

## Sanofi and GSK receive approval for Phase 3 efficacy trial of their COVID-19 vaccine candidate in India

- \* Clinical trial to assess the safety, efficacy and immunogenicity of an adjuvanted recombinant-protein COVID-19 vaccine candidate
- \* Phase 3 clinical trial will include more than 35,000 volunteers from several countries, including sites in the US, Asia, Africa and Latin America

**Mumbai, INDIA – July 08, 2021** - Sanofi and GSK received approval for their Phase 3 clinical study in India, to assess the safety, efficacy and immunogenicity of their adjuvanted recombinant-protein COVID-19 vaccine candidate. The global, randomized, double-blind Phase 3 study will include more than 35,000 volunteers aged 18 and older across sites in the US, Asia, Africa, and Latin America.

As COVID-19 vaccination becomes available, study participants are encouraged to receive an approved COVID-19 vaccine during the study, if they wish to do so. As part of the study design, all participants including the control group will be offered the study vaccine as soon as it is determined to be safe and effective.

*“India is participating in Sanofi Pasteur’s pivotal Phase 3 study, and subject to subsequent approvals, we should soon begin enrollment of study participants in the country.”* said Annapurna Das, Country Head, Sanofi Pasteur India.

*“As the virus continues to evolve, we are anticipating what will be needed in the coming months and years, and accordingly, have adapted our vaccine development program. We believe our COVID-19 adjuvanted, recombinant vaccine can make a significant contribution to the ongoing fight against COVID-19 and are committed to initiating our clinical program in India, at the earliest”* she added

### About the Phase 3 study

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 virus strain (D.614), while a second stage will evaluate a second formulation targeting the Beta variant (B.1.351). Recent scientific evidence<sup>1</sup>

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<sup>1</sup> Moyo-Gwete, T. et al. SARS-CoV-2 501Y.V2 (B.1.351) elicits cross-reactive neutralizing antibodies. bioRxiv (2021)

shows that antibodies created against the Beta variant may provide broad cross-protection against other more transmissible variants.

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. Sanofi and GSK will also run clinical studies to assess the ability of the adjuvanted recombinant-protein COVID-19 vaccine candidate to generate a strong booster response regardless of the type of vaccine initially received.

The Phase 3 study initiation follows the global 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 to 100% 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.

### **About the Sanofi and GSK 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.

### **Shots on goal in the fight against the COVID-19 pandemic**

In addition to the adjuvanted recombinant protein-based vaccine in collaboration with GSK, Sanofi is developing a messenger RNA vaccine in partnership with Translate Bio. In March 2021, Sanofi and Translate Bio [initiated](#) a Phase 1/2 clinical trial of their mRNA COVID-19 vaccine candidate, in order to assess safety, immune response and reactogenicity, after preclinical data showed high neutralizing antibody levels. First results are expected in the third quarter of 2021.

Sanofi is also committed to providing manufacturing support to other vaccine producers. The company recently [announced](#) it will manufacture up to 200 million doses of Moderna's COVID-19 vaccine for the U.S., starting in September 2021. Earlier this year, Sanofi also [announced](#) the company will provide support to BioNTech for 125 million doses for the European Union. In February, Sanofi [said](#) it would support Johnson & Johnson for the production of its COVID-19 vaccine at a rate of approximately 12 million doses per month.

In addition to developing its two COVID-19 vaccines, Sanofi is the only company to leverage its manufacturing capacity and expertise for three different COVID-19 vaccines to support the global vaccines supply and help combat the pandemic.

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](http://www.gsk.com).

#### **About Sanofi India**

As Sanofi India, we are in a great place to make a difference. For six decades, we have earned the trust of our customers and stakeholders, for our commitment to promoting health in India. As partners of hope in every Indian's health journey, we engage across the entire health cycle – from prevention with vaccines to wellness, treatment, patient support & capacity building.

#### **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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