

Sanofi to provide support to BioNTech in manufacturing their COVID-19 vaccine to help address public health needs

- * Sanofi will provide BioNTech access to its state-of-the-art production infrastructure
- * From summer 2021, Sanofi will perform late-stage manufacturing to supply over 125 million doses of COVID-19 vaccine for the European Union
- * This agreement between the two Companies reflects the shared commitment to increase vaccine accessibility

MEDIA UPDATE - JANUARY 27, 2021

Sanofi and BioNTech have today entered into an agreement under which Sanofi will support manufacturing and supply of BioNTech's COVID-19 vaccine which is being co-developed with Pfizer.

Sanofi will provide BioNTech access to its established infrastructure and expertise to produce over 125 million doses of COVID-19 vaccine in Europe. Initial supplies will originate from Sanofi's production facilities in Frankfurt from summer of 2021.

"We are very conscious that the earlier vaccine doses are available, the more lives can potentially be saved. Today's announcement is a pivotal step towards our industry's collective goal of putting all the effort in to curb this pandemic," said Paul Hudson, Chief Executive Officer, Sanofi. "Although vaccination campaigns have started around the world, the ability to get shots into arms is being limited by lower than expected supplies and delayed approval timelines owing to production shortages. We have made the decision to support BioNTech and Pfizer in manufacturing their COVID-19 vaccine in order to help address global needs, given that we have the technology and facilities to do so. As always, our top priority is to focus our efforts and capabilities on fighting this global pandemic. First and foremost, we will do this by continuing to develop our own COVID-19 vaccine candidates, in parallel with this industrial cooperation."

Sanofi's priority is to continue to develop its two COVID-19 vaccine candidates

- Sanofi is collaborating with GSK on a COVID-19 vaccine candidate using the same recombinant protein-based manufacturing technology as one of Sanofi's seasonal influenza vaccines, combined with GSK's established pandemic adjuvant platform.

Phase 1/2 study [results](#) of the vaccine candidate 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.

The Companies plan to initiate a new Phase 2 study 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), that will evaluate the vaccine candidate with an improved antigen formulation in order to achieve high-level immune response across all age groups. 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, with potential availability of doses in the fourth quarter of 2021.

- 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.

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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