SANOFI

Press Release

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

# Sanofi to build new facility in Canada to increase global availability of high-dose influenza vaccine

- Sanofi announces investment of more than €600 million to build a new vaccine facility in Toronto to increase supply of its differentiated influenza vaccines in Canada, the United States and Europe
- In partnership with the Governments of Canada and Ontario, and the City of Toronto, the new facility will also enhance influenza pandemic preparedness efforts
- Fluzone® High-Dose Quadrivalent influenza vaccine has four times more antigen than standard-dose vaccine and is specifically designed to provide superior protection against influenza for older adults[i]

**PARIS – March 31, 2021** – Sanofi today announced an investment of more than €600 million in a new vaccine manufacturing facility at its existing site in Toronto, Canada. The investment in a new facility will provide additional antigen and filling capacity for Sanofi's Fluzone® High-Dose Quadrivalent influenza vaccine, helping to increase supply availability in Canada, the United States and Europe.

*"As a leading vaccines Company, we continuously look ahead to address the fast-growing demand for those influenza vaccines that have demonstrated clinical superiority against standard-dose vaccines. Fluzone High-Dose provides a long-term competitive advantage and this new investment will ensure more seniors around the world are better protected against influenza and its complications. In addition, it will be a key resource to assist against future pandemics,"* said Paul Hudson, Chief Executive Officer, Sanofi. *"We welcome the ongoing partnership with the Canadian authorities, who supported us to make today's great news a reality; this will make the country, which has a strong legacy in vaccines research and development, one of our key hubs in our effort to protect and improve human health across the globe."*

François-Philippe Champagne, Minister of Innovation, Science and Industry said, *"Today's announcement demonstrates Canada's ability to attract foreign investment and to develop facilities with made-in-Canada solutions. This once-in-a-generation investment shows our government's commitment to rebuilding Canada's domestic biomanufacturing sector, focusing on both short-term strategic solutions and a long-term vision. By investing in this project, our government is helping to keep expertise in Canada, creating and maintaining highly skilled jobs, and securing the health and safety of Canadians. By fostering an environment*

*where companies can invest and grow, leading life sciences firms like Sanofi are increasingly looking to this country to establish their manufacturing facilities,"*

Sanofi expects this new facility to be operational in 2026, following design, construction, testing and qualification of the facility and equipment.

Fluzone High-Dose Quadrivalent influenza vaccine is currently manufactured exclusively by Sanofi Pasteur, Sanofi's vaccines global business unit, at its Swiftwater, Pennsylvania Site in the United States. Sanofi Pasteur has been continuously investing in expanding manufacturing capabilities for influenza vaccines. Two new, additional facilities in Swiftwater, Pa., US and Val-de-Reuil, France will start to operate in the coming years.

**Editor's Note:** This investment in a new vaccine manufacturing facility further demonstrates Sanofi's overall growth strategy, with vaccines contributing as a key growth driver through differentiated products, market expansion and new launches.

## About Fluzone High-Dose Quadrivalent influenza vaccine

Fluzone High-Dose Quadrivalent influenza vaccine is available in the United States and some European countries, and will be available in Canada in 2021, for use in adults 65 years and older, and has also been approved in Australia. The vaccine has received marketing authorizations in 25 countries in Europe (under the name Efluelda® outside of the UK) for use in adults 60 years of age and older. The high-dose vaccine has four times more antigen than standard-dose vaccine and is specifically designed to provide superior protection against influenza for older adults.[ii] Older adults have an elevated risk of pneumonia, heart attack and stroke following influenza and are at the greatest risk of influenza-related hospitalization and death.

Sanofi Pasteur's High-Dose influenza vaccine has earned recommendations for use over standard-dose influenza vaccine in individual adults 65 years and older by the National Advisory Committee on Immunization (NACI) in Canada[iii], along with a recommendation for priority use in people 60 years of age and older by Germany's Standing Committee on Vaccination (STIKO).[iv] Fluzone High-Dose Trivalent influenza vaccine demonstrated superior protection against influenza in adults aged 65 and above compared to standard-dose formulation[v].

## About the Sanofi Pasteur Canadian Facilities

Founded as the Connaught Antitoxin Laboratories and University Farm in 1917, Sanofi Pasteur's Canadian facility has supported numerous scientific breakthroughs while making significant public health contributions. One hundred years ago, the Toronto Site was home to some of the initial research for the discovery of insulin, as well as large-scale commercial insulin production for all of Canada until the 1980s. It also produced a highly accessible antitoxin for diphtheria, the leading public health threat to Canadian children in the early 1900s, and was an important partner in the eradication of polio in North America and smallpox around the world.

In 2018, Sanofi made another historic investment at the Toronto Site, to establish one of the most advanced vaccine bulk manufacturing facilities in the world. At the time, this was the largest investment ever made by Sanofi globally, at approximately €335 million. This manufacturing facility will produce seven antigens: five-component-pertussis, plus diphtheria and tetanus, to help meet global demand for more life-saving vaccines for children and adults worldwide. License approval for the United States and Canada is expected in 2024 for the five-component-pertussis and in 2025 for diphtheria and tetanus.

## Sanofi Pasteur's commitment to improve influenza prevention

As the leading manufacturer of influenza vaccines, Sanofi Pasteur is committed to researching and developing differentiated and proven solutions to protect people of all ages and risk groups against influenza and its complications.

During the 2020-2021 influenza season, Sanofi Pasteur supported health authorities in efforts to strengthen influenza vaccination campaigns in the unique context of the COVID-19 pandemic. Sanofi Pasteur delivered 20 percent more doses this year, reaching an unprecedented production level of 250 million doses, across its influenza vaccine portfolio. Eight countries in Europe, and Israel, procured Fluzone High-Dose Quadrivalent in 2020 – through special importation – to provide an additional protection to their older citizens

Sanofi Pasteur produces influenza vaccines each year across five international sites: Swiftwater (Pennsylvania, United States), Pearl River (New York, United States), Val-de-Reuil (France), Ocoyoacac (Mexico) and Shenzhen (China). This makes Sanofi Pasteur the largest manufacturer of influenza vaccines in the world.

**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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements*

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[i] *Diazgranados, C. A., et al. (2014). Efficacy of High-Dose versus Standard-Dose influenza vaccine in older adults. New England Journal of Medicine, 371(7), 635-645*

[ii] *Diazgranados, C. A., et al. (2014). Efficacy of High-Dose versus Standard-Dose influenza vaccine in older adults. New England Journal of Medicine, 371(7), 635-645*

[iii] *Public Health Agency of Canada (2020. An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI) Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2021–2022*

[iv] *Epidemiological Bulletin 1/2021. Decision and scientific justification of the STIKO for the update of the influenza vaccination recommendation for people aged ≥60 years. Accessed March 9, 2021.*

[v] *DiazGranados CA, et al. N Engl J Med. 2014;371(7):635-645 https://www.nejm.org/doi/full/10.1056/nejmoa1315727*