FDA Licenses New Influenza Vaccine Designed Specifically for People 65 Years of Age and Older

– Fluzone® High-Dose (Influenza Virus Vaccine) strengthens immune response in the 65+ population, an age group that suffers disproportionately from influenza and its complications –

Lyon, France and Swiftwater, Pa – December 23, 2009 – Sanofi Pasteur, the vaccines division of the sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), announced today that the U.S. Food and Drug Administration (FDA) has approved the company's supplemental biologics license application (sBLA) for licensure of Fluzone® High-Dose (Influenza Virus Vaccine). The new vaccine, for adults 65 years of age and older, will be available to health-care providers for immunizations administered this fall in preparation for the upcoming 2010-2011 influenza season.

"This new addition to Sanofi Pasteur's vaccine portfolio reflects our long-standing commitment to public health and to research and development of new vaccines for enhanced prevention of influenza," said Wayne Pisano, President and Chief Executive Officer of Sanofi Pasteur. *"In 2011 the first baby boomers will turn 65 and, by the year 2030, the number of adults over age 65 is anticipated to double and surpass 70 million people, or 20 percent of the U.S. population. We are excited to introduce Fluzone High-Dose vaccine which will provide health-care professionals with a new vaccine to help prevent influenza in their patients over the age of 65."*

Fluzone High-Dose vaccine was specifically designed to generate a more robust immune response in people 65 years of age and older. This age group typically does not respond as well to the standard dose of influenza virus vaccines as younger individuals because they have weakened immune systems.

About Influenza Disease in People 65+ Years of Age

Influenza vaccines have been shown to offer public health benefits in reducing influenza-related morbidity and mortality in older adults. However, as people age, research has shown that the immune system weakens. 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 and its complications, including severe illness leading to hospitalization and death.Although this group comprises only 15 percent of the U.S. population, it accounts for 65 percent of the estimated 226,000 hospitalizations and 90 percent of the 36,000 deaths attributed to seasonal influenza and its complications on average each year.

About Fluzone High-Dose Vaccine

Fluzone High-Dose vaccine is an inactivated influenza virus vaccine indicated for active immunization of people 65 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

This indication is based on the immune response elicited by Fluzone High-Dose vaccine and there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose vaccine.

Fluzone High-Dose vaccine contains 60 mcg of hemagglutinin per strain of influenza virus in the vaccine as compared to 15 mcg of influenza virus hemagglutinin per strain of influenza virus in standard-dose Fluzone vaccine.
Fluzone High-Dose vaccine is produced in the same production facility as Fluzone vaccine. Fluzone High-Dose vaccine is supplied as a single-dose, no preservative, prefilled syringe.

In a clinical study of 3,876 adults 65 years of age and older, Fluzone High-Dose vaccine was compared with the standard-dose Fluzone vaccine. The key finding was that the new high-dose vaccine induced statistically significant increases in immune responses compared to standard-dose Fluzone vaccine in the study population. After 28 days following immunization, investigators assessed serum hemagglutination inhibition (HAI) titers in study participants, a standard measurement of the immune response to influenza vaccination. Higher HAI titers were reported in those who received the high-dose vaccine compared with those who received the standard-dose vaccine. Immunogenicity results met pre-defined criteria for superiority of the high-dose vaccine. The primary endpoint of the study was the statistical superiority of immune responses to at least two of the strains contained in the vaccines when comparing Fluzone High-Dose vaccine to standard-dose Fluzone vaccine. Pre-defined criteria for overall superiority in the Phase III study were based on geometric mean titers (GMT) and seroconversion, which is defined as either a rise in HAI titer from <1:10 to ≥1:40 post-vaccination or a ≥4-fold increase in HAI titer post-vaccination from a pre-vaccination titer ≥1:10.There are no data demonstrating clinically relevant prevention of culture confirmed influenza or its complications after vaccination with Fluzone High-Dose vaccine compared to standard-dose Fluzone in adults 65 years of age and older.

In the clinical trial, Fluzone High-Dose vaccine was shown to have a clinically comparable safety profile to Fluzone vaccine. Rates of unsolicited and serious adverse events were similar between those who received Fluzone High-Dose vaccine and those who received Fluzone vaccine. Solicited local (injection site) adverse events and solicited systemic adverse events were more frequent after vaccination with Fluzone High-Dose vaccine compared to standard-dose Fluzone vaccine. More frequent mild to moderate local reactions were observed at the injection site as would be expected with increased antigen. The most common injection site reactions (≥10 percent) were injection site pain and redness. The most common systemic adverse events (≥10 percent) were malaise (feeling unwell), headache and myalgia (body aches).

Safety Information for Fluzone Vaccine and Fluzone High-Dose Vaccine

Side effects to Fluzone vaccines are soreness, pain and swelling at the injection site; fever, fatigue, headache and muscular pain. Other side effects may occur. Fluzone vaccines should not be administered to anyone with a history of serious allergic reaction to any vaccine component, including eggs, egg products, or thimerosal (the only Fluzone vaccine product containing thimerosal is the multi-dose vial), or to persons who have been previously diagnosed with Guillain-Barré syndrome (GBS). If you notice any other problems or symptoms following vaccination, please contact your health-care professional immediately. Vaccination with Fluzone vaccine or Fluzone High-Dose vaccine may not protect all individuals.

Before administering Fluzone High-Dose vaccine or Fluzone vaccine, please see full Prescribing Information at www.vaccineplace.com/products.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, please visit: www.sanofi-aventis.com

Sanofi Pasteur, the vaccines division of the sanofi-aventis Group, provided more than 1.6 billion doses of vaccine in 2008, 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 financial projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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-aventis' 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-aventis, 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 those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

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