# Sanofi Pasteur Announces Results of U.S. Clinical Trials in Adults Following One Dose of Influenza A (H1N1) Vaccine

- Data from studies in adults 18 years of age and older provide confirmation that one dose of vaccine produces a robust immune response even in those over the age of 65 years -

**Lyon, France and Swiftwater, Pa (United States) – October 1, 2009 -** Sanofi Pasteur, the vaccines division of the sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), announced today an interim analysis of data from clinical trials of the U.S. licensed Influenza A (H1N1) 2009 Monovalent Vaccine in adults 18 years through 64 years of age and over the age of 65 years.

These data indicate that a single 15 mcg dose of Sanofi Pasteur's Influenza A (H1N1) 2009 Monovalent Vaccine, administered to adults, including the oldest study participants, induces a robust antibody response 21 days post-vaccination that is considered protective. These data from a placebo controlled study of 849 adults help confirm preliminary data from a few vaccine recipients 10-days post immunization reported from another study by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH).

"The development of an A (H1N1) vaccine and the efficient execution of clinical trials to evaluate the safety and immunogenicity of this vaccine demonstrate the tremendous achievements that can occur when public and private sectors work collaboratively to address public health challenges," said Wayne Pisano, President and Chief Executive Officer of Sanofi Pasteur. "The independent clinical trials conducted by NIH and Sanofi Pasteur provide a rich data set that can be utilized to make informed decisions on vaccine administration. In addition, the consistency of findings among these separate independent trials will help build public confidence in the vaccine."

Sanofi Pasteur began clinical trials in the U.S. on August 6 to test the immunogenicity and safety of its Influenza A (H1N1) 2009 Monovalent Vaccine. Clinical trials are being conducted in adults 18 years of age and older including a group 65 years of age and older, and in children 6 months of age through 9 years of age. Final data from these clinical trials, following a second dose of vaccine, will provide additional information to guide recommendations on the optimal dosage, number of doses and schedule. Influenza A (H1N1) 2009 Monovalent Vaccine was licensed by the U.S. Food and Drug Administration on September 15 as a monovalent strain change to Sanofi Pasteur's licensed seasonal influenza vaccine.

#### Sanofi Pasteur Clinical Trial Design

Sanofi Pasteur reported today on interim immunogenicity and safety results following one dose of the company's Influenza A (H1N1) 2009 Monovalent Vaccine in adults. Interim data from clinical trials in children, 21 days post-dose vaccination, will be available in early October. Both clinical trials are continuing to evaluate immunogenicity and safety following a second dose of vaccine.

The multi-center, randomized, placebo-controlled adult trial is being conducted in 849 adults divided into two age cohorts: 18 years through 64 years of age or 65 years of age and older. Study participants in each age cohort were randomized to four treatment groups. Three groups received a 0.5 mL injection of



The vaccines division of sanofi-aventis Group



non-adjuvanted vaccine formulated to be either 7.5 mcg, 15 mcg, or 30 mcg. The fourth group received the saline placebo control.

In the trial two doses of vaccine were administered; the second dose 21 days after the first. Immunogenicity was measured at day 21 prior to administration of the second dose and will be measured again 21 days after the second dose at day 42. An antibody titer of 1:40 or greater is generally considered a marker of seroprotection. A lower rise in antibody titers following vaccination may minimize the occurrence of disease and its consequences but is not considered seroprotective. Adverse events are being monitored throughout the clinical trial and will continue for 6 months after the second dose of vaccine.

# Interim Results 21 Days Following the Initial Dose of Vaccine

Interim results announced today are from serum samples taken from all participants 21 days after the first dose. These data indicate that all doses administered in the trial are immunogenic and, based on the dose responses in this study, that one 15 mcg dose of Sanofi Pasteur's Influenza A (H1N1) 2009 Monovalent Vaccine would be expected to induce a strong immune response in adults 18 years of age and older. A 15 mcg dose is the standard dose for each influenza strain in the seasonal influenza vaccine.

In adults 18 years of age through 64 years of age, 98 percent of participants achieved seroprotective antibody titers at 21 days with the dose formulated to be 15 mcg used in the study. In adults 65 years of age and older, who received the same formulation, 93 percent achieved seroprotective titers.

No serious adverse events have been observed to date in this clinical trial. Local injection site redness, swelling and pain; and systemic complaints of mild fever, headache and fatigue were reported. Overall, the safety profile observed to date is very similar to that of the seasonal influenza vaccine.

# About Influenza A (H1N1) 2009 Monovalent Vaccine

The U.S. licensed Influenza A (H1N1) 2009 Monovalent Vaccine manufactured by Sanofi Pasteur is an inactivated influenza virus vaccine indicated for active immunization of persons six months of age and older against influenza disease caused by pandemic (H1N1) 2009 virus.

The Influenza A (H1N1) 2009 Monovalent Vaccine is manufactured by the same process as Sanofi Pasteur's seasonal trivalent influenza virus vaccine licensed in the U.S. Influenza A (H1N1) 2009 Monovalent Vaccine is formulated to contain 15 mcg hemagglutinin (HA) of influenza A/California/07/2009 (H1N1) v–like virus. Influenza A (H1N1) 2009 Monovalent Vaccine is licensed for single-dose presentations in syringes and vials and in multi-dose vials. There is no preservative used in the single-dose presentations. Multi-dose vials contain a preservative.

#### Safety Information for Influenza A (H1N1) 2009 Monovalent Vaccine

Influenza vaccine should not be administered to anyone with a known severe hypersensitivity to egg proteins, any vaccine component or life-threatening reactions after previous administration of any influenza vaccine. Recurrence of Guillain-Barré syndrome (GBS) has been temporally associated with the administration of influenza vaccine. The decision to give Influenza A (H1N1) 2009 Monovalent Vaccine to individuals who have a prior history of GBS should be based on careful consideration of the potential benefits and risks. Vaccination with Influenza A (H1N1) 2009 Monovalent Vaccine may not protect all individuals.

Before administering Influenza A (H1N1) 2009 Monovalent Vaccine, please see full U.S. Prescribing Information at www.vaccineplace.com/products.

# **About Influenza Vaccine Production at Sanofi Pasteur**

Sanofi Pasteur operates influenza vaccine production facilities in Val de Reuil, France and in Swiftwater, Pa. (U.S.). All Sanofi Pasteur influenza vaccine facilities have been designed and built to be able to switch from seasonal influenza vaccine production to pandemic influenza vaccine production.

Sanofi Pasteur produces approximately 40 percent of the influenza vaccines distributed worldwide and more than 45 percent of the influenza vaccines distributed in the U.S. for the 2008-2009 influenza season. More information about Sanofi Pasteur's pandemic preparedness efforts can be found at www.pandemic.influenza.com.

#### **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).

Sanofi Pasteur, the vaccines division of 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: http://www.sanofipasteur.com or www.sanofipasteur.us

# **Project Funding**

This project has been funded with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100200900121C. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government

# 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 sanofiaventis' 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.

#### Contacts

# **Global Media Relations**

Pascal Barollier
T. +33-(0)4-37-37-50-38
pascal.barollier@sanofipasteur.com
www.sanofipasteur.com

# **US Media Relations**

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