SANOFI

Press Release

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

FDA approves Fluzone® High-Dose Quadrivalent (Influenza Vaccine) for adults 65 years of age and older

* Will be available in fall 2020, in time for the 2020-2021 flu season

PARIS - November 4, 2019 – The U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application for Fluzone® High-Dose Quadrivalent (Influenza Vaccine) for use in adults 65 years of age and older.

Fluzone® High-Dose (Influenza Vaccine) was approved by the FDA in 2009 as a trivalent influenza vaccine, including two influenza A strains and one influenza B strain. Fluzone High-Dose Quadrivalent contains an additional influenza B strain. Fluzone High-Dose Quadrivalent is given to people 65 years of age and older to help prevent influenza disease caused by influenza A and B strains contained in the vaccine.

> *"Increasing protection and delivering improved influenza vaccines are critical to public health,"* said David Loew, Sanofi Executive Vice President and head of Sanofi Pasteur. *"We are excited to build upon the success of trivalent Fluzone High-Dose with this FDA approval to expand protection for an additional B strain. We have submitted filings with additional regulatory bodies outside the U.S. and anticipate approval in the European Union next spring."*

This approval is the final step toward the company's complete transition to quadrivalent influenza vaccines in the U.S. Fluzone High-Dose Quadrivalent will be made available for immunization efforts during the 2020-2021 influenza season. Sanofi Pasteur will continue to deliver and offer the trivalent formulation of Fluzone High-Dose through the end of the 2019-2020 influenza season.

> *"Influenza is a serious threat, especially for older adults who are more vulnerable to serious complications and even death. For the past 10 years, Fluzone High-Dose has helped protect millions of people 65 years of age and older from seasonal influenza,"* said John Shiver, PhD, Senior Vice President, Global Research and Development, Sanofi Pasteur. *"We are committed to helping protect as many people as possible from influenza and look forward to introducing this new formulation."*

FDA approval was based on data from a Phase 3 immunogenicity and safety study, in which Fluzone High-Dose Quadrivalent achieved the primary endpoint of non-inferior immunogenicity compared to two trivalent formulations of Fluzone High-Dose, each containing one of the two influenza B strains recommended for inclusion in the vaccine for the 2017-2018 influenza season. In a secondary endpoint of the trial, each B strain in

Fluzone High-Dose Quadrivalent induced a superior immune response compared to the trivalent formulation not containing the corresponding B strain.

Rates of local and systemic reactions that occurred following immunization with Fluzone High-Dose Quadrivalent were similar to those induced by trivalent formulations of Fluzone High-Dose. The most common reactions occurring after administration were injection-site pain (41.3 percent), myalgia (22.7 percent), headache (14.4 percent), and malaise (13.2 percent). Onset usually occurred within the first three days after vaccination, and the majority of solicited reactions were resolved within three days of vaccination. Results from the study were published in Vaccine in September 2019.

Fluzone High-Dose is the first and only influenza vaccine proven to provide superior efficacy compared to Fluzone® (Influenza Vaccine) in adults 65 years of age and older, based on results in a randomized controlled trial.[i] This study evaluated nearly 32,000 adults 65 years of age and older over two influenza seasons in the U.S. and Canada. Results showed that Fluzone High-Dose prevented 24 percent more cases of influenza caused by any circulating influenza strain and 51 percent more cases of influenza caused by strains similar to those contained in the vaccine compared to Fluzone. Based on data from Fluzone High-Dose, solicited injection site reactions and systemic adverse reactions were slightly more frequent after vaccination with Fluzone High-Dose compared to a standard-dose vaccine.[i]

As of the end of the 2018-2019 influenza season, over 112 million doses of Fluzone High-Dose have been distributed in the U.S. In the 2018-2019 influenza season, nearly two-thirds of U.S. adults 65 years of age and older who received an influenza vaccine received Fluzone High-Dose.[ii]

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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks 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, 2018. 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] Fluzone High-Dose Quadrivalent [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.

[ii] Sanofi Pasteur Inc. Data on file (Sanofi Pasteur Fluzone High-Dose vaccine doses sold).