



First Vaccinations against Dengue Mark Historic Moment in Prevention of Infectious Diseases

- *Dengvaxia[®], the first vaccine approved for the prevention of Dengue, is now being administered by healthcare providers in the Philippines -*

Lyon, France – February 22, 2016 - [Sanofi Pasteur](#), the vaccines division of [Sanofi](#), announced today that vaccinations with Dengvaxia[®] have commenced in the Philippines following official receipt of the first shipment of the vaccine earlier this month.

Dengvaxia[®], a tetravalent dengue vaccine, was approved in the Philippines on 22 December 2015 for the prevention of disease caused by all four Dengue types in individuals from 9-45 years of age living in endemic areas. The vaccine is administered in three doses given over a one-year period.

Asia bears 70% of dengue fever burden globally with an estimated 67 million people being sickened by the disease annually.¹ In the Philippines alone, over 110,000 people on average get Dengue every year.² Asian endemic countries spend an estimated 6.5 billion USD annually in both direct medical and indirect costs due to Dengue.³

“This is truly a great moment in the history of vaccinology,” states Guillaume Leroy, Vice-President of Dengue Vaccine, Sanofi Pasteur. *“Dengvaxia[®]’s availability for administration by healthcare providers in the Philippines, to be followed closely by the initiation of a public sector immunization program in the country is a landmark event for global Dengue prevention and a great achievement for the people of the Philippines.”*

Medical Societies in the Philippines held a media event in Manila earlier this month to welcome receipt of the first shipment of Dengvaxia[®] to the country. In attendance, Dr. Rose Capeding, chief of the Research Institute for Tropical Medicine’s department of microbiology, noted that the Philippines participated in all three phases of the clinical development of the vaccine and that healthcare providers there were delighted to be able to begin vaccinating against dengue, which continues to pose a major public health threat to the nation.

<http://www.gmanetwork.com/news/story/554826/scitech/science/dengue-vaccine-rolls-out-nationwide-in-ph>

Dengue is a growing public health threat in tropical and subtropical countries in Asia and Latin America. Mainly an urban disease found in over 120 countries where half the world’s population live, Dengue typically hits in the form of unpredictable outbreaks capable of paralyzing health care systems and disrupting social and economic activity in these city centers. Sanofi Pasteur is introducing Dengvaxia[®] first in endemic countries like the Philippines where the vaccine has the greatest potential to reduce dengue burden globally and help these countries to achieve the World Health Organization’s goal to reduce dengue mortality by 50% and morbidity by 25% by 2020 in endemic countries.

Dengvaxia[®] is also currently approved in Mexico, Brazil and El Salvador, which according to the Pan American Health Organization, collectively bear about 83% of the dengue burden in the Americas.⁴



About Dengvaxia®

In addition to the Philippines, Dengvaxia® is also registered in Mexico, Brazil and El Salvador to date. Regulatory review processes for Dengvaxia® are continuing in other countries where dengue is a public health priority.

Sanofi Pasteur's vaccine is the culmination of over two decades of scientific innovation and collaboration, as well as 25 clinical studies in 15 countries around the world. Over 40,000 volunteers participated in the Sanofi Pasteur dengue vaccine clinical study program (phase I, II and III), of whom, 29,000 volunteers received the vaccine.

Pooled efficacy and integrated safety analyses from the 25-month Phase III efficacy studies and the ongoing long-term studies, respectively, were published in *The New England Journal of Medicine* on July 27th 2015, affirming the vaccine's consistent efficacy and longer-term safety profile in study population 9-16 years of age. In the pooled efficacy analysis in this age group, Dengvaxia® was shown to reduce dengue due to all four serotypes in two-thirds of the participants and prevent 8 out of 10 hospitalizations and up to 93% of severe dengue cases.⁵

Dengvaxia® is the first vaccine licensed for the prevention of dengue in the world. First doses of the vaccine have been produced at the dedicated production site in France with planned full-scale production capacity of 100 million vaccine doses annually. Official receipt of the shipment of Dengvaxia® in the Philippines was announced earlier this month.

Additional information about Sanofi Pasteur's dengue vaccine is available on the web at 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 diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris ((EURONEXT: [SAN](http://www.euronext.com/quote/SAN)) and in New York (NYSE: [SNY](http://www.nyse.com/quote/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 a broad 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

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, 2014. 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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1 Nature. 2013 Apr 25;496(7446):504-7

2 Shepard D et al. Am. J. Trop. Med. Hyg., 92(2), 2015, pp. 360–366

3 Shepard DS, Halasa YA, Undurraga EA, Stanaway J. Global economic cost of dengue illness. Poster presented at: American Society of Tropical Medicine and Hygiene Annual Meeting; Oct. 25-29, 2015, Philadelphia, PA, Poster 781

4 http://www.paho.org/hq/index.php?option=com_topics&view=rdmore&cid=6290&Itemid=40734&lang=en

5 Hadinegoro, Sri Rezeki S., et al. Efficacy and Long-Term Safety of a Dengue Vaccine in Regions of Endemic Disease Integrated Analysis of Efficacy and Interim Long-Term Safety Data for a Dengue Vaccine in Endemic Regions. July 27, 2015DOI: 10.1056/NEJMoa1506223.