

## The World's First, Large-Scale Dengue Vaccine Efficacy Study Successfully Achieved Its Primary Clinical Endpoint

- *First available data demonstrated a 56% reduction of dengue disease cases in a study of more than 10,000 volunteers from Asia*
- *Initial safety data are consistent with the good safety profile observed in previous studies*

**Lyon, France - April 28, 2014** - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), today announced that the first of two pivotal Phase III efficacy studies with its dengue vaccine candidate has achieved its primary clinical endpoint. The efficacy study showed a significant reduction of 56% of dengue disease cases. Initial safety data are consistent with the good safety profile observed in previous studies. Full analysis of the data will be undertaken in the coming weeks and reviewed by external experts prior to disclosure at an upcoming international scientific congress and publication in a peer-reviewed journal later this year.

Dengue is a threat to nearly half the world's population<sup>1, 2</sup> and is a pressing public health priority in many countries in Asia and Latin America where epidemics occur. The annual incidence rate of 4.7% observed in the control group demonstrates the very high burden of disease in Asia.

*"This achievement is the result of more than 20 years of work in the field of dengue, collaborating with investigators, volunteers, authorities, scientific experts and international organizations,"* said Olivier Charmeil, President and CEO of Sanofi Pasteur. *"Developing a dengue vaccine for the benefit of children and their parents is at the heart of our mission. Our goal is to make dengue the next vaccine-preventable disease and to support the WHO's ambition to reduce dengue mortality by 50% and morbidity by 25% by 2020."*

*"This is the first time ever a dengue vaccine successfully completed a Phase III efficacy study,"* said Dr. Capeding, principal investigator, Research Institute for Tropical Medicine, the Philippines. *"These significant clinical results, associated with the good safety profile of the vaccine, bring real hope to more than 100 million people affected each year by dengue, a disease without any specific treatment today."*

The results of this first, large-scale efficacy study will be further complemented by results in Q3 2014 from a second, large-scale study currently conducted in Latin America, including more than 20,000 volunteers from Brazil, Colombia, Honduras, Mexico and Puerto Rico.

### **About the Phase III clinical study conducted in Asia**

The Phase III clinical study conducted in Asia is a randomized, observer-blind, placebo-controlled multicenter trial. A total of 10,275 children aged 2 to 14 years from dengue

endemic areas of Indonesia, Malaysia, the Philippines, Thailand and Vietnam participated in the study from 2011-2013 and were randomized to either receive three injections of the dengue vaccine or a placebo (2 to 1 ratio) at 6-month intervals. The primary endpoint was measured by the number of symptomatic virologically-confirmed dengue cases caused by any serotype. The study will continue with a long term follow up of the population. For more information about the clinical study:

<http://www.clinicaltrials.gov/ct2/show/NCT01373281?term=CYD14&rank=1>.

### **About Sanofi Pasteur's dengue vaccine clinical program**

Sanofi Pasteur has been working on a dengue vaccine for more than 20 years. The company's goal is to provide a safe and effective dengue vaccine accessible in all regions of the world where dengue is a public health issue.

Over 40,000 volunteers are participating in the Sanofi Pasteur dengue vaccine clinical study program (Phase I, II and III). Sanofi Pasteur's dengue vaccine candidate is in Phase III clinical studies. It is the most clinically and industrially advanced vaccine candidate in development and the first dengue vaccine in advance development.

The two, pivotal Phase III efficacy studies involve more than 31,000 volunteers from Asia (Indonesia, Malaysia, the Philippines, Thailand and Vietnam) and Latin America (Brazil, Columbia, Honduras, Mexico and Puerto Rico). The Phase III evaluations provide pivotal data on efficacy, safety, and immunogenicity of the vaccine candidate in a broad population and different epidemiological environments and assess the potential impact of the vaccine on the disease burden.

### **About Dengue**

Dengue is a threat to nearly half of the world's population. Currently, there is no specific treatment available for dengue. It is a health priority in many countries of Latin America and Asia where epidemics occur regularly. The WHO estimates up to 100 million infections per year but the overall number of people infected with dengue globally is not fully known.<sup>1</sup> The WHO has set the goal of estimating the true public health burden of dengue by 2015.<sup>2</sup> Dengue is underreported because the disease is often misdiagnosed due to a large spectrum of clinical symptoms from mild non-specific illness to life threatening complications and because of the limitations of the surveillance systems.

Each year, 500,000 people, including children, are affected with dengue hemorrhagic fever (DHF), the severe form of the disease. DHF is a leading cause of hospitalization, placing tremendous pressure on health systems and straining medical resources resulting in significant economic and social impact. Timely access to appropriate health care is critical to reduce the risk of mortality in case of severe dengue. The WHO has set the target to reduce dengue mortality by 50% and reduce morbidity by 25% by 2020.<sup>2</sup>

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

### **About Sanofi**

Sanofi, a global 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 one 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](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://www.sanofipasteur.us)

## References

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3. World Health Organization (WHO). Antiviral research and development against dengue virus. Available at: [http://www.who.int/tdr/research/ntd/dengue/dengue\\_full\\_length\\_report.pdf](http://www.who.int/tdr/research/ntd/dengue/dengue_full_length_report.pdf). Accessed March 24, 2013.

## 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, 2013. 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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