# **U.S. FDA Licenses Sanofi Pasteur's Pandemic Influenza Vaccine**

- Influenza A (H1N1) 2009 Monovalent Vaccine licensure a key U.S. milestone in preparing for pandemic response this Fall -

**Lyon, France and Swiftwater, Pa (United States) – September 15, 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 its Influenza A (H1N1) 2009 Monovalent Vaccine.

The U.S. licensed Influenza A (H1N1) 2009 Monovalent Vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 6 months of age and older against influenza disease caused by pandemic (H1N1) 2009 virus. Sanofi Pasteur provides the only influenza vaccine licensed in the U.S. for populations as young as 6 months of age and older.

"Obtaining FDA licensure of this vaccine for A (H1N1) pandemic response is a key milestone that will enable Sanofi Pasteur to provide a licensed vaccine to the U.S. government to support pandemic immunization efforts," said Wayne Pisano, President and Chief Executive Officer of Sanofi Pasteur. "Development and production of an A (H1N1) influenza vaccine remains a high priority for Sanofi Pasteur and we will continue to focus our vaccine production expertise and resources on addressing this public health challenge."

The sBLA had been filed by Sanofi Pasteur on August 7 in response to recommendations by the FDA for evaluation of Influenza A (H1N1) 2009 Monovalent Vaccine as a strain change using the same regulatory process by which it approves new viral strains contained in the annual seasonal influenza vaccine.

Sanofi Pasteur is testing the immunogenicity and safety of its Influenza A (H1N1) 2009 Monovalent Vaccine through clinical trials, which began in the U.S. on August 6. Final data from these clinical trials will provide additional information to guide recommendations on the optimal dosage, number of doses and schedule. Similarly, clinical development activities with Sanofi Pasteur's A (H1N1) vaccine manufactured in France are underway in close consultation with the European Authorities.

# About Influenza A (H1N1) 2009 Monovalent Vaccine

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.





# **U.S. Safety Information**

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, Pennsylvania (United States). 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: 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 sanofiaventis' 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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