



**sanofi pasteur**

The vaccines business of sanofi-aventis Group

**sanofi aventis**

Because health matters

P R E S S   R E L E A S E

## **SANOFI PASTEUR'S INVESTIGATIONAL H5N1 INFLUENZA VACCINE ACHIEVES HIGH IMMUNE RESPONSE AT LOW DOSAGE**

*- Clinical study demonstrates breakthrough dose-sparing formulation that increases stockpile capacities and expands potential production capacities to billions of doses in a pandemic situation -*

**Lyon (France), Sept. 18, 2007**– Sanofi pasteur, the vaccines division of sanofi-aventis Group, today announced data showing that its new investigational H5N1 pandemic influenza vaccine containing a proprietary adjuvant achieved a high immune response at the lowest dose of H5N1 antigen reported to date.

The vaccine containing only 1.9 µg of antigen generated a high level of seroprotective immune response in over 70 percent of the participants in a clinical trial and, in the same clinical trial, vaccine containing 3.75 µg of antigen generated a high level of seroprotective immune response in over 80 percent of the participants.

Once fully developed, this vaccine should give sanofi pasteur the potential to provide billions of doses in a pandemic situation and greatly increases its ability to produce vaccines for stockpiling in advance of a pandemic. This would be a significant achievement for public health and a breakthrough in research and development of pre-pandemic and pandemic vaccines that is fully in line with sanofi pasteur's early commitment to bring answers to the global threat posed by pandemic influenza.

Results are based on analysis of a clinical trial conducted in Belgium. The trial involved 266 healthy adults, 18 to 40 years of age. The vaccine tested was produced from inactivated H5N1 virus and contains a new, proprietary adjuvant aimed at stimulating the immune system to increase the response to the vaccine. Trial participants received two doses of each formulation. Four levels of antigen dose were tested, with 1.9 µg being the lowest dose.

Preliminary data also show good cross-reactivity to a more recently circulating H5N1 strain. Further assessment of the ability of this vaccine to provide cross-protection to variants of the H5N1 strains is ongoing.

Sanofi pasteur has committed, in the event of a pandemic being declared by the World Health Organization (WHO), to producing the largest possible number of doses of its most advanced pandemic influenza vaccine in the shortest possible time. In order to increase its capacity, sanofi pasteur initiated clinical trials with a novel adjuvant aimed at dramatically reducing the amount of antigen needed to elicit a protective immune response to the H5N1 strain currently identified by global health authorities and experts as a potential source for the next pandemic.

According to the WHO, the next influenza pandemic could result in 1 million to 2.3 million hospitalizations and 280,000 to 650,000 deaths in industrialized nations alone. Its impact is expected to be even more devastating in developing countries.

With production of 170 million doses of influenza vaccine in 2006, sanofi pasteur confirmed its leadership as the world's largest manufacturer of seasonal influenza vaccine, supplying a large portion of the estimated global production of about 350 million doses<sup>1</sup>. Sanofi pasteur's Vaxigrip® and Fluzone® influenza virus vaccines are licensed in over 100 countries.

Reference 1: [www.who.int/vaccine\\_research/diseases/ari/en/print.html](http://www.who.int/vaccine_research/diseases/ari/en/print.html)

### **Pandemic Influenza Overview**

Influenza is a disease caused by a highly infectious virus that spreads easily from person to person, primarily when an infected individual coughs or sneezes. An influenza pandemic is a global epidemic of an especially virulent virus, newly infectious for humans, and for which there is no preexisting immunity. This is why pandemic strains have such potential to cause severe morbidity and mortality. In an attempt to minimize the impact of a pandemic, many countries are developing national and transnational plans against a possible influenza pandemic situation.

### **Sanofi Pasteur and Pandemic Preparedness**

Sanofi pasteur is committed to global pandemic preparedness. As the world leader in research, development and manufacturing of influenza vaccines, sanofi pasteur is actively involved in several pandemic preparedness projects in the U.S. and Europe, with the goal of developing a vaccine to protect against a pandemic influenza virus. Sanofi pasteur is also investing in major expansions of its seasonal influenza vaccine production facilities in the U.S. and France, which could be used to produce pandemic influenza vaccine if the need arises.

For more information please visit <http://pandemic.influenza.com>

### **About sanofi-aventis**

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi pasteur, the vaccines division of the sanofi-aventis Group, provided more than a billion doses of vaccine in 2006, 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 EUR1 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, 2006. 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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