PRESS RELEASE

SANOFI PASTEUR

Sanofi Pasteur's Dengue Vaccine Candidate Successfully Completes Final Landmark Phase III Clinical Efficacy Study in Latin America

- Second, large-scale phase III study successfully meets primary endpoint with overall vaccine efficacy of 60.8 percent and shows efficacy against each of the four dengue serotypes -

- Additional observation of the results shows a significant reduction of the risk of hospitalization by 80.3 percent confirming the potential public health impact of the vaccine -

- Initial safety data are consistent with the favorable safety profile documented in all previous studies (phase I, II, III) -

Lyon, France - 3rd September, 2014 - Sanofi Pasteur, the vaccines division of Sanofi (EURONEXT: SAN and NYSE: SNY), today announced that the final landmark phase III efficacy study of its dengue vaccine candidate in Latin America successfully achieved its primary clinical endpoint. Results showed an overall significant reduction of 60.8 percent* of dengue disease cases in children and adolescents 9-16 years old after a three-dose vaccination schedule. Importantly, efficacy was observed against each of the four dengue serotypes.*

Additional observations of the results showed a clinically important reduction by 80.3 percent* in the risk of hospitalization due to dengue during the study. The results also showed in the study population an efficacy against dengue haemorrhagic fever (DHF), the severe form of dengue[1], which is consistent with the results released from Sanofi's phase III dengue study in Asia. Lastly, the results suggest better protection in case of prior exposure to dengue.

Safety analyses (solicited reactions, unsolicited events and Serious Adverse Events SAEs) during the study showed similar reporting rates between the vaccine and control groups and are consistent with the favorable safety profile documented in previous studies (phase I, II, III).

A full analysis of the efficacy and safety data from the phase III study will be completed and reviewed by external experts before publication in a peer-reviewed scientific journal and presentation at the American Society of Tropical Medicine and Hygiene (ASTMH) Annual Meeting, 2-6 November 2014, in New Orleans, Louisiana, US.

Dengue is a threat to nearly half the world's population and is a pressing public health priority in over 100 countries in the Americas and in Asia.[4] A dengue vaccine would represent a major advance for the control of the disease and could be an important tool for reaching the WHO's goal of reducing dengue mortality by at least 50 percent and morbidity by at least 25 percent by 2020.[2]

"For the first time ever, after 20 years of research and industrial commitment, dengue is set to become a vaccine preventable disease," said Olivier Charmeil, President and Chief Executive Officer, Sanofi Pasteur. *"The data generated from our comprehensive research and clinical program involving 40,000 children, adolescents and adults from 15 countries, will be submitted to the health authorities in countries where dengue is a public health priority."*

Each year, an estimated 500,000 people, including children, have severe dengue requiring hospitalization, putting a huge strain on health care systems during outbreaks.[2] Dengue has dramatically increased over the past 30 years with an acceleration over the last decade. Reported dengue cases in the Americas increased five-fold from 517,617 cases in 2003 to the unprecedented level of 2.3 million cases in 2013.[3]

"These compelling phase III results demonstrate the efficacy and good safety profile of this vaccine candidate against dengue. For the first time, we have a vaccine candidate that has the potential to offer protection to people who are at risk of dengue," commented Dr. Rivaldo Cunha, MD, Infectious Disease Specialist, Associate Professor, Faculty of Medicine Universidade de Mato Grosso do Sul, Brazil, and a principal investigator in the study.

"These new positive phase III results from Latin America are very encouraging because they are consistent with the results reported in July in the Asian phase III trial. Together, the results of these trials suggest that for the first time, a vaccine solution that can help control dengue, is on the horizon," commented Professor Duane Gubler, Professor and Founder of the Signature Research Program on Emerging Infectious Diseases, Duke-NUS Graduate Medical School, Singapore, and Chairman of the Partnership for Dengue Control. *"Scientific and public health experts will now be in a position to define the best way to implement dengue vaccination effectively, based on the country epidemiology, the vaccine profile and the goals defined by WHO to reduce the disease burden by 2020."*

*95 percent CIs overall efficacy [52.0 percent, 68.0 percent]; Efficacy per serotype (ST1 50.3%, ST2 42.3%, ST3 74.0%, ST4 77.7%); 95 percent CIs reduction of the risk of hospitalization [64.7 percent, 89.5 percent]

About the Phase III clinical study conducted in Latin America and the Caribbean

The primary objective of the phase III study in Latin America and the Caribbean was to assess the efficacy of the Sanofi Pasteur dengue vaccine candidate after three vaccinations in preventing symptomatic virologically-confirmed dengue cases. It is the second of two large-scale randomized, observer-blind, placebo-controlled multicenter trials. A total of 20,875 children aged 9 to 16 years from dengue endemic areas of Brazil, Colombia, Mexico, Honduras and Puerto Rico participated in the study and were randomized to either receive three injections of the dengue vaccine or a placebo (2 to 1 ratio) at 0, 6, and 12 months.

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 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 percent and morbidity by 25 percent by 2020.[2]

Two pivotal phase III efficacy studies involved more than 31,000 volunteers from Asia (Indonesia, Malaysia, the Philippines, Thailand and Vietnam) and Latin America and the Caribbean (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 impact of the vaccine on the disease burden.

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

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://es.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 public health priority in many countries of Latin America and Asia where epidemics occur regularly. The WHO estimates up to 100 million infections per year[4]; 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.[2] 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 percent of those affected die[4]. 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 strains 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.

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

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2. 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
3. PAHO May 2014 http://www.paho.org/hq/index.php?option=com_content&view=article&id=9657&Itemid=1926
4. WHO Dengue and severe dengue Fact sheet N°117 Updated March 2014. Available at http://www.who.int/mediacentre/factsheets/fs117/en/

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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