



Sanofi Pasteur Announces Publication in *The Lancet* of World's First Efficacy Results for its Dengue Vaccine Candidate

– Publication of detailed results of study conducted in Thailand shows protection against 3 out of 4 dengue virus serotypes and confirms excellent vaccine safety profile –

Lyon, France – September 11, 2012 – Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), announced today the online publication in *The Lancet* of clinical study results showing the ability of its vaccine candidate to protect against dengue fever caused by three dengue virus types. The results of the world's first efficacy study confirm the excellent safety profile of Sanofi Pasteur's dengue vaccine candidate.

"The complexity of dengue virus infection has hampered vaccine research for decades. This is the first time in 50 years of dengue research that I have seen a vaccine that protected a large group of children from clinical disease caused by dengue viruses. Best yet, the vaccine met the highest safety expectations," said Dr. Scott Halstead, International Vaccine Institute, Seoul, Republic of Korea. *"These results should be a source of hope for millions of parents whose children are at risk of severe dengue, a life-threatening disease which often requires hospitalization."*

The full analysis of vaccine efficacy against each serotype, reflecting real-life conditions (intent to treat analysis) showed vaccine efficacy to be 61.2% against dengue virus type 1, 81.9% against type 3 and 90% against type 4. One of the dengue virus types (serotype 2) eluded the vaccine. Analyses are ongoing to understand the lack of protection for serotype 2 in the particular epidemiological context of Thailand.

"Having worked in the field of dengue research for over four decades, with much of my efforts focused on prevention and control, it is very exciting for me to see a safe vaccine candidate that provides protection against 3 of the four dengue serotypes," said Professor Duane Gubler, Program on Emerging Infectious Diseases, Duke-NSU Graduate Medical School, Singapore. *"Dengue is a major public health concern for over half of the world's population and is a leading cause of hospitalization and death among children in endemic countries. Because mosquito control has failed to control this disease, an effective vaccine will be a critical tool that can change the life of millions living in endemic countries. I see this success as the beginning of a new era of effective control."*

According to Dr. Roberto Tapia Conyer, General Director of the Carlos Slim Health Institute, Former Undersecretary of Health in Mexico, *"These dengue vaccine results bring a significant promise in the context of the expanding dengue disease burden worldwide and the absence of specific treatment. Work will continue to study this vaccine and the circulation of dengue viruses globally, but in the meantime, the public health community can now formulate the best possible immunization policies and prepare for implementation of vaccination campaigns in countries heavily affected by dengue."*

A feature of dengue epidemiology is that the relative prevalence of virus types in a given area is evolving with time. Large-scale phase III clinical studies of Sanofi Pasteur's dengue vaccine candidate are underway with 31,000 children and adolescents in 10 countries in Asia and Latin



America. These studies will generate important additional data in a broader population and in a variety of epidemiological settings to define the best conditions to set up vaccination programs in order to protect people at risk of dengue.

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's 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 mosquito-borne disease caused by four dengue virus serotypes (1 to 4). It 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; a recent outbreak in Florida showed that dengue can hit the continental U.S. beyond endemic areas in Hawaii and Puerto Rico.²

Of the estimated 220 million people infected annually, two million—mostly children—develop dengue hemorrhagic fever (DHF), a severe form of the disease.³ DHF is a leading cause of hospitalization, placing tremendous pressure on strained medical resources and having a heavy economic and societal impact. The World Health Organization has set the objective to reduce dengue morbidity by at least 25% and dengue mortality by 50% by 2020.

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.⁴

Large-scale phase III clinical studies with 31,000 children and adolescents 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.^{5,6}

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.

Additional information, photos and videos about Sanofi Pasteur dengue vaccine candidate are available on the web at <http://www.dengue.info>

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, January 2012 Dengue and severe dengue
<http://www.who.int/mediacentre/factsheets/fs117/en/index.html>
2. Morbidity and Mortality Weekly Report (MMWR) Locally Acquired Dengue --- Key West, Florida, 2009—2010 - May 21, 2010 / 59(19);577-581
3. Beatty M Letson GW Margolis HS, Estimating the global burden of dengue, Am J Trop Med Hygiene 81, 5:231 2009
4. 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
5. Dengue vaccine efficacy trials in progress, www.thelancet.com/infection, vol 9, November 2009
- 6 Jean Lang, Recent progress on Sanofi Pasteur's dengue vaccine candidate, Journal of Clinical Virology 46, S2 (2009) 20-24

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 labeling 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, 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.

Contacts:

Global Media Relations

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

Investor Relations

Sebastien Martel
T. +33-(0)1-53-77-45-45
ir@sanofi.com