Sanofi and GSK selected for Operation Warp Speed to supply United States government with 100 million doses of COVID-19 vaccine

- Promising vaccine candidate selected by U.S. government’s Operation Warp Speed
- U.S. government to provide funding up to $2.1 billion for development, including clinical trials and manufacturing scale-up, and delivery of an initial 100 million doses
- Ongoing discussions with the European Commission, with France and Italy on the negotiation team, and other governments to ensure global access to a novel coronavirus vaccine

PARIS and LONDON – July 31, 2020 – Sanofi and GSK today announce a collaborative effort with the U.S. government to accelerate the development and manufacturing of a COVID-19 recombinant protein-based 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 pandemic adjuvant technology.

Collaborating with the U.S. Department of Health and Human Services (HHS) and Department of Defense will help fund the development activities and secure scale-up of Sanofi’s and GSK’s manufacturing capabilities in the United States for the recombinant protein-based, adjuvanted vaccine, resulting in a significant increase in capacity.

The U.S. government will provide up to $2.1 billion, more than half of which is to support further development of the vaccine, including clinical trials, with the remainder used for manufacturing scale-up and delivery of an initial 100 million doses of the vaccine. Sanofi will receive the majority of the U.S. government funding. The U.S. government has a further option for the supply of an additional 500 million doses longer term. This helps the U.S. government’s Operation Warp Speed goals of providing millions of doses of a safe and effective COVID-19 vaccine.

“The global need for a vaccine to help prevent COVID-19 is massive, and no single vaccine or company will be able to meet the global demand alone,” said Thomas Triomphe, Executive Vice President and Global Head of Sanofi Pasteur. “From the beginning of the pandemic, Sanofi has leveraged its deep scientific expertise and resources to help address this crisis, collaborating with the U.S. Department of Health and Human Services to unlock a rapid path toward developing a pandemic
vaccine and manufacturing at large scale. With our partner GSK, we expect our Phase 1/2 study for the recombinant adjuvanted approach to start in September.”

Roger Connor, President of GSK Vaccines added, “GSK is proud to be working in partnership with Sanofi to make this vaccine available at scale as soon as possible. We thank the U.S. government for playing a very important role in providing early, significant funding to enable the development and scale-up of this potentially important vaccine.”

“The portfolio of vaccines being assembled for Operation Warp Speed increases the odds that we will have at least one safe, effective vaccine as soon as the end of this year,” said HHS Secretary Alex Azar. “Today’s investment supports the Sanofi and GSK adjuvanted product all the way through clinical trials and manufacturing, with the potential to bring hundreds of millions of safe and effective doses to the American people.”

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 the data are positive, the companies can request U.S. regulatory approval in 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 globally.

**Sanofi and GSK are committed to making the vaccine available globally**

Active discussions are ongoing with global organizations and with the EU Commission – with France and Italy on the negotiation team on supplying European countries from Sanofi’s and GSK’s European industrial network. The partners also 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 being 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 the 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.