# EMERFLU<sup>®</sup>, pandemic influenza vaccine for humans, approved in Australia

**Lyon, France – March 26, 2009 -** Sanofi Pasteur, the vaccines division of sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), announced today that its pandemic influenza vaccine for human use Emerflu<sup>®</sup>\*, has been granted marketing authorization from the Australian Therapeutic Goods Administration (TGA). Emerflu<sup>®</sup> vaccine is now approved for the prevention of pandemic influenza in Australia upon official declaration of a pandemic. Emerflu<sup>®</sup> vaccine is intended to be manufactured and distributed with the identified pandemic strain and used in Australia in accordance with official Australian government guidance.

The Australian approval of Emerflu<sup>®</sup> vaccine granted today follows the positive recommendation by the Australian Drug Evaluation Committee (ADEC) on February 13 2009, based on a review of results from clinical trials, which began in late 2004 on H5N1 alum-adjuvanted\*\* inactivated influenza vaccine candidates. These trials evaluated the safety and ability of Emerflu<sup>®</sup> vaccine to elicit a protective immune response to the H5N1 strains currently identified by global health authorities and experts as a potential source for the next pandemic.

"The Australian TGA's recommendation of Emerflu<sup>®</sup> vaccine marks a new milestone in pandemic preparedness," said Wayne Pisano, President and CEO of sanofi pasteur. According to the World Health Organization (WHO), influenza vaccines are considered to be the most important and potentially effective intervention for mitigating the effects of an influenza pandemic<sup>1</sup>. The optimal choice of strain and formulation for an effective vaccine will be possible when the pandemic influenza strain has emerged<sup>1,2</sup>. "As the world's leading influenza vaccine manufacturer, sanofi pasteur aims at contributing to the efforts of WHO, Australia and other countries around the world to safeguard human health in the event of an influenza pandemic," added Pisano.

Sanofi pasteur is actively involved in pandemic preparedness and has invested in a major expansion of its influenza vaccine production capacity in the U.S., France, China and Mexico. Sanofi Pasteur is also committed to continuing its robust research and development program by exploring strategies for protecting more people. This includes the evaluation of new vaccine formulations to generate immune responses against other strains of the H5N1 virus as well as the use of adjuvants or immunostimulators\*\*\* to increase the response to the vaccine.

\* Emerflu<sup>®</sup> is a registered trademark of sanofi pasteur's mock-up pandemic influenza vaccine in Australia and other countries. \*\*alum is an additive commonly used to increase the immune response to vaccines.

\*\*\* adjuvants or immunostimulators are additives aimed at reducing, in pandemic influenza vaccines, the amount of antigen needed to elicit a protective immune response to the avian influenza [H5N1 or other virus] circulating strains





The vaccines division of sanofi-aventis Group

## 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 EUR1 million in research and development. For more information, please visit: www.sanofipasteur.com or www.sanofipasteur.us

#### **References:**

1. www.who.int/vaccine\_research/diseases/influenza/flu\_trials\_tables/en/print.html

2. www.who.int/vaccine\_research/diseases/ari/en/print.html

### 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 sanofiaventis' 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.

## **Global Media Relations**

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

#### **US Media Relations**

Len Lavenda T. +1-570-957-0717 len.lavenda@sanofipasteur.com www.sanofipasteur.us