PRESS RELEASE

SANOFI PASTEUR

First Ever Dengue Vaccine Candidate To Show Efficacy Against Dengue Fever and Dengue Haemorrhagic Fever in Asia

- 88.5% reduction of Dengue Haemorrhagic Fever shown in detailed analyses of world's first phase III efficacy study published in The Lancet -

- Two thirds reduction in hospitalization observed -
- Favorable safety profile is consistent with safety documented in previous studies -

Lyon, France – July 11, 2014 – Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), today announced the publication in *The Lancet* of the detailed results of its first landmark phase III dengue vaccine efficacy study conducted in five countries in Asia. Results show overall efficacy against symptomatic dengue of 56.5%* in children aged 2 to 14 years old after a three-dose vaccination schedule. Importantly, analyses show an 88·5%* reduction of dengue haemorrhagic fever, the severe form of dengue, according to the WHO criteria[1]. The study also showed a clinically important reduction in the risk of hospitalization due to dengue by 67%* during the study. The favorable vaccine safety profile observed during the 25 month follow up of the phase III study in Asia is consistent with the safety profile documented in other studies (phase I, II, IIb).

Dengue is a threat to nearly half the world's population, and is a pressing public health priority in many countries in Asia and Latin America where epidemics occur. The study confirmed the very high burden of disease by revealing that one in twenty children in the control group suffered from dengue each year, which was three-fold higher than initially expected. Each year, an estimated 500,000 people, including children, have severe dengue requiring hospitalization.[2] This puts huge strain on hospitals and health care systems during outbreaks.[2]

"The results of this first phase III study show the potential of the vaccine to have a significant impact on public health," commented Dr. Maria Rosario Capeding, study principal investigator, Research Institute for Tropical Medicine, the Philippines. *"The threat of severe dengue disease creates fear in the community. The vaccine's impact on preventing dengue haemorrhagic fever is noteworthy. A vaccine that is able to avoid the personal suffering and reduce this significant health burden would change the lives of millions."*

Safety analyses (solicited reactions, unsolicited events and Serious Adverse Events SAEs) during the study showed similar reporting rates between the vaccine and control groups. SAEs were consistent with medical disorders in this age group and were mainly infections and injuries. Safety is continuously reviewed by an independent data monitoring committee. To date, 27,000

children, adolescents and adults have been vaccinated with three doses of the candidate dengue vaccine throughout the clinical studies.

"The high efficacy observed against severe dengue and the reduction of hospitalization by two thirds is an extremely important public health outcome. Furthermore this dengue vaccine continues to meet the highest safety expectations, which is very reassuring," commented Professor Duane Gubler, Professor and Founding Director of the Signature Research Program on Emerging Infectious Diseases, Duke-NUS Graduate Medical School, Singapore, and Chairman of the Partnership for Dengue Control.

"These pivotal phase III vaccine efficacy study results take us closer to our ambition to bring the first vaccine against dengue to the world," said John Shiver, Senior Vice President, R&D at Sanofi Pasteur. *"After more than 20 years of commitment in collaboration with the scientific community, we are on course to make dengue the next vaccine-preventable disease. The public-health implications of a future dengue vaccine are significant and these findings are an important stride towards meeting the WHO's strategic goals of reducing dengue mortality by half and morbidity by at least 25% by 2020."*

The four dengue virus serotypes have circulated during the study with a distribution representative of the epidemiology in Asia. The measured efficacy of the vaccine during the 25 months observation of the study is consistent across countries and appears to vary by dengue serotype (between 34.7% and 72.4%) and by age. The results of this first, large-scale efficacy study will be supplemented by results from a second, large-scale phase III study in Latin America and the Caribbean, including more than 20,000 children and adolescents aged 9 to 16 years old from Brazil, Colombia, Honduras, Mexico and Puerto Rico.

* 56.5% (95% CI: 43.8-66.4); 88·5% (95% CI 58·2 to 97·9); 67.2% (95% CI: 50.3 to 78.6).

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 study population until 2017. More information about the clinical study is posted on Clinicaltrial.gov under study code NCT01373281.

About Sanofi Pasteur's dengue vaccine program

Sanofi Pasteur has been working on a dengue vaccine for more than 20 years. The company's goal is to make dengue the next vaccine-preventable disease with a safe and effective dengue vaccine accessible in all regions of the world where dengue is a public health issue. The company is committed to support the WHO's ambition to reduce dengue mortality by 50% and morbidity by 25% by 2020.[3]

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

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, Colombia, 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 public health impact of the vaccine on the disease burden.

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

About dengue

Dengue is caused by four distinct virus serotypes transmitted by mosquitoes. It 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[2]; however, the overall number of people infected with dengue globally is not fully known. The WHO has set the goal of estimating the true public health burden of dengue by 2015.[3] 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, an estimated 500,000 people, including children, with severe dengue require hospitalization. About 2.5% affected would die.3 Severe dengue (also known as dengue haemorrhagic fever) is a potentially deadly complication due to plasma leakage, fluid accumulation, respiratory distress, severe bleeding, or organ impairment.[2] Dengue places 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.[3]

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 or www.sanofipasteur.us

References

1. World Health Organisation. Dengue haemorrhagic fever: diagnosis, treatment, prevention and control. 2nd edition. 1997. http://www.who.int/csr/resources/publications/dengue/Denguepublication/en/ (accessed 7 June 2014 2014)
2. WHO Dengue and severe dengue fact sheet # 117 Updated March 2014 Available at http://www.who.int/mediacentre/factsheets/fs117/en/
3. World Health Organization (WHO). Global strategy for dengue prevention control: 2012-2020. Available at: http://reliefweb.int/sites/reliefweb.int/files/resources/9789241504034_eng.pdf. Published 2012. Accessed April 3, 2014

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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