



## Sanofi Pasteur's Fluzone High-Dose Vaccine Significantly More Effective Than Standard Dose Fluzone Vaccine in Preventing Influenza in Adults 65 Years of Age and Older

*– Efficacy trial in more than 30,000 older adults meets primary endpoint for superior efficacy –*

**Lyon, France - August 26, 2013** - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), today announced topline results of a large-scale, multi-center efficacy trial in people 65 years of age and older showing a superior clinical benefit of Fluzone<sup>®</sup> High-Dose (Influenza Virus Vaccine) relative to the standard dose of Fluzone vaccine in preventing influenza.

Today's announcement reflects the positive findings related to the primary endpoint for the study population. Further data analyses of secondary endpoints are ongoing, including an evaluation of the relative efficacy based on the match of the vaccine strains to circulating influenza virus strains. Sanofi Pasteur anticipates submitting the full clinical study report to the FDA for review by early 2014 and will seek a modification to the label for Fluzone High-Dose vaccine reflecting the superior efficacy data in adults 65 years of age and older.

*"We are pleased that this study demonstrates the superior relative efficacy of Fluzone High-Dose vaccine compared to Fluzone vaccine in preventing influenza in older adults,"* said David P. Greenberg, M.D., Vice President, U.S. Scientific and Medical Affairs, Sanofi Pasteur. *"This efficacy trial complements the previous evidence of superior immune responses for Fluzone High-Dose vaccine compared to Fluzone vaccine and reaffirms the Phase III safety data in this population that were the basis for FDA licensure of Fluzone High-Dose vaccine in 2009."*

In the study, Fluzone High-Dose vaccine was 24.2 percent more effective in preventing influenza in adults 65 years of age and older than Fluzone vaccine. The results met the pre-specified primary objective of the study, demonstrating statistically superior efficacy for Fluzone High-Dose vaccine. Additionally, the study results suggested consistent clinical benefit across the study years, influenza virus types, clinical illness definitions, and laboratory methods of influenza confirmation. This large, multi-year trial also reaffirmed the safety of Fluzone High-Dose vaccine as demonstrated in previous studies.

*"Influenza vaccines have been shown to offer public health benefits in preventing influenza and its complications in all age groups; however, older adults still have the highest rates of influenza-related hospitalization and death despite having high immunization rates,"* said John Shiver, Senior Vice President, Research and Development, Sanofi Pasteur. *"This led Sanofi Pasteur to develop Fluzone High-Dose vaccine, which this trial has confirmed provides better protection against influenza compared to Fluzone vaccine in people 65 years of age and older."*

Fluzone High-Dose vaccine was licensed in the United States by the Food and Drug Administration (FDA) in December 2009 based on the vaccine's safety profile and superior immunogenicity compared



to Fluzone vaccine. Immunogenicity (the ability of a vaccine to trigger the body to produce antibodies against an infectious agent) is commonly used to evaluate vaccines in clinical trials. Fluzone High-Dose vaccine contains 60 mcg of hemagglutinin antigen per strain of influenza virus in the vaccine as compared to 15 mcg of influenza virus hemagglutinin antigen per strain of influenza virus in standard dose Fluzone vaccine. Fluzone High-Dose vaccine was licensed by the FDA under an accelerated approval process to address the medical need in older adults. As a requirement of the accelerated approval pathway, Sanofi Pasteur embarked on this large-scale, two-season, confirmatory efficacy trial, involving more than 30,000 participants 65 years of age and older, to evaluate the clinical benefit of Fluzone High-Dose vaccine compared to Fluzone vaccine in the prevention of influenza disease.

### **About Influenza Disease in People 65+ Years of Age**

Research has shown that the immune system weakens as people age. Older adults are not only more susceptible to infections, but also less responsive to vaccination. When infected with the influenza virus, they are less able to mount an effective immune response to neutralize the attack. Compared to younger adults, people 65 years of age and older suffer disproportionately from seasonal influenza disease and its complications, including severe illness leading to hospitalization and death. Although this group comprises only 15 percent of the U.S. population, on average it accounts for 65 percent of the estimated 226,000 hospitalizations and 90 percent of the 3,000 to 49,000 deaths attributed to seasonal influenza and its complications each year. The first baby boomers began to turn 65 in 2011 and, by the year 2030, the number of adults 65 years of age and older is anticipated to double and surpass 70 million people, comprising 20 percent of the U.S. population. Thus, better prevention of influenza in older adults can have a significant impact on public health, quality of life, and healthcare costs.

### **About Fluzone High-Dose Vaccine**

#### **Indication**

Fluzone High-Dose vaccine is an inactivated influenza virus vaccine given for active immunization in persons 65 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. Approval of Fluzone High-Dose vaccine is based on superior immune response relative to Fluzone vaccine. Data demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose vaccine relative to Fluzone vaccine have not yet been reviewed by FDA.

#### **Safety Information**

The most common side effects to Fluzone High-Dose vaccine include pain, swelling, and redness at the injection site; fever, headache, fatigue, and muscle aches. Other side effects may occur. Fluzone High-Dose vaccine should not be given to anyone with a severe allergic reaction to any vaccine component, including eggs or egg products, or to a previous dose of any influenza vaccine.

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

Before administering Fluzone Quadrivalent vaccine or Fluzone vaccine, please see full Prescribing Information available at [www.sanofipasteur.us](http://www.sanofipasteur.us) or [www.vaccineshoppe.com](http://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 health care 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](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://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.*

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