Sanofi and GSK sign agreements with the Government of Canada to supply up to 72 million doses of adjuvanted COVID-19 vaccine

- Agreements relate to vaccine candidate using Sanofi’s recombinant protein-based technology and GSK’s pandemic adjuvant
- Both companies are committed to making their COVID-19 vaccine affordable and available globally

PARIS and LONDON – September 22, 2020 – Sanofi and GSK have today signed agreements with the Government of Canada for the supply of up to 72 million doses of an adjuvanted COVID-19 vaccine, beginning in 2021.

“Today’s announcement showcases our unwavering commitment to develop a COVID-19 vaccine that is available to everyone when it comes to market,” said Thomas Triomphe, Executive Vice President and Global Head of Sanofi Pasteur. “To address a global health crisis of this magnitude, it takes partnerships and we are grateful to Canada for its collaboration, and to GSK for partnering with us to develop a safe and effective vaccine.”

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 Canada. Both companies have significant R&D and manufacturing capability world-wide and are already working hard to scale up production. This announcement from the Government of Canada supports our ongoing efforts.”

Both companies have vaccine manufacturing sites in Canada that are contributing to overall global COVID-19 vaccine development, and these plus their global industrial network will play a pivotal role to the production of the COVID-19 vaccine doses for Canada – as agreed today.

The Companies initiated a Phase 1/2 study on September 3 with a total of 440 subjects being enrolled, and anticipate first results in early December 2020, to support the initiation of a pivotal Phase 3 study before the end of the year. If these data are sufficient for licensure application, it is planned to request regulatory approval in the first half of 2021. In parallel, Sanofi and GSK are scaling up manufacturing of the antigen and adjuvant respectively with the target of producing up to one billion doses in total per year, globally.

Sanofi and GSK are committed to making the vaccine available globally
On September 18, Sanofi and GSK signed a final agreement with the European Commission to supply European countries with up to 300 million doses from their European industrial network. In July 2020, Sanofi and GSK announced a collaborative effort with the U.S. government to supply up to 100 million doses of their COVID-19 recombinant protein-based vaccine to meet the U.S. government's Operation Warp Speed goal of making hundreds of millions of doses of safe and effective COVID-19 vaccines available in the United States as quickly as possible. The U.S. government has a further option to discuss the purchase of up to 500 million doses longer term. Both companies also agreed (subject to final contract) with the UK government to supply up to 60 million doses of recombinant protein-based COVID-19 vaccine.

The partners plan to supply a significant portion of total worldwide available supply 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 developing a messenger RNA vaccine in partnership with Translate Bio. With several innovative vaccine platforms currently being investigated across the industry, mRNA is considered among the most promising. Preclinical data shows 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 November, with earliest potential approval 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
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 impact 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.