

Sanofi Pasteur's Dengue Vaccine in Final Stage of Clinical Development

First Phase 3 Study Underway in Australia

LYON, France, Nov. 4 /CNW/ - Sanofi Pasteur, the vaccines division of sanofi-aventis Group (EURONEXT: SAN and NYSE: SNY), announced today that its dengue vaccine is in final stage of clinical development. Sanofi Pasteur's dengue vaccine, the world's most clinically advanced dengue vaccine candidate(1,2), entered its first phase 3 clinical study in Australia.

This study is part of a global phase 3 clinical study program aimed at advancing the development of a novel vaccine for the prevention of dengue disease in children and adults. Currently, there is no specific treatment available for dengue fever, which is a threat to nearly three billion people and a public health priority in many countries of Latin America and Asia where epidemics occur.(3)

Phase 3 studies are the ultimate steps in the clinical development of a vaccine before it is submitted to regulatory authorities for evaluation for market authorization. Sanofi Pasteur's candidate dengue vaccine is the first to reach phase 3 of clinical development.

"To address the global health challenge represented by dengue fever, we are conducting an unprecedented dengue vaccine research and development program as well as a scale up of the vaccine production," said Wayne Pisano, President and Chief Executive Officer of Sanofi Pasteur. "We are now entering the final laps of a long run that Sanofi Pasteur started almost 20 years ago. If successful, we are committed to introducing the vaccine in countries where dengue is of highest public health priority."

The study in Australia is the first to use dengue vaccine doses produced with industrial scale processes. The study is aimed at demonstrating that production of the vaccine at industrial scale will meet consistency criteria required for market authorization by regulatory authorities. Details of the phase 3 study in Australia as well as results of already completed studies are presented at the 59th annual conference of ASTMH (American Society of Tropical Medicine and Hygiene), held in Atlanta (Georgia, United States), November 3-7.

Sanofi Pasteur's global dengue vaccine clinical study program

Sanofi Pasteur's candidate dengue vaccine-which targets all four virus serotypes-has been evaluated in clinical studies (Phase 1, 2) in adults and children in the U.S., Asia and Latin America. Overall, a balanced immune response against all four serotypes was observed after three doses of the vaccine. The vaccine is well tolerated with a similar safety profile after each dose.(4)

Clinical studies in adults and children are ongoing in Mexico, Colombia, Honduras, Puerto Rico, Peru, the Philippines, Vietnam, Singapore, Australia, and Thailand.

About dengue fever

Dengue fever is a mosquito-borne disease caused by four dengue virus serotypes (1 to 4). Overall, the disease is a potential threat to almost half of the world's population. Of the estimated 220 million people infected annually, two million-mostly children-develop dengue hemorrhagic fever (DHF), a severe form of the disease.(5) DHF is a leading cause of hospitalization, placing tremendous pressure on strained medical resources and having a heavy economic and societal impact. 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 virus serotypes.

For continuous up to date information about dengue fever outbreaks, visit <http://www.denguewatch.org>, a news hub reporting worldwide alerts on dengue, provided by the Pediatric Dengue Vaccine Initiative.

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, please visit: <http://www.sanofi-aventis.com>

Sanofi Pasteur, the vaccines division of sanofi-aventis Group, provided more than 1.6 billion doses of vaccine in 2009, 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 <http://www.sanofipasteur.us>

- Dengue vaccine efficacy trials in progress, <http://www.thelancet.com/infection>, vol 9, November 2009
- Jean Lang, Recent progress on Sanofi Pasteur's dengue vaccine candidate. Journal of Clinical Virology 46, S2 (2009) 20-24
- WHO Fact sheet No117, March 2009 Dengue and dengue haemorrhagic fever
- Saville et al, Clinical development of a tetravalent dengue vaccine for endemic areas, ICID Miami, March 2010; Lang et al, Toward a tetravalent dengue vaccine in Brazil, Tropical Medicine meeting, Iguacu Falls, March 2010P
- PDVI Newsletter No 7, April 2010 accessible at http://www.pdvi.org/PDVI_newsletter/newsletter.asp

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 projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential 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 EMA, 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, the Group's ability to benefit from external growth opportunities 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, 2009. 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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