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New England Journal of Medicine Publishes New Analyses Confirming that Sanofi Pasteur's Vaccine Candidate Safely Protects Pre-Adolescents to Adults Against Dengue

- The highest burden of dengue disease globally in endemic countries is in pre-adolescent to adults age group[1,2,3] -

- ***In a new pooled analysis, dengue vaccine candidate protected two out of three volunteers aged 9 years and older against all four dengue serotypes***
- ***Protection against severe dengue reached 93% and prevention of hospitalizations due to dengue 80% in this age group***

- Based on this clinical profile in 9 years of age and older, the dengue vaccine candidate has the potential to significantly reduce disease burden in endemic countries -

Lyon, France, - July 27, 2015 - Sanofi Pasteur, the vaccines division of Sanofi, announced today that new data analyses published in *the New England Journal of Medicine (NEJM)* provide a comprehensive picture of the potential public health impact of vaccinating endemic populations from pre-adolescence to adulthood against dengue. Not only is this the largest population at risk of dengue globally, but individuals 9 years of age and older also represent a highly mobile group capable of spreading disease more broadly during outbreaks and also contributing substantially to the economic burden of dengue, for example in number of lost school and work days due to the disease.

The NEJM article reported results from a new pooled efficacy analysis of individuals 9 years of age and older at vaccination from the two Phase III studies of Sanofi Pasteur's dengue vaccine. The new analysis documented that the vaccine protects two-thirds of these individuals (66%) against dengue, providing even greater protection against two clinically-relevant manifestations of dengue, namely severe dengue (93%) and prevention of hospitalizations due to dengue (80%) that account for the greatest human and economic burden of dengue in endemic countries. In addition, the dengue vaccine candidate protected volunteers 9 years of age and older who were previously exposed to dengue (82%), as well as those who were naïve to dengue (52.5%) prior to vaccination.

The clinical development program for the vaccine candidate includes studies with four-year, long-term follow-up phases, in line with WHO guidelines for dengue vaccine development. Results from first 25 months of the two Phase III efficacy studies were published in 2014.[4,5] Interim data from the third year of these studies and interim data from the third and fourth years of the Phase II extension study in Thailand published in the new NEJM article confirm the continuing reduction of hospitalized dengue in the vaccinated population 9 years of age and older.

The third-year interim data from the Asian Phase III study identified the need for further long-term surveillance in children under 9 years of age to assess the impact of the dengue vaccine candidate in these younger children.

"*It is not unusual to require additional data on a new vaccine to determine its value in a specific age group, particularly young children, whose immune response to the vaccine and the disease itself*

may differ significantly from that of older children and adults," notes Professor Tim Endy, MD., MPH, Upstate University Hospital, New York. "*It is reassuring to have confirmation of the safe protection that this vaccine offers against dengue in the endemic preadolescent to adult population, particularly coupled with its consistent efficacy and safety profile reported last year from the PIII studies across diverse geographic regions, ethnic study populations and dengue epidemiology covered*."

Dr. Maria Rosario Capeding from the Research Institute for Tropical Medicine in the Philippines, who is a lead author on the NEJM article, points out the potential public health benefit of having a first dengue vaccine available to protect individuals 9 years of age and older. "*This large, at-risk population includes the most dynamic members of the community who have the potential to spread disease widely and also contribute most to dengue's heavy societal impact in terms of school absences and lost work productivity. Certainly, individuals 9 years of age and older represent a compelling target group for an immunization program against dengue aimed at significantly reducing overall disease burden.*"

Dengue is the world's fastest growing vector-borne disease, endemic in over 100 countries where almost half the world's population resides. Dengue poses considerable economic and human burden in these endemic countries as it is prone to unpredictable outbreaks and spreads readily in densely populated urban areas, often paralyzing local healthcare systems and requiring cost-intensive intervention efforts. Today, no specific treatment or prevention for dengue is available.

The WHO has set objectives to reduce mortality due to dengue by 50% and morbidity by 25% by 2020. Introduction of an effective and safe dengue vaccine as an integral part of dengue prevention efforts will be critical to achieving this goal.

Based on the totality of the safety and efficacy data for its dengue vaccine candidate, Sanofi Pasteur has decided to recommend a targeted age indication for the vaccine of 9 years of age and older in endemic countries, where the combination of disease burden and the vaccine's proven impact profile in this age group point to the greatest potential for reduction of dengue disease burden in these countries.

[1] *L'Azou M, Moureau A, Sarti E, et al. Incidence of symptomatic pediatric dengue in ten Asian and Latin American countries. . N Engl J Med 2015; Manuscript resubmitted.*
[2] *L'Azou M, Taurel AF, Flamand C, Quenel P. Recent epidemiological trends of dengue in the French territories of the Americas (2000-2012): a systematic literature review. PLoS Negl Trop Dis 2014;8:e3235.*
[3] *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.*
[4] *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*
[5] *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*

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 offers a broad range of vaccines protecting against 20

infectious diseases. 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 policies 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, 2014. 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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