

# Sanofi Pasteur Dengue Vaccine Enters Pediatric Efficacy Clinical Study

## Global clinical study program across dengue endemic regions in Latin America and Asia

**Lyon, France, February 18, 2009** - Sanofi Pasteur, the vaccines division of sanofi-aventis Group (EURONEXT : SAN et NYSE : SNY), announced today that its investigational tetravalent dengue vaccine is entering into a pediatric clinical study in Thailand to assess the efficacy of the vaccine in protecting children against dengue, the most widespread tropical disease after malaria. Sanofi Pasteur's tetravalent dengue vaccine candidate is the first to reach this stage of clinical development.

Sanofi Pasteur is collaborating with Mahidol University of Thailand, the Ministry of Public Health, and the Pediatric Dengue Vaccine Initiative (PDVI) to conduct this efficacy study in the province of Ratchaburi.

*"Large scale pediatric studies are instrumental for the development of a safe and efficacious dengue vaccine to protect against a disease that primarily affects children,"* said Dr. Pratap Singhasivanon, Dean of the Faculty of Tropical Medicine, Mahidol University. *"We are happy to contribute to an important milestone with the actual start of an efficacy study in Ratchaburi."*

The sanofi pasteur clinical study program follows guidelines from the Initiative for Vaccine Research (IVR) led by the World Health Organization (WHO), which fosters the global efforts towards dengue vaccine development.

*"WHO is committed to the availability of a dengue vaccine that will ultimately benefit children in endemic countries,"* said Dr. Joachim Hombach, Coordinator Implementation Research for IVR, WHO.

## **About sanofi pasteur dengue vaccine global clinical study program**

Sanofi Pasteur started the development of a dengue vaccine in the 90's. Clinical studies with the most advanced tetravalent candidate vaccine started in the 2000's. In a study in the United States, immunization with three doses of sanofi pasteur's tetravalent dengue vaccine candidate generated a sero-neutralizing antibody response against all four serotypes of the virus responsible for dengue fever in 100 percent of adults who participated in the trial<sup>1</sup>. The sanofi pasteur dengue vaccine research program includes ongoing clinical studies in Mexico, Peru, and The Philippines with adults and children.

### **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 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>2</sup>. DHF is a leading cause of hospitalization in South-East Asia, placing tremendous pressure on strained medical resources.

Dengue fever occurs mostly in tropical and subtropical countries and is spreading to new parts of the globe each year. The WHO has warned that the Western Pacific Region may be heading for a major dengue outbreak<sup>3</sup>. Outbreaks recently have been observed in Paraguay and the Middle East. 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).

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)

#### **References:**

1. Data generated by the WHO Flavivirus Laboratory Reference Center, Mahidol University, Bangkok, Thailand, presented at the American Society of Tropical Medicine and Hygiene's (ASTMH) 56th annual meeting held in Philadelphia, Pennsylvania, USA
2. Pediatric Dengue Vaccine Initiative (PDVI), presentation "Estimating the global burden of dengue" at 2nd Int Conf on Dengue & DHF, 15-17 Oct 08, Phuket, Thailand
3. WHO alarmed about the spread of dengue, [http://www.wpro.who.int/media\\_centre/press\\_releases/pr\\_23072007.htm](http://www.wpro.who.int/media_centre/press_releases/pr_23072007.htm)

### **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 product development, product potential 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 among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMEA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as 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, 2007. 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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