

Sanofi and GSK announce a delay in their adjuvanted recombinant protein-based COVID-19 vaccine program to improve immune response in the elderly

- * Phase 1/2 interim results showed an immune response comparable to patients who recovered from COVID-19 in adults aged 18 to 49 years
- * Insufficient response in older adults demonstrates the need to refine the concentration of antigen in order to provide high-level immune response across all age groups
- * Companies plan a Phase 2b study with an improved antigen formulation
- * With support from BARDA as part of Operation Warp Speed, study to start in February 2021, including a proposed comparison with an authorized COVID-19 vaccine
- * Product availability now expected in Q4 2021 pending successful completion of the development plan

PARIS and LONDON – December 11, 2020 – Sanofi and GSK announce a delay in their adjuvanted recombinant protein-based COVID-19 vaccine program to improve immune response in older adults. Phase 1/2 study interim results showed an immune response comparable to patients who recovered from COVID-19 in adults aged 18 to 49 years, but a low immune response in older adults likely due to an insufficient concentration of the antigen.

A recent challenge study in non-human primates performed with an improved antigen formulation demonstrated that the vaccine candidate could protect against lung pathology and lead to rapid viral clearance from the nasal passages and lungs, within 2 to 4 days. These results increase the Companies confidence in the capacity of the adjuvanted recombinant platform to deliver a highly efficient vaccine for all adults.

Sanofi's recombinant technology and GSK's pandemic adjuvant are established vaccine platforms that have proven successful against influenza. The recombinant technology 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.

"We care greatly about public health which is why we are disappointed by the delay announced today, but all our decisions are and will always be driven by science and data. We have identified the path forward and remain confident and committed

to bringing a safe and efficacious COVID-19 vaccine. Following these results and the latest encouraging new preclinical data, we will now work to further optimize our candidate to achieve this goal,” said Thomas Triomphe, Executive Vice President and Head of Sanofi Pasteur. *“No single pharma company can make it alone; the world needs more than one vaccine to fight the pandemic.”*

Roger Connor, President of GSK Vaccines added: *“The results of the study are not as we hoped. Based on previous experience and other collaborations, we are confident that GSK’s pandemic adjuvant system, when coupled with a COVID-19 antigen, can elicit a robust immune response with an acceptable reactogenicity profile. It is also clear that multiple vaccines will be needed to contain the pandemic. Our aim now is to work closely with our partner Sanofi to develop this vaccine, with an improved antigen formulation, for it to make a meaningful contribution to preventing COVID-19.”*

The Companies plan a Phase 2b study expected to start in February 2021 with support from the Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) under contract W15QKN-16-9-1002. The study will include a proposed comparison with an authorized COVID-19 vaccine. If data are positive, a global Phase 3 study could start in Q2 2021. Positive results from this study would lead to regulatory submissions in the second half of 2021, hence delaying the vaccine’s potential availability from mid-2021 to Q4 2021.

Sanofi and GSK adjuvanted recombinant protein-based vaccine candidate was selected in July 2020 by U.S. government’s Operation Warp Speed in order to accelerate its development and manufacturing.

The Companies have updated Governments and the European Commission where a contractual commitment to purchase the vaccine has been made.

Phase 1/2 study

The interim Phase 1/2 results showed a level of neutralizing antibody titers after two doses comparable to sera from patients who recovered from COVID-19, a balanced cellular response in adults aged 18 to 49 years, but insufficient neutralizing antibody titers in adults over the age of 50. The candidate showed transient but higher than expected levels of reactogenicity likely due to the suboptimal antigen formulation, with no serious adverse events related to the vaccine candidate. The most favorable results were observed in the group which tested the highest antigen concentration, combined with the GSK adjuvant, showing neutralization titers in 88% of participants. Seroconversion was observed in 89.6% of the 18 to 49 age group; 85% in the >50 age group; and 62.5% in the >60 age group.

The Phase 1/2 clinical study is a randomized, double blind and placebo-controlled study designed to evaluate the safety, reactogenicity and immunogenicity (immune response)

of the COVID-19 vaccine candidate. A total of 441 healthy adults participated in the study, across 10 investigational sites in the United States. The participants received one or two doses of the vaccine candidate, or placebo at 21 days apart.

Full results of the Phase 1/2 study will be published as soon as all data are available, following peer-reviewed publication process.

Latest preclinical results

A recent preclinical study using a highly virulent challenge in non-human primates, showed high ability for the vaccine to protect against lung pathology and reduce virus in the nose and lungs within 2 to 4 days. Results from this pre-clinical study confirm strong ability of the vaccine candidate to stop the replication of the virus with an optimal antigen formulation.

These data are being prepared for submission to a peer-reviewed publication.

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. 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 expects the Phase 1/2 study to start in Q1 2021, with earliest potential approval in the second half of 2021.

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

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