

# New Four-Strain Influenza Vaccine from Sanofi Pasteur Now Licensed By FDA for Broad Age Range of Children and Adults

New Fluzone® Quadrivalent (Influenza Virus Vaccine):

- The first and only 4-strain influenza vaccine option for patients as young as six months
  of age,
- Helps protect children and adults against additional influenza B strain,
- Newest addition to the Fluzone family of influenza vaccines.

Lyon, France – June 10, 2013 – Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today that the U.S. Food and Drug Administration has approved the supplemental biologics license application (sBLA) for licensure of its four-strain influenza vaccine, Fluzone Quadrivalent vaccine is the newest addition to the Fluzone family of influenza vaccines. Like Sanofi Pasteur's Fluzone vaccine, which is administered to more than 50 million people in the U.S. each year, Fluzone Quadrivalent vaccine is licensed for use in children six months of age and older, adolescents, and adults.

The 2013 influenza season will be the first in which quadrivalent influenza vaccines will be available in the U.S. Until this year, seasonal influenza vaccines included only one B strain. Fluzone Quadrivalent vaccine includes two A strains and two B strains to help protect against influenza disease. Epidemics of influenza B occur every two to four years in all age groups. Influenza B is a common cause of influenza-related morbidity and mortality in children and has been associated with pneumonia and other respiratory illnesses, nervous system disease, muscle pain and inflammation, and other complications. In recent years, up to 44 percent of influenza-associated deaths in children and adolescents 18 years of age and younger were due to influenza B.

"Sanofi Pasteur is committed to providing new immunization options for the prevention of influenza to help healthcare providers meet the specific immunization needs of all types of patients, and we are excited to introduce Fluzone Quadrivalent vaccine as an important new addition to our Fluzone family of specialized influenza vaccines," said David Greenberg, MD, Vice President U.S. Scientific and Medical Affairs, Sanofi Pasteur. "Protection against the type B flu strain may be an especially important factor that healthcare providers consider when immunizing children since influenza B causes a substantial number of illnesses, hospitalizations and deaths in the pediatric population."

Each winter the strains for the seasonal influenza vaccines are selected from the influenza strains anticipated to circulate in the Northern Hemisphere during the approaching influenza season. Seasonal influenza vaccines in the U.S. contained only two strains (one strain of type A influenza and one strain of type B influenza) until 1978, when the decision was made to incorporate a second type A influenza strain to help provide protection against both A strains that were co-circulating. For the past 35 years, influenza vaccines have been trivalent to help protect against three strains of influenza virus: a type A(H1N1), a type A(H3N2) and one type B. However, since the 2001-2002 season, two distinct influenza B types (the Victoria and Yamagata lineages) have co-circulated with varying prevalence, making it difficult to predict the next season's dominant B lineage strain. In six of the past 12 seasons,



the dominant circulating B strain was from the B-lineage not selected for the vaccine. Even in years where the correct B lineage strain was selected for the vaccine, some influenza disease was caused by the B lineage omitted from the vaccine likely reducing the overall vaccine effectiveness against circulating influenza viruses.

Fluzone Quadrivalent vaccine will be available to healthcare providers in the U.S. for the 2013-2014 influenza season in prefilled syringes and single-dose vials for intramuscular administration. These presentations of Fluzone Quadrivalent vaccine do not contain preservatives and are not made with natural rubber latex. Healthcare providers wishing to reserve vaccine can do so by visiting www.vaccineshoppe.com or by calling 1-800-VACCINE (1-800-822-2463).

#### **About Influenza**

Influenza is a serious respiratory illness. Each year in the U.S., on average, influenza and its related complications result in approximately 226,000 hospitalizations. Depending on virus severity during the influenza season, deaths can range from 3,000 to a high of about 49,000 people. The U.S. Centers for Disease Control and Prevention recommends vaccination to help prevent influenza for everyone six months of age and older in the U.S.. Children ages six months through eight years of age receiving a flu shot for the first time need two doses approximately one month apart for the best protection.

Immunization to prevent influenza can begin as soon as vaccine is available in the late summer and early fall. However, for those who can't get vaccinated early in the influenza season, such as children who are not yet six months of age or any others who missed their annual shot, immunization through the winter and even into the spring is beneficial. In fact, as long as influenza viruses are in circulation, it's not too late to get vaccinated. This is because, in many seasons, influenza activity doesn't peak until winter or early spring. It takes about two weeks for the vaccine to help protect against the influenza virus.

## **Important Safety Information**

Fluzone Quadrivalent vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons six months of age and older against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.

The most common local and systemic adverse reactions to Fluzone Quadrivalent vaccine include pain, erythema (redness), and swelling at the vaccination site; myalgia (muscle ache), malaise, headache, and fever (irritability, crying and drowsiness in young children). Other adverse reactions may occur. Fluzone Quadrivalent vaccine should not be administered to anyone with severe allergic reactions (eg. anaphylaxis) to any vaccine component, including egg protein, or to a previous dose of any influenza vaccine.

The decision to give Fluzone Quadrivalent vaccine should be based on the potential benefits and risks, especially if Guillain-Barré syndrome has occurred within six weeks of receipt of a prior influenza vaccine. Vaccination with Fluzone Quadrivalent vaccine may not protect all individuals.

Before administering Fluzone Quadrivalent vaccine or Fluzone vaccine, please see full Prescribing Information available at www.sanofipasteur.us or www.vaccineshoppe.com

## **About Sanofi**

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven



growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur offers the broadest range of vaccines protecting against 20 infectious diseases. The company's heritage, to create vaccines that protect life, dates back more than a century. Sanofi Pasteur is the largest company entirely dedicated to vaccines. Every day, the company invests more than EUR 1 million in research and development. For more information, please visit: www.sanofipasteur.com or www.sanofipasteur.us

# 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 absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those 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, 2012. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

#### **Contacts:**

U.S. Media Relations
Donna Cary
T. + 1-570-957-0717
donna.cary@sanofipasteur.com
www.sanofipasteur.us

Global Media Relations
Alain Bernal
T. +33-4-37-37-50-38
alain.bernal@sanofipasteur.com
www.sanofipasteur.com

Investor Relations
Sébastien Martel
T. +33-1-53-77-45-45
ir@sanofi.com
www.sanofi.com