

## Sanofi Pasteur Global Dengue Vaccine Clinical Program Expanded in Latin America

*- New study in Mexico, Colombia, Honduras and Puerto Rico advance the development of novel vaccine for dengue prevention in Latin America -*

**Mexico City (Mexico) - December 9, 2009** - Sanofi Pasteur, the vaccines division of the sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), announced today the expansion of its dengue vaccine clinical program in Latin America with a new multicenter study in children and adolescent in Mexico, Colombia, Honduras and Puerto Rico. This new multicenter study complements an earlier study in Mexico and an ongoing study in Peru.

These studies are aimed at advancing the development of a novel vaccine for the prevention of dengue infections in Latin America. Currently, there is no specific treatment available against dengue fever, which is the most widespread tropical disease after malaria.

*"Latin America was considered almost free of dengue in the 1960s. Since then, urbanization and travel have contributed to the fast re-emergence of the disease. Today, dengue disease is a severe public health issue throughout Latin America,"* said Dr. Roberto Tapia-Conyer, Director General at Carso Health Institute. *"So far, controlling the mosquitoes that transmit dengue didn't stop this trend. A safe and effective vaccine would be most welcome to prevent dengue epidemics in the region."*

### **Dengue in Latin America: a growing burden**

Nineteen Latin American countries were certified as dengue free between 1952 and 1965. The first reappearance of dengue fever was recorded in 1968, and by 2007 the disease had once more taken hold in all those countries<sup>1</sup>. In 2008 and 2009, severe dengue epidemics have been reported in Mexico, Paraguay, Brazil, Bolivia and Argentina. Many factors have contributed to the re-emergence and dramatic increase in dengue fever including urbanization and increased travel which facilitates dissemination of dengue viruses and the circulation of all four dengue serotypes in the region.

*"Fighting dengue is of the utmost public health importance: We must remain on epidemiological alert as dengue continues to circulate in Latin America",* said Dr. Jorge Mendez, Investigator at the children's hospital Federico Gomez in Mexico and co-investigator for the evaluation of a dengue vaccine in Mexico. *"Clinical studies in Mexico are critical steps to advance the development of a vaccine for the prevention of dengue. We are happy that Mexico contributes to scientific research that would benefit the entire region."*

*“Most of the severe dengue cases are among children under the age of 15 years old. It is an important cause of hospitalization which contributes highly to the burden of disease and increases costs for our health system,”* said Dr. Diana Patricia Rojas Alvarez, Expert for vector born diseases, dengue and yellow fever, at the National Institute of Health in Colombia. *“A safe and effective vaccine for children is much needed and we are pleased to support pediatric clinical studies in Colombia.”*

### **Sanofi Pasteur global clinical study program for a dengue vaccine**

Sanofi Pasteur started the development of a dengue vaccine in the '90s. Clinical studies with its most advanced tetravalent candidate vaccine started in the 2000s. Sanofi Pasteur's dengue vaccine candidate has been evaluated in clinical trials (Phase I, II) in adults and children from non-endemic (U.S.) and endemic countries (Mexico, Philippines). Overall, a balanced immune response against all four serotypes was observed after three doses of the vaccine. The vaccine appears to be well tolerated with a similar safety profile after each dose<sup>2</sup>.

Sanofi Pasteur's dengue vaccine research program includes ongoing clinical studies with adults and children in Mexico, Colombia, Honduras, Puerto Rico, Peru, the Philippines, Vietnam, Singapore, and Thailand. These studies follow the highest standards from the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Sanofi Pasteur's tetravalent dengue vaccine is the leading dengue candidate vaccine in development<sup>3,4</sup>.

### **About dengue fever**

Dengue fever is a mosquito-borne disease caused by four types of dengue viruses (type 1 to 4). Overall, the disease is a potential threat for almost half of the world's population. Of the estimated 230 million people infected annually, two million, mostly children, develop dengue hemorrhagic fever (DHF), a severe form of the disease<sup>5</sup>. DHF is a leading cause of hospitalization, placing tremendous pressure on strained medical resources.

Dengue fever occurs mostly in tropical and subtropical countries in Asia and Latin America and is spreading to new parts of the globe each year. In addition, dengue affects countries such as Australia (Queensland) and the United States (Puerto Rico, Texas-Mexico border, Hawaii and the US-affiliated Pacific Islands). A substantial number of people traveling to endemic regions are also infected each year.

### **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). For more information, visit: [www.sanofi-aventis.com](http://www.sanofi-aventis.com)

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](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.*

#### **References:**

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