# Panenza®\* and Humenza®\* Influenza A(H1N1) Vaccines Demonstrate Robust Immune Response After One Dose

- Interim data from European studies confirm that one dose of Panenza<sup>®</sup> or Humenza<sup>®</sup> pandemic influenza vaccines induces robust seroprotective antibody response in children and adults -

**Lyon, France – October 8, 2009 -** Sanofi Pasteur, the vaccines division of the sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), announced today that a single dose of influenza A (H1N1) 2009 monovalent vaccines, Panenza® (15 mcg dose, non-adjuvanted) or Humenza® (3.8 mcg dose, adjuvanted), administered to children (3 years of age and older) and adults induces a robust immune response, according to results from clinical trials conducted in Europe.

One dose of Panenza or Humenza Influenza A (H1N1) 2009 monovalent vaccine induces a robust antibody response that is considered protective in 93 percent or more of adults 18 to 59 years old and in 83 percent or more of adults 60 years of age and older. In children 3 years of age through 17 years of age, 94 percent or more of study participants achieved seroprotective antibody response. Both vaccines tested met the three European Medicines Agency's (EMEA) criteria.

"These significant clinical data concerning Sanofi Pasteur's pandemic influenza vaccines will help build public confidence in the vaccine and will support efforts by health authorities to face the challenge posed by pandemic influenza," said Wayne Pisano, President and Chief Executive Officer of Sanofi Pasteur. "Humenza and Panenza vaccines are effective answers to different public health needs. Humenza, a low-dose adjuvanted vaccine, has the potential to expand pandemic production capacities and to increase the number of doses of vaccine available, making it possible to immunize more people; Panenza, standard-dose non-adjuvanted vaccine, may be considered by European authorities as the vaccine of choice to protect specific at-risk populations."

Results announced today are based on interim analysis following the first vaccination dose from clinical trials conducted in France and Finland. These data, from serum samples taken from all participants 21 days after the first dose, indicate that adjuvanted and non-adjuvanted vaccines administered in the trial induce a strong immune response in most participants. No serious adverse events have been observed to date in these clinical trials. Safety and tolerability profiles were as expected. Local injection site (redness, swelling and pain) and systemic complaints of mild fever, headache and fatigue were reported.

\* Panenza® and Humenza® are registered trademarks of Sanofi Pasteur's influenza A(H1N1) vaccines in EU and other countries.





# Sanofi Pasteur Clinical Trial Design

Sanofi Pasteur reported today on interim antibody response and safety results following one dose of the company's two influenza A (H1N1) 2009 monovalent vaccines in children aged 3 years of age and older, and in adults.

Sanofi Pasteur began clinical trials in Europe on August 18, 2009 to test the immunogenicity and safety of its influenza A (H1N1) 2009 monovalent vaccines. Two multi-center, randomized controlled studies are being conducted in Finland, involving 300 children 3 years of age through 17 years of age, and in France, involving 450 adults divided into two age cohorts: 18 years of age through 59 years of age (300 volunteers) or 60 years of age and older (150 volunteers).

Both trials are continuing to evaluate the immunogenicity and safety of a second dose of these vaccines. Final data from these clinical trials, following a second dose of vaccine, will provide additional information on the human immune response to this new influenza strain.

Study participants in each age cohort were randomly divided into three treatment groups. Each group received a 0.5 mL injection of either a non-adjuvanted 15 mcg dose vaccine, or an AF03-adjuvanted 7.5 mcg dose vaccine or an AF03-adjuvanted 3.8 mcg dose vaccine.

In the trials 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 monitoring will continue for six months after the second dose of vaccine.

#### **About Panenza and Humenza**

Sanofi Pasteur's influenza A (H1N1) 2009 monovalent inactivated influenza virus vaccines, Panenza and Humenza, are manufactured at Sanofi Pasteur's facility in Val de Reuil, France, using the same process as Sanofi Pasteur's seasonal trivalent influenza virus vaccine licensed in Europe.

Panenza is a non-adjuvanted vaccine formulated to contain 15 mcg hemagglutinin (HA) of influenza A/California/07/2009 (H1N1) v-like virus.

Humenza vaccine is formulated to contain 3.8 mcg hemagglutinin (HA) of influenza A/California/07/2009 (H1N1) v-like virus and includes AF03-adjuvant, Sanofi Pasteur's proprietary adjuvant, aimed at stimulating the immune system to increase its response.

Panenza and Humenza vaccines are not intended to be distributed in the U.S. where Sanofi Pasteur produces another A(H1N1) pandemic vaccine licensed by the F.D.A.

# **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. For the 2008-2009 influenza season, the company produced more than 45 percent of the influenza vaccines distributed in the U.S. More information about Sanofi Pasteur's pandemic preparedness efforts can be found at <a href="https://www.pandemic.influenza.com">www.pandemic.influenza.com</a>.

#### **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: <a href="http://www.sanofipasteur.com">http://www.sanofipasteur.com</a> or <a href="http://www.sanofipasteur.us">www.sanofipasteur.us</a>

### 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 fillings 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.

#### Contact:

# **Global Media Relations**

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