First dengue vaccination program in the Americas starts in Paraná State of Brazil

Paranagua, Brazil – July 26, 2016 - Sanofi Pasteur, the vaccines division of Sanofi, announced today that Paraná State has launched the first public dengue immunization program in the Americas, targeting vaccination of 500,000 of the state's residents this year. In addition, Brazilians can also get access to dengue vaccination in private healthcare clinics around the country.

Paraná State is located in the South of Brazil and is the sixth most densely-populated state with an estimated 10,444,526 residents; over 85% of whom live in urban settings. In the last few years, dengue incidence in the state has increased three fold from 2013 to 2015. The public program announced today will target individuals living in highly urban centers of the State, where dengue continues to bring significant human and economic burden every year.

“The world finally has a clinical prevention tool against dengue that has been shown to be efficacious in the Brazilian population, as well as endorsed by the WHO,” says, Michele Caputo Neto, Minister of Health for Paraná State. “With our strong disease surveillance and community mobilization infrastructure in Paraná State, we are well-positioned to introduce the first public dengue immunization program in the Americas to significantly reduce our disease burden.”

The safety, efficacy and public health value of Sanofi Pasteur’s dengue vaccine has been independently endorsed by the Strategic Advisory Group of Experts on Immunization (SAGE) to the World Health Organization (WHO). This positive WHO recommendation for use of the vaccine in endemic countries like Brazil as part of integrated dengue prevention efforts is based on extensive clinical documentation for the vaccine involving over 40,000 individuals from 15 countries around the world. In these studies, Dengvaxia® demonstrated consistent safety and efficacy across a diverse ethnic, geographic and socio-economic population.

Dengue continues to represent a growing public health threat for Brazilians with disruptive outbreaks that often paralyze local healthcare systems. In 2015, over 1.6 million Brazilians reported being ill with dengue. Almost 60% of the dengue cases in the country occur in individuals 10 to 39 years of age, which falls within the approved age indication 9 to 45 years for Dengvaxia® in Brazil. This pre-adolescent to adult population represents a highly mobile and social segment of the community who contribute significantly to spread of the infection.

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 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.\(^4\)

An integrated safety analysis was recently published showing that Dengvaxia\(^®\) had a 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.\(^5\)

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) 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 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.

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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2 Weekly epidemiological record 27 May 2016 http://www.who.int/wer/2016/wer9121.pdf ?ua=1