

Press Releases

FDA approves use of 0.5 mL dose of Fluzone® Quadrivalent (influenza vaccine) in children as young as 6 months of age

- The 0.5 mL dose is now approved for use in children 6 months through 35 months of age
- This new option offers health care providers the convenience of using the same 0.5 mL dose for all eligible children when immunizing against the flu

BRIDGEWATER, N.J., Jan. 23, 2019 /PRNewswire/ -- The U.S. Food and Drug Administration has approved the use of the 0.5 mL dose of Fluzone® Quadrivalent (influenza vaccine) to include children age 6 through 35 months. Sanofi Pasteur, the vaccine division of Sanofi, will have the 0.5 mL dose, in addition to the 0.25 mL dose, available for the upcoming 2019-20 season for this expanded age range.

"Offering pediatricians the convenience of the same 0.5 mL dose option for children, may help streamline immunization efforts," said Dr. David P. Greenberg, Regional Medical Head North America, Sanofi Pasteur. "The potentially life-threatening effects of influenza in children reported during the 2017-18 season, especially among those who were not vaccinated, is sobering. We commit ourselves every day to bring solutions to help meet ongoing public health needs related to influenza, especially among vulnerable groups such as young children."

Today's approval is supported by clinical data from a Phase IV safety and immunogenicity study conducted in nearly 2,000 children, which demonstrated that one or two doses of 0.5 mL of vaccine in children 6 through 35 months of age had a safety profile that was comparable to one or two doses of 0.25 mL of vaccine with no new safety concerns observed, and induced a robust immune response. Detailed results were presented at the Pediatric Academic Societies meeting in April 2018, as well as at the Advisory Committee on Immunization Practices meeting and the American Academy of Family Physicians Family Medicine Experience conference in October 2018.

Sanofi Pasteur's flu vaccine portfolio includes options to help protect all eligible patients from influenza. In addition to Fluzone Quadrivalent vaccine, the product portfolio includes Flublok® Quadrivalent (influenza vaccine) and Fluzone® High-Dose (influenza vaccine), the only two flu vaccines proven to help prevent more cases of flu in older adults, compared to their standard-dose flu vaccine comparators in randomized controlled trials. In these same trials, the most common local and systemic adverse reactions to Flublok Quadrivalent and Fluzone High-Dose vaccines include pain at the injection site, headache and myalgia.

Health care providers can place 2019-20 reservations for all Sanofi Pasteur vaccines, including the 0.5 mL presentations of Fluzone Quadrivalent vaccine for use in all appropriate pediatric patients via www.VaccineShoppe.com. The 0.25 mL dose of Fluzone Quadrivalent vaccine will remain available for 2019-20 reservations.

Important Safety Information for Flublok Quadrivalent Vaccine, Fluzone Quadrivalent Vaccine and Fluzone High-Dose Vaccine

Indication

Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose influenza vaccines are indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus(es) contained in each vaccine. Flublok Quadrivalent vaccine is approved for use in

persons 18 years of age and older. Fluzone Quadrivalent vaccine is approved for use in persons 6 months of age and older. Fluzone High-Dose vaccine is approved for use in persons 65 years of age and older.

Safety Information

Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines should not be given to anyone who has had a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine (including egg or egg products for Fluzone Quadrivalent and Fluzone High-Dose) or after a previous dose of the corresponding vaccine. In addition, Fluzone Quadrivalent and Fluzone High-Dose should not be given to anyone who has had a severe allergic reaction after a previous dose of any influenza vaccine.

Tell your health care professional if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) after a previous dose of influenza vaccine. If you notice any other problems or symptoms following vaccination, please contact your health care professional immediately.

In adults, the most common side effects to Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose include pain where the shot is given; headache and muscle aches. In children, the most common side effects to Fluzone Quadrivalent include pain, redness, and swelling where the shot is given; muscle aches, fatigue, and headache (irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever in young children). Other adverse reactions to these vaccines may occur.

Vaccination with Flublok Quadrivalent, Fluzone Quadrivalent, or Fluzone High-Dose may not protect all individuals.

Before administration, please see the full Prescribing Information for Flublok Quadrivalent, Fluzone Quadrivalent or Fluzone High-Dose vaccine. Also, please see complete Patient Information for Fluzone Quadrivalent or Fluzone High-Dose vaccine.

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

Media Relations Contact

Nicolas Kressmann

+1 (732) 532-5318

Nicolas.Kressmann@sanofi.com

Investor Relations Contact

George Grofik

Tel.: +33 (0)1 53 77 45 45

ir@sanofi.com

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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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

SOURCE Sanofi
