# Panenza®\*, Sanofi Pasteur's Influenza A(H1N1) 2009 Vaccine, Approved in France

- Panenza<sup>®</sup>, non-adjuvanted pandemic vaccine, licensed for use in adults and children 6 months of age and older -

**Lyon, France – November 16, 2009 -** Sanofi Pasteur, the vaccines division of the sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY) announced today that the French drug agency Afssaps (Agence française de sécurité sanitaire des produits de santé) has granted marketing authorization in France for Panenza<sup>®</sup>, its non-adjuvanted Influenza A(H1N1) 2009 monovalent vaccine, produced at Sanofi Pasteur's facility in Val de Reuil, France. The vaccine was made available to French health authorities.

"Registration and on-schedule delivery of A(H1N1) 2009 influenza vaccines remain high priorities for Sanofi Pasteur to help support authorities' pandemic immunization efforts and address this public health challenge," said Wayne Pisano, President and Chief Executive Officer of Sanofi Pasteur. "The marketing authorization approval for Panenza® represents a key regulatory step, as this non-adjuvanted vaccine could initially be selected in national immunization programs to protect specific populations in some European countries."

Sanofi Pasteur has filed a decentralized marketing authorization application for Panenza® vaccine in six European Union countries - Belgium, France (acting as "Reference Member State"), Germany, Italy, Luxembourg and Spain - in response to recommendations by the authorities from these countries to make a non-adjuvanted influenza A(H1N1) 2009 vaccine available. Panenza® is an inactivated monovalent influenza A(H1N1) 2009 virus, 15 mcg dose, non-adjuvanted vaccine indicated for the active immunization of adults and children 6 months of age and older against influenza disease caused by pandemic A(H1N1) 2009 virus.

The approval of Panenza® vaccine was supported by the review of data from clinical trials conducted in France and Finland in adults and children aged 6 months and older. Panenza® vaccine's safety profile was similar to that of Sanofi Pasteur's seasonal trivalent influenza vaccine. In adults and children over 3 years of age, immune response measurements showed that a single dose of Panenza® influenza A (H1N1) 2009 monovalent vaccine induced a high antibody response 21 days post-vaccination that is considered protective. Panenza® vaccine met the European Medicines Agency's (EMEA) three immunological criteria. However, one or two doses of Panenza may be indicated depending on the age groups.

\* Panenza® is a registered trademark of Sanofi Pasteur's influenza A(H1N1) vaccine in EU and other countries.

## **About Panenza®**

Influenza A(H1N1) 2009 monovalent inactivated influenza virus vaccine Panenza<sup>®</sup> is manufactured at Sanofi Pasteur's facility in Val de Reuil, France, using the same robust, "tried and true" process as Sanofi Pasteur's seasonal trivalent influenza virus vaccine licensed in Europe. Sanofi Pasteur's seasonal influenza vaccine manufacturing process has been successfully used for decades and the seasonal vaccine has a proven record of safety and efficacy. As the world's leading influenza





vaccine manufacturer, Sanofi Pasteur has acquired unmatched expertise in the protection against influenza. To date Sanofi Pasteur has distributed more than 1.5 billion doses of seasonal influenza vaccine throughout the world. Building on Sanofi Pasteur's vast experience in influenza vaccine production, Panenza<sup>®</sup> vaccine is manufactured in strict accordance with the European Pharmacopeia and with the highest GMP (Good Manufacturing Practice) standards.

Panenza<sup>®</sup> is a non-adjuvanted vaccine formulated to contain 15 mcg hemagglutinin (HA) of influenza A/California/07/2009 (H1N1) v–like virus. It is not intended to be distributed in the U.S. where Sanofi Pasteur produces another non-adjuvanted A(H1N1) pandemic vaccine licensed in September 2009 by the U.S. Food and Drug Administration.

#### **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="http://pandemic.influenza.com">http://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: http://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.

### **Contacts**

#### **Global Media Relations**

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