



World's First Public Dengue Immunization Program Starts in the Philippines

- 1 million students from 6,000 public schools to begin dengue vaccinations this year -

- Launch in the Philippines represents strong endorsement of new model to get innovative new vaccines faster to populations at greatest risk -

Paris, France - April 4, 2016 - [Sanofi](#) and its vaccines global business unit [Sanofi Pasteur](#) announced today that the first public dengue immunization program has started in the Philippines. At a major launch event, hosted by the Department of Health (DoH) of the Philippines, details about the country's plan to vaccinate 1 million public school children were shared with both international and national press. The Filipino health authorities, led by DoH Secretary Janette Garin, stand as global frontrunners in dengue prevention. This initiative sends a strong message to the rest of the endemic world that dengue vaccination is a critical addition to the integrated disease prevention efforts needed to more effectively manage dengue burden.

Sanofi Pasteur's tetravalent dengue vaccine, Dengvaxia[®], was approved for use in individuals 9-45 years of age for the prevention of dengue fever caused by all four serotypes on 22nd December 2015 in the Philippines. The vaccine's anticipated impact on dengue burden is expected to stem from its documented ability to prevent 8 out of 10 dengue hospitalizations and up to 93% of severe dengue that includes hemorrhagic dengue fever that can be fatal in vaccinated study participants 9 years and older.

The public immunization program launched today in the Philippines will begin vaccinating 1 million students from 6,000 public schools this year in three highly dengue-endemic regions of the country. Dengvaxia[®] was made available for private sector vaccination in the Philippines in February.

Olivier Charmeil, Executive Vice President, Sanofi Pasteur, commends the Philippines on the launch of the first public dengue immunization program in the world: *"The Philippines' scientific and healthcare communities have been important collaborators in the development of Dengvaxia[®] participating in all three phases of the clinical study program that involved over 40,000 individuals from 15 countries. Ensuring access to this approved vaccine in a public immunization program attests to the Filipino health authority's commitment to add this new dengue prevention tool to their integrated disease management strategy for a disease that continues to represent a major public health threat to their country."*

Asia currently bears 70% of the world's dengue burdenⁱ; in the Philippines alone 200,000 cases of dengue were reported in 2013.ⁱⁱ A new analysis published in the New England Journal of Medicine on 24th March reports that the Philippines had the highest incidence of confirmed dengue in the 10 endemic countries that participated in the clinical efficacy studies for Dengvaxia[®]. The analysis also reported that up to 15% of febrile disease in children 9 years and older in the Philippines is due to dengue.ⁱⁱⁱ



Dr. Cecilia Montalban, President of The Philippine Foundation for Vaccination, said: *“This first dengue vaccine has been developed and proven effective in countries like the Philippines where dengue is a major public health priority. As a physician and a mother, I am proud that my country plays a historic role in dengue prevention.”*

Sanofi Pasteur is committed to working closely with the Philippines government to facilitate successful introduction of the dengue vaccine, as well as monitor the impact of dengue vaccination in the country with an extensive post-marketing communication and surveillance plan, consistent with the recent Call to Action on countries issued by the Asian Dengue Vaccination Advocacy (ADVA) at the Asia Dengue Summit in February.^{iv}

About Dengvaxia[®]

Besides the Philippines, Dengvaxia[®] is also registered in Mexico, Brazil and El Salvador to date. Regulatory review processes for Dengvaxia[®] are continuing in other countries where dengue is a public health priority. Doses have already been shipped and received in the Philippines to support both private and public sector access to dengue vaccination.

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. Dengvaxia[®] successfully completed phase III clinical studies in 2014 to evaluate the primary objective of vaccine efficacy^{v,vi}. The Philippines participated in all three phases of the clinical development of Dengvaxia[®].

Pooled efficacy and integrated safety analyses from the 25-month Phase III efficacy studies and the ongoing long-term studies, respectively, were published in *The New England Journal of Medicine* on July 27th 2015 documenting the vaccine’s consistent efficacy and longer-term safety profile in study population 9-16 years of age. In the pooled efficacy analysis in this age group, Dengvaxia[®] was shown to reduce dengue 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.^{vii}

Dengvaxia[®] is the first vaccine licensed for the prevention of dengue in the world. The vaccine is produced in a dedicated production site in France with planned full-scale production capacity of 100 million vaccine doses annually.

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](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 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 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



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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ⁱ Nature. 2013 Apr 25;496(7446):504-7

ⁱⁱ Department of Health National Epidemiology Center Public Health Surveillance and Informatics Division Disease surveillance report Morbidity week 46 November 10 – 16, 2013. [Nec.doh.gov. or ph. 02 651 7800 2930](http://www.nec.doh.gov.ph)

ⁱⁱⁱ Azour M.L. et al. N. Engl J Med, DOI: 10.1056/NEJM.org, 2016, 1155-1166.

^{iv} <http://adva.asia/>

^v Capeding M.R. et.al, Clinical efficacy and safety of a novel tetravalent dengue vaccine in healthy children in Asia: a phase 3, randomised, observer-masked, placebo-controlled trial ; Volume 384, Issue 9951, 11–17 October 2014, Pages 1358–1365.

^{vi} Villar L, Dayan GH, Arredondo-Garcia JL, Rivera DM, Cunha R, Deseda C et al. Efficacy of a tetravalent dengue vaccine in children in Latin America. N Engl J Med. 2015.

^{vii} Hadinegoro, Sri Rezeki S., et al. Efficacy and Long-Term Safety of a Dengue Vaccine in Regions of Endemic Disease Integrated Analysis of Efficacy and Interim Long-Term Safety Data for a Dengue Vaccine in Endemic Regions. July 27, 2015 DOI: 10.1056/NEJMoa1506223.