



Dengvaxia[®], World's First Dengue Vaccine, Approved in Mexico

- First marketing authorization of Dengvaxia[®] is a historic milestone paving the way to significantly impact dengue burden in endemic countries -

Lyon, France - December 9, 2015 - [Sanofi Pasteur](#), the vaccines division of [Sanofi](#), announced today that the Mexican authorities have granted marketing authorization to Dengvaxia[®], making it the first vaccine to be licensed in the world for the prevention of dengue.

The Federal Commission for the Protection against Sanitary Risks (COFEPRIS) has approved Dengvaxia[®], tetravalent dengue vaccine, for the prevention of disease caused by all four dengue virus serotypes in preadolescents, adolescents and adults, 9 to 45 years of age living in endemic areas.

"When Sanofi set out to develop a dengue vaccine 20 years ago together with local and global public health and scientific communities, it was with the intention of developing an innovative vaccine to tackle this global public health need," said Olivier Brandicourt, MD, Chief Executive Officer, Sanofi. *"Today, with this first marketing authorization of Dengvaxia[®], we have achieved our goal of making dengue the next vaccine-preventable disease. This is a historic milestone for our company, for the global public health community and, most importantly, for half the world's population who lives at risk of dengue."*

The COFEPRIS approval of Dengvaxia[®] is based on results from an extensive clinical development program involving over 40,000 people of different ages, geographic and epidemiological settings, and ethnic and socio-economic backgrounds living in 15 countries. Dengue-endemic regions of Mexico participated in all three phases of the clinical development program for the vaccine.

"Dengue is a growing health threat in Mexico and many other tropical and subtropical countries in Latin America and Asia. The first vaccine approved to prevent dengue fever is a major innovation and a public health breakthrough. Dengvaxia[®] will be a critical addition to the integrated dengue prevention and control efforts. It will be an essential tool to boost on-going community efforts to relieve the long-standing suffering that this disease continues to bring to people in endemic countries like ours," asserts José Luis Arredondo García, Associate Director of Clinical Research in the National Institute of Pediatrics*.

Regulatory review processes for Dengvaxia[®] are continuing in other endemic countries. Manufacturing of Dengvaxia[®] has already started at vaccine facilities in France and first doses are already produced. Sanofi Pasteur remains committed to introducing Dengvaxia[®] first in countries where dengue is a major public health priority.

The World Health Organization (WHO) has called for development of a dengue vaccine as an essential part of the integrated dengue prevention effort needed to significantly lower the dengue burden globally. The WHO has called on endemic countries to reduce dengue mortality by 50% and morbidity by 25% by 2020. Disease impact modelling results indicate if you vaccinate 20% of the population in the 10 endemic countries that participated in the Phase III efficacy studies for

*Pediatrician specialized in infectious diseases and coordinator of the Medical Science Master and PHD programs in the UNAM (National Autonomous University of Mexico), campus National Institute of Pediatrics.



Dengvaxia, in the ages 9 and above indication, you could potentially reduce your dengue burden by 50% in five years.¹ Such a significant disease reduction in this large at-risk population would result in a smaller pool of infected individuals in a given country and, therefore, fewer mosquitoes capable of transmitting the disease, potentially leading to an overall lowering of transmission risk for all.

Dengue disease burden

According to the WHO, dengue is the fastest growing mosquito-borne disease in the world today, causing nearly 400 million infections every year.² Factors such as increased urbanization, mobility of populations and climate changes that increase the range of the dengue mosquito vector have created a perfect storm for dengue expansion. 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}

The mosquito that transmits dengue feeds mainly at dawn and dusk and can breed in very small amounts of standing water, making it a formidable foe for public-health workers and endemic community residents alike. Dengue is a painful disease that is also known as ‘break bone’ fever due to the terrible bone and joint pain it causes. In addition to this human suffering, dengue also has the ability to break the back of local healthcare systems during outbreaks. Globally, dengue is estimated to cost 9 billion USD annually in direct and indirect costs.⁵

Although dengue affects people from all ages and walks of life, the greatest number of dengue cases worldwide occurs in the highly mobile and social segment of the population that includes preadolescent to adult ages.⁶

About Sanofi Pasteur’s dengue vaccine

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. Dengvaxia[®] successfully completed phase III clinical studies in 2014 to evaluate the primary objective of vaccine efficacy.^{7,8}

Long-term follow-up studies of the vaccine, recommended by WHO for all dengue vaccines in development, are currently ongoing. Additional pooled efficacy and integrated safety analyses from the 25-month Phase III efficacy studies and the ongoing long-term studies, respectively, were recently published in *The New England Journal of Medicine* reconfirming the vaccine’s consistent efficacy and longer-term safety profile in populations 9 years of age and older. In a pooled efficacy analysis in volunteers aged 9-16 who participated in the two Phase III 25-month efficacy studies, Dengvaxia[®] was shown to reduce dengue due to all four serotypes in two-thirds of the participants. Furthermore, this pooled efficacy analysis showed that Dengvaxia[®] prevented 9 out of 10 cases of severe dengue and 8 out of 10 hospitalizations due to dengue in this age group.⁹

Dengvaxia[®] is the first vaccine licensed for the prevention of dengue in the world. First doses of the vaccine have been produced and full scale production capacity will be reaching 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](#)) and in New York (NYSE: [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 initiatives 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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- ³ Ibid.
- ⁴ <http://www.who.int/csr/disease/dengue/impact/en/>
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