



Sanofi Pasteur Dengue Vaccine Approved in Paraguay to Strengthen Dengue Burden Reduction Efforts in Southern Cone

- Paraguay becomes the sixth country in the world to approve the dengue vaccine as a key new tool to address dengue burden, which continues to increase in the Southern Cone region of South America -

- In July, the WHO ratified SAGE recommendation on Dengvaxia® and provided independent endorsement of the safety, efficacy and public health value of the dengue vaccine for endemic countries where dengue is a public health priority -

Paraguay – August 16th, 2016 - Today [Sanofi Pasteur](#), [Sanofi](#)'s vaccine division, announced that the National Bureau of Health Surveillance of the Ministry of Public Health and Social Welfare of Paraguay (DINAVISA) has approved Sanofi Pasteur's tetravalent dengue vaccine, *Dengvaxia*®, for pre-adolescents, adolescents and adults from 9 to 60 years of age living in endemic areas.

This approval in Paraguay is the fifth registration of the dengue vaccine in Latin America, and the sixth in the world. Sanofi Pasteur's dengue vaccine has already been approved in Mexico, Brazil, El Salvador, Costa Rica, and the Philippines. Public vaccination against dengue began in the Philippines in April, with the goal of vaccinating 1 million fourth-grade students in over 6,000 public schools in three highly-endemic regions of the country this year. Also, Parana state in Brazil launched the first public dengue vaccination program in the Americas, targeting 500,000 people living in the most highly endemic parts of the State. In addition, Brazilians will be able to access the dengue vaccine at private clinics in the country inland.

"Dengue is a disease that has severely affected our country, and cases have significantly increased in recent years due to multiple factors, some of which are beyond human intervention in the short term, such as climate change and globalization," said Dr. Celia Martínez de Cuellar, Professor of the Pediatrics Chair at the National University of Asunción. *"The approval of the first dengue vaccine is encouraging news, as it is a key new tool for the prevention of dengue, and it will undoubtedly contribute to control this disease, which continues to pose a major public health threat to the people of Paraguay."*

Dengue is endemic in Paraguay, which had seen a large epidemic in 2013 with more than 130,000 cases reported.¹ As of Epidemiological Week 28/2016, an accumulated total of 11,652 cases hospitalized by dengue has been recorded. Cases of dengue are reported from all countries in the Southern Cone region in 2016, where circulation of all four serotypes has been confirmed.²

The safety, efficacy and public health value of the dengue vaccine have been ratified by the World Health Organization (WHO) in its position statement about *Dengvaxia*® published on July 29³, which is consistent with the previous positive recommendation of the Strategic Advisory Group of Experts (SAGE) on immunization to the World Health Organization.⁴ The WHO has set the objectives of reducing mortality by dengue by 50% and morbidity by 25% by 2020 in the endemic countries.⁵



The global burden of dengue

According to the WHO, dengue is currently the fastest-growing mosquito-transmitted disease in the world, causing around 400 million infections every year. Over the last 50 years, dengue has spread; initially present in a handful of countries, it is now endemic in 128, inhabited by around 4 billion people. Also, the incidence of this disease has increased 30 times in this same period.⁶

Even though dengue affects people of all ages and lifestyles, the greatest number of dengue cases worldwide occurs in individuals 9 years of age and older, who represent a highly mobile and social segment of the community capable of contributing significantly to spread of the disease.^{7,8}

About Sanofi Pasteur's dengue vaccine

In addition to Paraguay, Sanofi Pasteur Dengue Vaccine is also registered in Brazil, Mexico, Philippines, El Salvador and Costa Rica to date. Regulatory review processes for Dengue Vaccine 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.⁹

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.¹⁰

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 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](https://www.euronext.com/paris/stocks/SAN)) and in New York (NYSE: [SNY](https://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 produces a portfolio of high quality vaccines that matches its



areas of expertise and meet 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

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, 2015. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Contacts:

Southern Cone

Valeria Castro

Tel. +54 11 4732 5000

valeria.castro@sanofipasteur.com

Global Media Relations

Alain Bernal

Tel. +33 (0)4 37 37 50 38

alain.bernal@sanofipasteur.com

www.sanofipasteur.com

¹ <http://vigisalud.gov.py/wp-content/uploads/2016/08/Bolet%C3%ADn-Epidemiol%C3%B3gico-SE-28.pdf> (accessed on August 10, 2016)

² Pan American Health Organization, Number of reported dengue and severe dengue cases in America, by country: Epidemiological Week / EW 18 (updated May 13, 2016), available at http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&Itemid=&gid=34589&lang=en, accessed on August 10, 2016

³ <http://www.who.int/wer/2016/wer9130.pdf?ua=1>

⁴ http://www.who.int/immunization/sage/meetings/2016/april/SAGE_April_2016_Meeting_Web_summary.pdf (Último acceso 10_08_2016)

⁵ World Health Organization. Global strategy for dengue control and prevention 2012-2020. Geneva: WHO, 2012. Available at: http://apps.who.int/iris/bitstream/10665/75303/1/9789241504034_eng.pdf. Last accessed on August 10, 2016.

⁶ World Health Organization. Dengue and severe dengue. Factsheet No 117

⁷ Egger JR. Age and clinical dengue illness. *Emerg Infect Dis.* 2007;13:924-5

⁸ 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

⁹ Hadinegoro SR, et al. *N Engl J Med* 2015; 373:1195-206

¹⁰ 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