



Mexico Starts Dengue Vaccinations

- Sanofi's dengue vaccine, *Dengvaxia*[®], is now available in private healthcare clinics in Mexico bringing the total number of countries in Latin America and Asia that have approved the vaccine to 9 -

- *Dengvaxia*[®]'s public program introduction in Mexico has been recommended by CONAVA (national vaccination council) following the World Health Organization's endorsement of the safety, efficacy and public health value of the vaccine in endemic settings -

Lyon, France – September 12, 2016 - [Sanofi Pasteur](#), the vaccines global business unit of [Sanofi](#), announced today that the *Dengvaxia*[®] dengue vaccine is now available in private healthcare clinics of Mexico for vaccination of individuals 9 to 45 years of age.

"Dengue is a major public health risk in parts of Mexico with no specific treatment available to healthcare professionals to manage outcomes with this disease," says Dr. José Ramos Castañeda, Professor of Virology and Researcher at the Center for Population Health Research of the National Institute of Public Health (INSP). *"The Mexican medical community welcomes the ability to vaccinate people against dengue with the first clinical preventive tool for this often debilitating disease which continues to be a growing health issue in our country."*

In 2013, a peak year for dengue in Mexico, 231,400 suspected dengue cases were reported, leading to 34,100 reported hospitalizations due to dengue at an average cost per hospitalization in Mexico of \$USD 1,327.^{1,2} The majority of dengue cases are reported in those 9 years of age and older globally, 90% of dengue cases in Mexico are in this age group, which represents a highly mobile and social segment of the community who contribute significantly to both burden and spread of dengue infection in endemic countries.³

Dengvaxia[®] is now approved in nine countries globally, with 4 new registrations (Paraguay, Peru, Indonesia and Guatemala) granted in the last 6 weeks following the World Health Organization's official endorsement of the vaccine's safety, efficacy and public health value in endemic countries published on July 29th.⁴

"The private clinic launch of the dengue vaccine in Mexico is good news and follows closely CONAVA, the country's National Vaccination Council, publication of recommendations for use of the dengue vaccine which provides the framework for the nation's health authorities to consider implementation of the dengue vaccine in public programs to reduce disease burden in Mexico and reach the WHO 2020 ambition for dengue reduction," adds Dr. Cesar Mascareñas, Global Head of Medical Affairs for Dengue at Sanofi Pasteur.

The CONAVA recommendation is an endorsement of the advice given last April by the Group of Dengue Experts in Mexico (comprising more than 50 representatives from over 20 academic institutions), that was commissioned by the Minister of Health to work on a recommendation for the introduction of the vaccine following its licensure in Mexico last December.

After setting out to develop a dengue vaccine 20 years ago, the company remains committed to introducing the vaccine first in endemic countries where dengue is a public health priority and where a dengue vaccine can have the greatest disease reduction impact. To achieve this goal, the dengue vaccine was studied in a comprehensive clinical development program involving over 40,000



participants from 15 countries worldwide where dengue is endemic. Mexico participated in all three phases of the clinical development program for the vaccine and was the first country to approve the vaccine at the end of last year.

About Sanofi Pasteur in Mexico

Sanofi Pasteur is a leading vaccine provider in Mexico and a committed and longtime partner for public health in the country. Since 1981, Sanofi Pasteur has been committed to ensuring broad access to vaccination to the Mexican population. We are the leader company in the vaccines market in Mexico. We have the first vaccines manufacturing plant in the country that produces 30 million doses of flu vaccine per year, to guarantee the supply of vaccines against seasonal influenza, as well as the benefits of local production in case of a pandemic.

About Sanofi Pasteur Dengue Vaccine

In addition to Mexico, the Sanofi Pasteur Dengue Vaccine is also registered in Brazil, Philippines, El Salvador, Costa Rica, Paraguay, Indonesia, Guatemala and Peru 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.

A summary of the efficacy documentation on Dengvaxia[®] for the study population 9 years and older population was published in *The New England Journal of Medicine* on July 27th 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.⁵

An integrated safety analysis was recently 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.⁶

Sanofi Pasteur 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.

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](http://www.sanofi.com)) and in New York (NYSE: [SNY](http://www.sanofi.com)).

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 or www.sanofipasteur.us

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1 Pan American Health Organization. Number of Reported Cases of Dengue and Severe Dengue in the Americas, by Country (EW 52) 2013. Available at: http://www.paho.org/hq/index.php?option=com_topics&view=rdmore&cid=6290&Itemid=40734&lang=en Last accessed July 1, 2016.

2 Undurraga EA, et al. Economic and disease burden of dengue in Mexico. *PLoS Negl Trop Dis.* 2015;9:e0003547

3 Jackson N. et al. Recent scientific and clinical advances in Sanofi Pasteur's Dengue Vaccine Program ASTMH 64th Annual Meeting October 25-29, 2015. Philadelphia, USA.

4 World Health Organization. Dengue vaccine: WHO position paper – July 2016 <http://www.who.int/wer/2016/wer9130.pdf?ua=1> [Last accessed: 15 August 2016]

5 Hadinegoro SR, et al. *N Engl J Med* 2015; 373:1195-206

6 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