SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Sanofi and GSK in advanced discussions with European Union to supply up to 300 million doses of COVID-19 vaccine

- Discussions relate to vaccine candidate using Sanofi's recombinant protein-based technology combined with GSK's pandemic adjuvant system
- Both companies are committed to making their COVID-19 vaccine affordable and available globally

PARIS and LONDON – July 31, 2020 – Sanofi and GSK are in advanced discussions, with the European Commission (EC) for the supply of up to 300 million doses of a COVID-19 vaccine. The vaccine candidate developed by Sanofi in partnership with GSK, is based on the recombinant protein-based technology used by Sanofi to produce an influenza vaccine, and GSK's established adjuvant technology. The doses would be manufactured in European countries including France, Belgium, Germany and Italy. This marks a key milestone in protecting and serving the European population against COVID-19.

> *"Today's announcement helps to ensure that millions of Europeans will have access to a potential vaccine protecting against COVID-19, once proven safe and effective. It has been our steadfast commitment to provide a vaccine that is affordable and accessible to everyone, and we are grateful to the European Commission for their ongoing engagement and shared support of this effort,"* said Thomas Triomphe, Executive Vice President and Global Head of Sanofi Pasteur. *"Together with GSK, we are working relentlessly to develop and produce a vaccine to address this global health crisis."*
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> Roger Connor, President of GSK Vaccines added *"GSK is proud to be working in partnership with Sanofi to make this vaccine available as soon as possible in Europe. Both companies have significant R&D and manufacturing capability in Europe and are already working hard to scale up production across our networks. This announcement from the EC supports our ongoing efforts"*

Sanofi is leading the clinical development and registration of the COVID-19 vaccine and expects a Phase 1/ 2 study to start in September, followed by a Phase 3 study by the end of 2020. If data are positive, regulatory approval could be achieved by the first half of 2021. In parallel, Sanofi and GSK are scaling up manufacturing of the antigen and adjuvant to produce up to one billion doses per year overall.

Sanofi and GSK are committed to making the vaccine available globally

Sanofi and GSK recently signed agreements with the United States where they have longstanding partnerships with the Biomedical Advanced Research and Development Authority, and also with the UK Government. The partners plan to provide a significant portion of total worldwide available supply capacity in 2021/22 to the global initiative "Access to COVID-19 Tools (ACT) Accelerator," a global collaboration of leaders of governments, global health organizations, businesses and philanthropies to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

On the front lines in the fight against COVID-19

In addition to the recombinant protein-based vaccine in collaboration with GSK, Sanofi is also developing a messenger RNA vaccine candidate in partnership with Translate Bio. With several innovative vaccine platforms currently investigated across the industry, mRNA is considered among the most promising. Sanofi expects a Phase 1 study to start by the end of the year, and, if data are positive, an approval at the earliest in the second half of 2021. Translate Bio has established mRNA manufacturing capacity and Sanofi expects to be able to supply annual capacity of 90 to 360 million doses.

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

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.