



## Dengue Immunization Public Program in Paraná State of Brazil Set To Achieve WHO 2020 Ambition

- *First dengue immunization public program in the Americas starts today targeting broad age range of individuals at highest risk of disease consistent with recent WHO position*
- *Paraná state will lead Dengue prevention in Brazil launching benchmark public program to immunize 500,000 individuals with Dengvaxia<sup>®</sup> dengue vaccine over next three weeks -*

**Paris, France - August 13th, 2016** - [Sanofi](#) and its vaccines global business unit [Sanofi Pasteur](#) announced that 500,000 doses of Dengvaxia<sup>®</sup> have been received in Paraná to support a large-scale public dengue immunization program initiated today in the State's 30 most highly endemic municipalities.

Paraná State, home to 10 million people, has seen a steep 3-fold increase in both dengue incidence and deaths in recent years. In the last year, there have been 55,000 cases reported, costing the State an estimated R\$ 330 million (~91 M Euro) in related healthcare expenses.

*"For the public immunization program being launched today, we have used our extensive dengue surveillance data to ensure that we are targeting people at highest risk of disease. We will vaccinate all individuals 15-27 years of age in 28 municipalities and 9-44 years of age in the two municipalities with the top dengue burden in our State over the next three weeks,"* said Michele Caputo Neto, Paraná Health Secretary.

*"Paraná has a good track record in vaccination coverage in general and successful implementation of this dengue immunization strategy could result in 74% reduction in disease burden in these highly impacted municipalities within 5 years, according to a dengue vaccine impact study published in the Brazilian Journal of Health Economics<sup>1</sup>,"* Secretary Neto noted.

Dr. Stephen J. Thomas, a physician-scientist at the Walter Reed Army Institute of Research in Silver Spring, Maryland who is an international dengue expert commented on the public immunization program initiated by Paraná State today. *"Dengue remains one of the world's most important mosquito transmitted diseases causing significant human suffering and financial cost. The strategic deployment of a safe and effective dengue vaccine offers the best hope of reducing dengue's burden, especially in highly endemic countries like Brazil."*

Dengvaxia's safety and efficacy have been documented in a large clinical study program involving more than 40,000 people in studies conducted in 15 countries around the world including Brazil which participated in both phases II and III of the clinical development of the vaccine. The safety, efficacy and public health value of the dengue vaccine has been independently endorsed by the World Health Organization (WHO) in position paper on Dengvaxia published on 29<sup>th</sup> July 2016<sup>2</sup>, which is consistent with the earlier positive recommendation on the dengue vaccine issued by the WHO's Strategic Advisory Group of Experts on Immunization last April.



Guillaume Leroy, of Sanofi Pasteur, added *“Introduction of the dengue vaccine first in endemic countries like Brazil has always been Sanofi Pasteur’s priority because this is where the vaccine can have the greatest impact on disease burden globally. Furthermore, successful implementation of Dengvaxia in a large-scale public program in Paraná will serve as a benchmark for dengue prevention efforts elsewhere in the country and in the world.”*

Sanofi Pasteur will continue to address all supply demands coming from all clinics in Brazil, both public and private, as well as any additional requests from other countries supported by company’s ample dengue vaccine supply capacity from its production facility in France.

### **About Sanofi Pasteur commitment to public health in Brazil**

Sanofi Pasteur is a leading vaccine provider in Brazil and a committed and longtime partner for public health in the country. Going back to 1974 the company produced and delivered 90 million doses of meningitis vaccine in record time to respond to an outbreak in Brazil. Sanofi Pasteur has partnered with the Butantan Institute in Brazil since 1999 to deliver seasonal influenza vaccines to the Brazilian population. In 2009 this partnership was instrumental in providing the pandemic A/H1N1 flu vaccine to the Brazilian government. In 2008, Sanofi Pasteur responded to a yellow fever outbreak in Brazil by delivering four million doses of yellow fever vaccine at the request of local health authorities and United Nation agencies. Since 2011, Brazilian infants have been receiving inactivated poliomyelitis vaccine provided via an agreement between Sanofi Pasteur and FIOCRUZ/ Biomanguinhos.

### **About Sanofi Pasteur Dengue Vaccine**

In addition to Brazil, Sanofi Pasteur Dengue Vaccine is also registered in 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 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>3</sup>

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.<sup>4</sup>

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](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)

### Sanofi 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, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, 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.*

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<sup>1</sup> Denizar V A, et al. Jornal Brasileiro de Economia da Saúde Brazilian Journal of Health Economics ABRIL 2016, VOLUME 8, NÚMERO 1 | APRIL 2016, VOLUME 8, NUMBER 1

<sup>2</sup> (<http://www.who.int/wer/2016/wer9130.pdf?ua=1>)



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<sup>3</sup> Hadinegoro SR, et al. N Engl J Med 2015; 373:1195-206

<sup>4</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