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

PUBLISHED MAY 27, 2021
BY GSK

For media and investors only

- 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 programme will begin in the coming weeks to complement the Phase 3 trial

- Pending positive Phase 3 outcomes and regulatory reviews, the vaccine could be approved in Q4 2021

Today, Sanofi and GlaxoSmithKline plc (GSK) started enrolment 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 shows that antibodies created against the B.1.351 variant may provide broad cross-protection against other more transmissible variants.1 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.

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 the 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 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 to100% 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 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 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.

GSK commitment to tackling COVID-19

GSK's response to COVID-19 has been one of the broadest in the industry, with three potential treatments in addition to our vaccine candidates in development with partner organisations.

GSK is collaborating with several organisations on COVID-19 vaccines by providing access to our adjuvant technology. In addition to our work with Sanofi, our collaboration with Medicago on an adjuvanted, plant-derived vaccine candidate is now in late-stage clinical trials. An earlier stage collaboration with SK Bioscience is also ongoing. SK Bioscience receives funding from CEPI and the Bill and Melinda Gates Foundation to develop differentiated, affordable COVID-19 vaccines for supply globally through the COVAX facility. The use of an adjuvant can be of particular importance in a pandemic since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and contributing to protecting more people.

GSK is also working with mRNA specialist, CureVac, to jointly develop next generation, multi-valent mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine. GSK

will also support manufacturing of up to 100m doses of CureVac's first generation COVID-19 vaccine. GSK is also providing manufacturing support for up to 60m doses of Novavax' COVID-19 vaccine in the UK.

GSK is also exploring potential therapeutic or treatment options for COVID-19 patients. We are collaborating with Vir Biotechnology to develop existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options for COVID-19. We recently reported that an Independent Data Monitoring Committee recommended that the Phase 3 COMET-ICE trial evaluating VIR-7831 as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalisation be stopped for enrolment due to evidence of profound efficacy, based on an interim analysis of data from the trial. We have received Emergency Use Authorization in the U.S. and are seeking authorisations in other countries. We are also assessing whether an investigational monoclonal antibody, otilimab, can help severely ill COVID-19 patients aged over 70 who experience an overreaction of their immune system.

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.

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com/about-us.

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-

19 pandemic.

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

Press release distributed by Wire Association on behalf of GSK, on May 27, 2021. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/sanofi-and-gsk-initiate-global-phase-3-clinical-efficacy-study-of-covid-19-vaccine-candidate-1938

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
Website: https://www.gsk.com/
Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/
