

Sanofi and GSK COVID-19 vaccine candidate demonstrates strong immune responses across all adult age groups in Phase 2 trial

GSK PUBLISHED MAY 17, 2021
BY [GSK](#)

For media and investors only

- Adjuvanted recombinant COVID-19 vaccine candidate triggered strong neutralizing antibody responses in all adult age groups
- High immune response after a single dose in patients with prior infection shows strong booster potential
- Global Phase 3 study expected to start in the coming weeks

The Sanofi and GSK adjuvanted recombinant COVID-19 vaccine candidate achieved strong rates of neutralizing antibody responses, in line with those measured in people who have recovered from COVID-19, in all adult age groups in a Phase 2 study with 722 volunteers. A global pivotal Phase 3 study is expected to start in the coming weeks.

The Phase 2 interim results showed 95% to 100% seroconversion following a second injection in all age groups (18 to 95 years old) and across all doses, with acceptable tolerability and with no safety concerns. Overall, the vaccine candidate elicited strong neutralizing antibody levels that were comparable to those generated by natural infection, with higher levels observed in younger adults (18 to 59 years old). After a single injection, high neutralizing antibody levels were generated in participants with evidence of prior SARS-CoV-2 infection, suggesting strong potential for development as a booster vaccine.

Our Phase 2 data confirm the potential of this vaccine to play a role in addressing this ongoing global public health crisis, as

we know multiple vaccines will be needed, especially as variants continue to emerge and the need for effective and booster vaccines, which can be stored at normal temperatures, increases,” said Thomas Triomphe, Executive Vice President and Head of Sanofi Pasteur. “With these favourable results, we are set to progress to a global Phase 3 efficacy study. We look forward to generating additional data and working with our partners around the world to make our vaccine available as quickly as possible.

Roger Connor, President of GSK Vaccines added,

These positive data show the potential of this protein-based adjuvanted vaccine candidate in the broader context of the pandemic, including the need to address variants and to provide for booster doses. We believe that this vaccine candidate can make a significant contribution to the ongoing fight against COVID-19 and will move to Phase 3 as soon as possible to meet our goal of making it available before the end of the year.

Based on these positive Phase 2 interim results, the Companies plan to initiate a global Phase 3 randomized, double-blind study with the 10µg dose, in combination with GSK’s pandemic adjuvant, in the coming weeks. The Phase 3 trial is expected to enrol more than 35,000 adult participants from a broad range of countries and will assess the efficacy of two vaccine formulations including the D614 (Wuhan) and B.1.351 (South African) variants.

In parallel, the Companies intend to conduct booster studies with various variant formulations in order to assess the ability of a lower dose of the vaccine to generate a strong booster response regardless of the initial vaccine platform received.

Pending positive Phase 3 outcomes and regulatory reviews, the vaccine is expected to be approved in the fourth quarter of 2021.

The Phase 2 study interim results show that the adjuvanted recombinant vaccine candidate triggered a strong immune response amongst adults of all age groups with 95% to 100% seroconversion rates and neutralizing antibodies that were comparable to those generated by natural infection. The high titers observed in the non-naïve population after one dose of the vaccine candidate also suggest

it may have strong potential for use as a booster vaccine. Full results of the Phase 2 study will be published in a peer-reviewed journal.

The randomized, double-blind, multi-center dose-ranging study was conducted in healthy adults aged 18 years of age and older, including those with high risk medical conditions, to evaluate the safety, reactogenicity, and immunogenicity of two injections given 21 days apart, with 3 antigen dose levels of 5, 10 and 15 µg. Beginning in February 2021, the study enrolled 722 volunteers, in the U.S. and Honduras. It included equivalent numbers of adults 18 to 59 years and those 60 years and above.

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 also offers 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 are seeking Emergency Use Authorization in the US and 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.

Press release distributed by Wire Association on behalf of GSK, on May 17, 2021. For more information subscribe and [follow](#) us.

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