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Sanofi Pasteur's Dengue Vaccine Demonstrates Proof of Efficacy

- Early data analysis confirms excellent safety profile and shows vaccine ability to protect against disease caused by three of the four dengue virus serotypes circulating in Thailand in world's first ever efficacy study -

Lyon, France - July 25, 2012 - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today that its tetravalent dengue vaccine candidate demonstrated proof of efficacy against dengue, a threat to almost 3 billion people, in the world's first ever dengue efficacy trial conducted in Thailand, with excellent safety.

The vaccine generated antibody response for all four dengue virus serotypes. Evidence of protection was demonstrated against three of the four virus serotypes circulating in Thailand. Analyses are ongoing to understand the lack of protection for the fourth serotype in the particular epidemiological context of Thailand.

"Results of this first efficacy trial with Sanofi Pasteur's dengue vaccine candidate represent a key milestone in the quest to develop a safe and efficacious human vaccine against dengue," said Michel De Wilde, Ph.D., Executive Vice President, Research & Development, Sanofi Pasteur. *"This is also an important development for global public health, since there is currently no specific treatment or prevention for dengue. We are fully committed to making dengue a vaccine preventable disease by bringing a safe and effective vaccine to people living in endemic regions of the world."*

Importantly, the results confirm the excellent safety profile of the vaccine candidate. The full data resulting from this first efficacy trial are currently under review by scientific and clinical experts, as well as public health officials. Detailed results of this study will be published in a peer-reviewed journal and presented to the scientific community later this year.

Large scale phase III dengue vaccine clinical studies with 31,000 participants are underway in 10 countries of Asia and Latin America. These studies will generate important additional data in a broader population and in a variety of epidemiological settings to demonstrate vaccine efficacy against the four circulating dengue virus serotypes.

About the Study

The study was conducted in 4,002 children aged 4 to 11 years, in partnership with the Mahidol University under the patronage of the Thai Ministry of Public Health in Muang district of the Ratchaburi Province. Sanofi Pasteur dengue vaccine candidate is a live attenuated vaccine. The vaccination schedule is 3 doses given 6 months apart (at 0, 6 and 12 months).

About Dengue

Dengue is a threat to nearly 3 billion people and a health priority in many countries of Latin America and Asia where epidemics occur.[1] There is no specific treatment available for this disease. Dengue is expanding geographically; the recent outbreak in Florida shows that dengue can hit the continental U.S. beyond endemic areas in Hawaii and Puerto Rico.[2]

Dengue fever is a mosquito-borne disease caused by four types of dengue virus (types 1 to 4). Overall, the disease is a potential threat to 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.[6] DHF is a leading cause of hospitalization, placing tremendous pressure on strained medical resources and having a heavy economic and societal impact.

About Sanofi Pasteur's Dengue Vaccine Clinical Program

Sanofi Pasteur's investigational dengue vaccine - which targets all four virus types - has been evaluated in clinical studies (Phase I, II) in adults and children in the U.S., Asia and Latin America. Overall, an 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.[3]

Large scale phase III dengue vaccine clinical studies in 31,000 adults and children are ongoing in Latin America (Mexico, Colombia, Honduras, Puerto Rico and Brazil) and in Asia (the Philippines, Vietnam, Malaysia, Indonesia, 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 candidate dengue vaccine in development.[4,5]

The U.S. Food and Drug Administration (FDA) has granted fast-track designation to the company's investigational dengue vaccine. The FDA fast-track designation recognizes that a dengue vaccine would address an important unmet medical need for a serious disease.

The Sanofi Pasteur investigational dengue vaccine is intended for the prevention of dengue disease in children and adults living in endemic areas of Asia and Latin America as well as for children and adults who are travelling to endemic countries, including expatriates and military personnel.

About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, 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 or www.sanofipasteur.us

[1] WHO Fact sheet N°117, March 2009 Dengue and dengue haemorrhagic fever http://www.who.int/mediacentre/factsheets/fs117/en/
[2] Morbidity and Mortality Weekly Report (MMWR) Locally Acquired Dengue --- Key West, Florida, 2009—2010 - May 21, 2010 / 59(19);577-581
[3] 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 2010
[4] Dengue vaccine efficacy trials in progress, www.thelancet.com/infection, vol 9, November 2009
[5] Jean Lang, Recent progress on Sanofi Pasteur's dengue vaccine candidate, Journal of Clinical Virology 46, S2 (2009) 20-24
[6] Beatty M Letson GW Margolis HS, Estimating the global burden of dengue, Am J Trop Med Hygiene 81, 5:231 2009

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's 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, 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 product candidates, the absence of guarantee that the product 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, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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