 1/2 study.” said Thomas Triomphe, Executive Vice President and Head of Sanofi Pasteur. *“We are confident that our vaccine candidate has strong potential and we are very encouraged by the latest preclinical data. This new Phase 2 study will enable us to identify the final vaccine formulation for adults of all ages. We have demonstrated our commitment to focusing efforts and capabilities towards the global fight against the pandemic, and this new study takes us a step closer to achieving our primary goal of developing a COVID-19 vaccine with a good efficacy and safety profile.”*

Roger Connor, President of GSK Vaccines added: *“We are pleased to be starting this new Phase 2 study. The world needs multiple vaccines and we are confident that combining our proven pandemic adjuvant system with this improved antigen formulation will have significant potential as the pandemic evolves. We look forward to further progressing this vaccine candidate to Phase 3 in Q2 2021, if this Phase 2 study is successful.”*

In parallel to the new Phase 2 study and recognizing the global emergence of new SARS-CoV-2 variants and their potential impact on vaccine efficacy, Sanofi has commenced development work against new variants, which will be used to inform next stages of the Sanofi/GSK development program.

About the Phase 2 study

The new Phase 2 trial is a randomized, double-blind, multi-center dose finding study conducted in adults aged 18 years of age and older to evaluate the safety, reactogenicity,

and immunogenicity of two injections given 21 days apart. The trial will include equal numbers of adults 18 to 59 years and those 60 years and above.

Three different antigen doses with a fixed dose of adjuvant will be tested in a total study population of 720 volunteers, in the United States, Honduras and Panama. Results of the Phase 2 trial will inform the Phase 3 protocol.

In December 2020, Phase 1/2 study results [showed](#) an immune response comparable to patients who had recovered from COVID-19 in adults aged 18 to 49 years, but a lower immune response in older adults, likely due to an insufficient concentration of the antigen. If data from the new Phase 2 trial are positive, a global Phase 3 study is planned for Q2 2021. Positive results from the Phase 3 study would lead to regulatory submissions in the second half of 2021, with the vaccine expected to be available in Q4 2021, if approved.

The advancement of the trial program is supported by the United States' Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response under contract W15QKN-16-9-1002. Sanofi and GSK's adjuvanted recombinant protein-based COVID-19 vaccine candidate was [selected](#) in July 2020 by the U.S. government in order to accelerate its development and manufacturing.

About the GSK / Sanofi 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 offers the advantages of stability at temperatures used for routine vaccines, the ability to generate high and sustained immune responses, and the potential to prevent virus transmission.

On the front line in the fight against the COVID-19 pandemic

In addition to the recombinant protein-based vaccine in collaboration with GSK, Sanofi is developing a messenger RNA COVID-19 vaccine in partnership with Translate Bio. Encouraging preclinical data showed 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 and Translate Bio are planning to start a phase 1/2 study in Q1 2021.

Sanofi earlier announced an agreement with Pfizer-BioNTech under which Sanofi will support the manufacturing and supply of more than 125 million doses their COVID-19 vaccine.

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.

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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.