



## First Dengue Vaccine Approved in More than 10 Countries

*- Recent approvals for Dengvaxia® granted by health authorities in Indonesia, Thailand and Singapore -*

*- First dengue vaccine continues to get growing support from regional and national medical societies -*

**Lyon, October 4, 2016** -- [Sanofi Pasteur](#), the vaccines global business unit of [Sanofi](#), announced today that Dengvaxia® dengue vaccine has now received its 11<sup>th</sup> marketing approval, four of which granted from Regulatory Authorities recognized by the World Health Organization (WHO). To date the vaccine is approved in Mexico, The Philippines, Brazil, El Salvador, Costa Rica, Paraguay, Guatemala, Peru, Indonesia, Thailand and Singapore.

The vaccine is also receiving endorsements from key medical societies at national and regional level. Notably, the Latin American Society for Pediatric Infectious Diseases (SLIPE for Sociedad Latino Americana de Infectología Pediátrica) just [published its support for dengue vaccination](#). National medical societies in Indonesia, Brazil and Mexico have recently also recommended vaccination with Dengvaxia®. These recommendations are consistent with the World Health Organization position paper issued on July 29<sup>th</sup> recommending that countries with high burden of disease should consider introduction of Dengvaxia® as part of an integrated dengue management program.<sup>1</sup>

*“We’re pleased to see the growing medical and public health recognition for the vaccine,”* notes Su Peing Ng, MD, Head of Global Medical Affairs for Sanofi Pasteur. *“With this new tool in hand, public health communities in dengue-endemic countries now have additional means to achieve the WHO objectives for 50% reduction in mortality and 25% reduction in morbidity due to dengue by 2020.”*

Parana State in Brazil has administered first doses in its public vaccination campaign and the Philippines have just initiated 2<sup>nd</sup> dose administration to students in public schools in three highly endemic areas of the country. The vaccine is also being launched through private clinics.

In the clinical study population 9 years old and older, the dengue vaccine has been documented to prevent two-thirds of dengue cases due to all four serotypes of dengue. The dengue vaccine also prevented 8 of 10 hospitalizations due to dengue and 93% of serious dengue cases like the deadly hemorrhagic form of the disease, over the 25-month study follow-up period of the large-scale efficacy studies conducted in 10 endemic countries in Latin America and Asia.<sup>2</sup>

An integrated safety analysis was recently published documenting Dengvaxia®’s satisfactory safety profile comparable to placebo during the late stage clinical study program involving around 30,000 participants from 15 countries. In addition, the results of this analysis documented that the vaccine provided beneficial protection against hospitalization due to dengue and severe dengue for up to 4 years post dose 1 of vaccination compared to placebo in the study population 9 years and older.<sup>3</sup>



## About Sanofi Pasteur 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.

A summary of the efficacy documentation on Dengvaxia® for the study population 9 years and older was published in *The New England Journal of Medicine* on July 27<sup>th</sup> 2015. These findings affirm the vaccine's consistent efficacy in reducing dengue due to all four serotypes in two-thirds of the study participants 9 years and older and also documents the ability of the vaccine to prevent 8 out of 10 hospitalizations and up to 93% of severe dengue cases in this age group during the 25 month follow-up phase of the studies.<sup>4</sup>

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Sanofi Pasteur's Dengue Vaccine is the first vaccine licensed for the prevention of dengue in the world. The vaccine is supplied from a dedicated production site in France.

Additional information about Sanofi Pasteur's dengue vaccine is available on the web at [www.dengue.info](http://www.dengue.info).

## About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial. 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 vaccines each year, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur produces a portfolio of high quality vaccines that matches its areas of expertise and meets public-health demand. 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](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://www.sanofipasteur.us)

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<sup>1</sup> World Health Organization. Dengue vaccine: WHO position paper – July 2016 <http://www.who.int/wer/2016/wer9130.pdf?ua=1>



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<sup>2</sup> Hadinegoro SR, et al. *N Engl J Med* 2015; 373:1195-206

<sup>3</sup> Safety overview of a recombinant live-attenuated tetravalent dengue vaccine: pooled analysis of data from 18 clinical trials. Gailhardou et al *PLoS Negl Trop Dis*. 2016 Jul 14;10(7):e0004821. doi: 10.1371/journal.pntd.0004821

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<sup>5</sup> Safety overview of a recombinant live-attenuated tetravalent dengue vaccine: pooled analysis of data from 18 clinical trials. Gailhardou et al *PLoS Negl Trop Dis*. 2016 Jul 14;10(7):e0004821. doi: 10.1371/journal.pntd.0004821