



Dengvaxia[®] First Dengue Vaccine Approved in Brazil

- *Global introduction of the first Dengue Vaccine gains further momentum with this third approval in a row in an endemic country-*
- *With 1.4 million dengue cases reported this year, Brazil stands to gain tremendous value from this new dengue prevention tool -*

Lyon, France - December 28, 2015 - [Sanofi Pasteur](#), the vaccines division of [Sanofi](#), announced today that Brazil has granted regulatory approval to Dengvaxia[®], representing the third successful licensure of the dengue vaccine, which was also approved in Mexico and the Philippines earlier this month.

The Brazilian regulatory authorities ANVISA approved Dengvaxia[®], tetravalent dengue vaccine, for the prevention of disease caused by all four dengue types in individuals from 9-45 years of age living in endemic areas.

Dengue continues to hit hard in Brazil with over 1.4 million Brazilians directly affected by the disease during this year's outbreak season alone. Up to 70% of dengue cases in Brazil are reported in individuals 9 years and older, a highly mobile and socially active segment of the population who contributes to the spread of the disease within communities.

Dengvaxia[®] was shown to reduce dengue due to all four serotypes in two-thirds of the participants and prevent 8 out of 10 hospitalizations due to dengue and up to 93% of severe dengue cases.¹

"This new Approval of Dengvaxia[®] by the ANVISA, a well-recognized and World Health Organization (WHO) certified regulatory authority is an important milestone for Sanofi Pasteur," says Guillaume Leroy, Vice President of Dengue Vaccine, Sanofi Pasteur. *"Dengvaxia[®] has the potential to significantly reduce the dengue disease burden and to help Brazil reach the WHO's 2020 dengue reduction objectives."*

Approval of the first dengue vaccine is an important public health breakthrough with critical importance to our country, which bears the greatest dengue burden in Latin America," says Joao Bosco Siqueira Junior of the Department of Community Health, Institute of Tropical Pathology and Public Health, Federal University of Goias, Goiania, Brazil. *"The 2015 dengue outbreak is still very present in the minds of Brazilians so Dengvaxia's approval is a most welcome addition to our ongoing dengue prevention efforts."*

Dengue is a major public health priority in tropical and subtropical countries in Latin America and Asia. Sanofi Pasteur is introducing Dengvaxia[®] first in these countries where the vaccine has the greatest potential to reduce dengue burden globally and help to achieve the WHO's goal to reduce dengue mortality by 50% and morbidity by 25% by 2020 in endemic countries. Sanofi Pasteur enrolled over 40,000 participants in extensive safety and clinical efficacy studies conducted mainly in endemic countries and built a dedicated vaccine production facility in France to secure adequate quality and quantity supply of the vaccine to meet endemic country demand upon introduction.



Dengue disease burden globally

According to the WHO, dengue is the fastest growing mosquito-borne disease in the world today, causing nearly 400 million infections every year.² In the last 50 years dengue has spread from being present in a handful of countries to being endemic in 128 countries, where about 4 billion people live, and dengue incidence has likewise increased 30-fold in this time period.^{3,4}

Although dengue affects people from all ages and socio-economic backgrounds, the greatest number of dengue cases worldwide occurs in the highly mobile and social segment of endemic populations that include preadolescents to adult ages of 9 years and older.⁵

Dengue disease burden in Brazil

This year, over 1.4 million Brazilian citizens were reportedly sickened by the virus.⁶ On top of this considerable human suffering, the cost of dengue is substantial in terms of direct medical costs, as well as indirect losses such as lowered work productivity. Estimated spending on dengue disease for Brazil is \$1.2 billion USD every year; an average of \$448 USD per hospitalized case and \$173 USD per ambulatory case⁷.

About Dengvaxia®

Besides Brazil, Dengvaxia® is also registered in Mexico and in The Philippines. 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.

Brazil participated in a global phase III efficacy studies including more than 30,000 volunteers from 10 different countries which was successfully completed in 2014.

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.⁸

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.

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/paris/stocks/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 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, 2015 DOI: 10.1056/NEJMoa1506223.

2 <http://www.who.int/mediacentre/factsheets/fs117/en/>

3 Ibid.

4 <http://www.who.int/csr/disease/dengue/impact/en/>

5 Joseph R. Egger, Paul G. Coleman. Age and Clinical Dengue Illness. Emerg Infect Dis. 2007 June; 13(6): 924–927.

San Martin JL, Brathwaite O, Zambrano B, et al. The epidemiology of dengue in the americas over the last three decades: a worrisome reality. Am J Trop Med Hyg 2010;82:128-35.

6 Secretaria de Vigilância em Saúde – Ministério da Saúde. Epidemiological Bulletin - Volume 46 - No. 24-2015 -

Monitoring of cases of dengue fever and chikungunya. Epidemiological Week 36, 2015. Available at: <http://portalsaude.saude.gov.br/images/pdf/2015/outubro/15/svsbe-denchikzik-v46-n31.pdf>. Accessed 21 October 2015.

⁷ Martelli CM, et al. Economic Impact of Dengue: Multicenter Study across Four Brazilian Regions. PLoS Negl Trop Dis. 2015 Sep 24;9(9):e0004042. doi: 10.1371/journal.pntd.0004042.



8 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, 2015 DOI: 10.1056/NEJMoa1506223.