Sanofi to provide manufacturing support to Johnson & Johnson for their COVID-19 vaccine to help address global supply demands

- This marks Sanofi’s second commitment to leverage its manufacturing network to address vaccine supply in Europe and support the global supply of COVID-19 vaccines
- For Johnson & Johnson, Sanofi will provide several manufacturing steps from Q3 2021

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Sanofi has entered into an agreement with Janssen Pharmaceutical NV and Janssen Pharmaceuticals, Inc., two of the Janssen Pharmaceutical Companies of Johnson & Johnson, under which Sanofi will support manufacturing of Janssen’s COVID-19 vaccine in order to address the COVID-19 pandemic and supply needs. Janssen has submitted an application to the U.S. Food and Drug Administration (FDA) requesting Emergency Use Authorization for its single-dose Janssen COVID-19 vaccine candidate and an application for conditional marketing authorisation to the European Medicines Agency.

Once authorized, Sanofi will provide Johnson & Johnson access to the established infrastructure and expertise of its vaccine manufacturing plant in Marcy l’Etoile, France, to formulate and fill vials of Janssen’s COVID-19 vaccine candidate in 2021, at a rate of approximately 12 million doses per month.

“Today’s agreement is the second of its kind and demonstrates Sanofi’s ongoing commitment to the collective effort to ending this crisis as quickly as possible,” said Paul Hudson, Chief Executive Officer, Sanofi. “While our priority remains advancing our two COVID-19 vaccine programs, we recognize there are opportunities to increase supply and expand access to COVID-19 vaccines. As such, without compromising other essential medicines and vaccines, and where we have the right manufacturing capabilities, we are stepping forward to show solidarity in the industry and continue doing our part in the fight against COVID-19.”

Sanofi earlier announced an agreement with Pfizer-BioNTech under which Sanofi will support the manufacturing and supply of more than 125 million doses their COVID-19 vaccine.

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.

The Companies initiated a new Phase 2 study in February 2021 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. A Phase 1/2 study is expected to start in Q1 2021.

Find out more about our COVID-19 vaccine candidates.

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
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.