

## **Sanofi Pasteur Receives Additional Order from U.S. Government to Produce Influenza A (H1N1) Vaccine**

**- Company has now committed to produce 75.3 million doses of vaccine for the U.S. government -**

**Lyon, France and Swiftwater, Pa (United States) - September 21, 2009** - Sanofi Pasteur, the vaccines division of the sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), announced today that the company has received an additional order from the U.S. Department of Health and Human Services (HHS) to produce vaccine to help protect against the Influenza A (H1N1) 2009 virus. The new order is for the production of bulk antigen equivalent to 27.3 million doses based on 15 mcg of antigen per dose. Specifications for formulation and filling of this new bulk order will be the subject of a separate order. To date, Sanofi Pasteur has committed to the U.S. government a total of 75.3 million doses of Influenza A (H1N1) 2009 Monovalent Vaccine.

*"We are pleased to be able to support the U.S. government's pandemic response efforts through the production of additional doses of A (H1N1) vaccine," said Wayne Pisano, President and Chief Executive Officer of Sanofi Pasteur. "As the only company manufacturing inactivated influenza vaccine in the U.S., we recognize the important role Sanofi Pasteur serves in the country's pandemic response plan and we have committed our resources to responding to our public health needs."*

Sanofi Pasteur began commercial production of the new influenza vaccine in June using the novel virus strain to provide doses for clinical trials and to respond to the initial order from HHS. Influenza A (H1N1) 2009 Monovalent Vaccine was licensed by the U.S. Food and Drug Administration on September 15. Sanofi Pasteur is testing the immunogenicity and safety of the Influenza A (H1N1) 2009 Monovalent Vaccine produced in the U.S. 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.

Sanofi Pasteur operates influenza vaccine production facilities in the U.S. and in France. Production of the new A (H1N1) vaccine for HHS is being performed at the company's U.S.-based production facility.

### **About 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 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](http://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](http://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](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://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](mailto:pascal.barollier@sanofipasteur.com)  
[www.sanofipasteur.com](http://www.sanofipasteur.com)

### **US Media Relations**

Donna Cary  
T. +1-570-957-0717  
[donna.cary@sanofipasteur.com](mailto:donna.cary@sanofipasteur.com)  
[www.sanofipasteur.us](http://www.sanofipasteur.us)