



## Strategic Advisory Group of Experts on Immunization Convened by the World Health Organization Recommends Use of Sanofi Pasteur's Dengue Vaccine in Endemic Countries

- *Recommendations from the WHO SAGE recognize the strong public health benefit to be gained by introduction of Dengvaxia<sup>®</sup>, dengue vaccine -*
- *Dengue vaccination expected to play a critical role in integrated disease prevention efforts to achieve WHO 2020 objectives to reduce dengue morbidity and mortality -*

**Paris, France - April 15th, 2016** – [Sanofi](#) and its vaccines global business unit [Sanofi Pasteur](#), announced today that the Strategic Advisory Group of Experts on Immunization (SAGE) has issued its recommendations to the WHO on the use of Dengvaxia<sup>®</sup> dengue vaccine. The SAGE advises that countries with high dengue transmission consider introduction of the dengue vaccine as part of an integrated disease prevention strategy including vector control to effectively lower their dengue disease burden. Successful introduction of dengue immunization alongside other prevention efforts should help endemic countries to achieve the WHO objectives to reduce dengue morbidity by 25% and mortality by 50% by 2020.

*“We welcome these recommendations for Dengvaxia<sup>®</sup> from SAGE, the advisory group to the WHO, for vaccines and immunization.”* said Elias Zerhouni, MD, President of global R&D, Sanofi. *“Dengvaxia<sup>®</sup> has been approved in four countries already, including Mexico and Brazil, which have regulatory authorities recognized by the WHO. These WHO SAGE recommendations further validate the scientific and medical value of Dengvaxia<sup>®</sup> and send a clear message to endemic countries about the strong public health benefit to be gained by introducing the dengue vaccine in integrated disease management efforts to combat their dengue burden.”*

Dengvaxia<sup>®</sup> vaccine's anticipated impact on dengue fever disease burden is expected to stem from the vaccine's proven ability to prevent 8 out of 10 dengue hospitalizations and up to 93% of severe dengue cases--including dengue hemorrhagic fever--in study participants 9 years and older, as demonstrated during 25 months of follow-up of phase III efficacy studies.<sup>1</sup>

The recommendations from the SAGE are based on the technical review of clinical data from 25 clinical studies conducted in 15 different endemic and non-endemic countries around the world, including more than 40,000 study participants.

### **About Dengvaxia<sup>®</sup>**

As of March 2016, Dengvaxia<sup>®</sup> was licensed in Mexico, the Philippines, Brazil and El Salvador for prevention of dengue from all four serotypes in individuals 9-45 years of age living in endemic areas. Regulatory review processes for Dengvaxia<sup>®</sup> are continuing in other countries where dengue



is a public-health priority. Both public and private vaccinations have already begun in the Philippines and discussions are underway in the other approval countries for launches later this year.

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 development program (phase I, II and III), with 29,000 volunteers receiving the vaccine. Large-scale efficacy studies of Dengvaxia<sup>®</sup>, including 25-month follow up, were successfully completed in 2014.<sup>2,3</sup>

Pooled efficacy and integrated safety analyses from the 25-month Phase III efficacy studies and their ongoing long-term follow-up were published online in *The New England Journal of Medicine* on July 27<sup>th</sup> 2015, documenting the vaccine's consistent efficacy and longer-term safety profile in the study population of 9-16 years of age. In the pooled efficacy analysis in this age group, Dengvaxia<sup>®</sup> was shown to reduce dengue fever due to all four serotypes in two-thirds of the participants and prevent 8 out of 10 hospitalizations and up to 93% of severe dengue cases.<sup>1</sup>

Dengvaxia<sup>®</sup> is the first vaccine in the world licensed<sup>®</sup> for the prevention of dengue fever. The vaccine is produced in a dedicated production site in France, with a full-scale production capacity of 100 million vaccine doses annually.

Additional information about Sanofi Pasteur's dengue vaccine is available 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 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 produces a portfolio of high quality vaccines that match its areas of expertise and ensure a sustainable future. 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)

### 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.*

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<sup>1</sup> Hadinegoro SR, et al. *N Engl J Med* 2015; 373:1195-206

<sup>2</sup> Capeding MR, et al. *Lancet* 2014;384:1358-65.

<sup>3</sup> Villar L, et al. *N Engl J Med* 2015;372:113-23.