Sanofi Pasteur Announces Publication of Positive Data for Fluzone® High-Dose Vaccine in *The New England Journal of Medicine*

- Study Demonstrates Fluzone High-Dose Vaccine 24.2 Percent More Effective Than Standard-Dose Fluzone Vaccine in Preventing Influenza in Adults 65 Years of Age and Older -

LYON, France - August 13, 2014 - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), today announced that *The New England Journal of Medicine* published positive results from a large-scale, multi-center efficacy trial, which found that Fluzone® High-Dose (Influenza Vaccine) was more efficacious in preventing influenza ("the flu") in adults 65 years of age and older compared to standard-dose Fluzone vaccine.

Fluzone High-Dose vaccine was found to be 24.2 percent (95% CI, 9.7 to 36.5) more effective in preventing influenza relative to standard-dose Fluzone vaccine for the primary endpoint, indicating that about one in four breakthrough cases of influenza could be prevented if Fluzone High-Dose vaccine were used instead of the standard-dose Fluzone vaccine in this population. Additionally, relative efficacy was 35.4 percent (95% CI, 12.5 to 52.5) in an analysis restricted to influenza cases caused by vaccine-similar strains.

Fluzone High-Dose vaccine is an inactivated influenza vaccine that contains four times the amount of antigen than is contained in standard-dose Fluzone vaccine and induces a higher antibody response.

"*We are thrilled that the results of this trial have shown that Fluzone High-Dose vaccine is significantly more effective than standard-dose Fluzone vaccine in providing protection against influenza in the 65 and over population*," said David P. Greenberg, M.D., Vice President, Scientific & Medical Affairs, and Chief Medical Officer, Sanofi Pasteur US. *"Fluzone High-Dose vaccine is the only influenza vaccine in the US that is designed specifically to address the age-related decline of the immune system in older adults."*

Investigators compared the vaccine's efficacy in a large-scale, randomized, double-blind, trial that spanned two influenza seasons. The trial enrolled nearly 32,000 participants; 14,500 and 17,489 adults 65 years of age and older during the 2011-2012 and 2012-2013 influenza seasons, respectively, from 126 research centers in the United States and Canada. The primary endpoint of the study was the occurrence of laboratory-confirmed influenza at least 14 days post-vaccination caused by any influenza viral type or subtype. Investigators determined that participants in the Fluzone High-Dose vaccine group were less likely to get the flu than those in the standard-dose Fluzone vaccine group. Specifically, 228 people in the Fluzone High-Dose vaccine group (1.43 percent) and 301 people in the standard-dose Fluzone vaccine group (1.88 percent) had laboratory-confirmed influenza, demonstrating that Fluzone High-Dose vaccine was 24.2 percent (95% CI, 9.7 to 36.5) more effective in preventing influenza than standard-dose Fluzone vaccine. Additionally, researchers determined that most rates for pneumonia, cardio-respiratory conditions, hospitalizations, non-routine medical office visits and medication use were lower for the Fluzone High-Dose vaccine group compared to the standard-dose Fluzone vaccine group.

"Eighty-six percent of older adults have one or more chronic conditions, such as, cardiovascular disease and respiratory illnesses that can be exacerbated by influenza,"[i] said Keipp Talbot, MD, MPH, Assistant Professor of Infectious Diseases, Vanderbilt University Medical Center, Nashville, Tenn. and coordinating investigator of the trial. *"Considering the burden of influenza in older adults, it is encouraging to see that this trial demonstrated the ability of Fluzone High-Dose vaccine to provide better protection in this high-risk population."*

The full results from this trial formed the basis for a regulatory submission to the U.S. Food and Drug Administration (FDA) late last year to seek a modification to the Prescribing Information for Fluzone High-Dose vaccine reflecting the improved efficacy compared to standard-dose Fluzone vaccine in adults 65 years of age and older. Sanofi Pasteur anticipates a decision later this year.

"Adults age 65 years and older typically account for more than half of influenza-related hospitalizations and about 90 percent of influenza-related deaths," said John Shiver, Senior Vice President, Research and Development, Sanofi Pasteur. *"We are fully committed to helping to offer protection against influenza by delivering a more effective vaccine option designed specifically to address the needs of people aged 65 years and older."*

Influenza is a serious illness impacting up to 20 percent of Americans each year, translating to approximately 15 to 60 million cases annually.[ii] Adults 65 years of age and older remain at high risk for influenza, despite high vaccination rates.[iii,iv] People aged 65 years and older do not respond to standard-dose influenza vaccine as well as younger adults and may be left without sufficient protection[v] especially against influenza A/H3N2, which is considered the most burdensome in older adults.[vi,vii]

The study safety data were consistent with previous Fluzone High-Dose vaccine studies. During the surveillance period (approximately six to eight months post-vaccination each season), 1,323 (8.27 percent) and 1,442 (9.02 percent) people who received Fluzone High-Dose vaccine and standard-dose Fluzone vaccine, respectively, experienced at least one serious adverse event (SAE). Overall, the risk of experiencing at least one SAE was lower for the Fluzone High-Dose vaccine group compared to the standard-dose Fluzone vaccine group (relative risk 0.92, 95% CI 0.85-0.99), suggesting that Fluzone High-Dose vaccine may protect against the occurrence of influenza-related serious events. Three SAEs in the Fluzone High-Dose vaccine group were deemed vaccine-related; none resulted in discontinuation from the study. Cardiac disorders and infections were the most frequent types of SAEs in both groups. There were a total of 83 deaths in the Fluzone High-Dose vaccine group and 84 deaths in the standard-dose Fluzone vaccine group during the six-month surveillance period, none of which were considered by the investigators as related to vaccination.

Fluzone High-Dose vaccine was licensed in the United States by the FDA in December 2009 based on the vaccine's safety profile and superior immunogenicity compared to standard-dose 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 µg of influenza hemagglutinin antigen per strain as compared to 15 mcg of hemagglutinin antigen per strain in standard-dose Fluzone vaccine. Post-vaccination, Fluzone High-Dose vaccine induces significantly higher antibody responses compared to standard-dose Fluzone vaccine.

In response to the unmet medical need in older adults, Fluzone High-Dose vaccine was licensed by the FDA under the agency's accelerated approval process. 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 standard-dose Fluzone vaccine in the prevention of influenza disease.

About Influenza Disease in People 65 Years of Age and Older

The immune system weakens as people age. Older adults are not only more susceptible to infections, but they also are less responsive to vaccination. When infected with the influenza virus, they are less able to mount an effective immune response to neutralize the attack.[viii,ix] 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[x] Although this group comprises only 15 percent of the U.S. population, on average it accounts for 60 percent of the estimated 225,000 hospitalizations and 90 percent of the 3,000 to 49,000 deaths attributed to seasonal influenza and its complications each year.[xi,xii] 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.[xiii] 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 (Influenza Vaccine)

Indication

Fluzone High-Dose vaccine is indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus contained in the vaccine.

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

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 are not available.

Safety Information

The most common local and systemic adverse reactions to Fluzone High-Dose vaccine include pain, erythema, and swelling at the injection site; myalgia, malaise, headache, and fever. Other adverse reactions may occur. Fluzone High-Dose vaccine should not be administered to anyone with a known hypersensitivity (eg, anaphylaxis) to any vaccine component, including egg protein, or to a previous dose of any influenza vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following previous influenza vaccination, the decision to give Fluzone High-Dose vaccine should be based on careful consideration of the potential benefits and risks. Vaccination with Fluzone High-Dose vaccine may not protect all individuals.

Before administering Fluzone High-Dose vaccine, please see accompanying full Prescribing Information.

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 a broad 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, 2013. 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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