El Salvador Begins Dengue Immunizations with Sanofi Pasteur Vaccine

- Sanofi Pasteur’s dengue vaccine, approved in El Salvador in February, is now available in private immunization clinics throughout the country -

- The nation’s health care professionals welcome the ability to prevent dengue hospitalizations and severe disease amongst their patient populations with this new clinical prevention tool against dengue -

El Salvador, San Salvador, – July 27, 2016 – Sanofi Pasteur, the vaccines division of Sanofi, announced today that its new dengue vaccine can now be administered by healthcare professionals in El Salvador, as the first clinical preventive tool against dengue.

People in El Salvador can be vaccinated against dengue during medical consultation with their healthcare providers including pediatricians, internists, and primary care doctors.

At a medical event held by Sanofi Pasteur in collaboration with the Scientific Society of Internal Medicine, the Scientific Society of Infectiology, and the Scientific Society of Pediatrics of El Salvador, the dengue vaccine was recognized as a crucial new clinical tool in the integrated efforts towards dengue prevention in the country. “By vaccinating our patients against dengue, we anticipate being able to prevent thousands of ambulatory cases, hospitalizations and deaths due to dengue infection every year,” noted Mario Gamer, President of the Salvadorian Association of Infectiology and member of the Pediatrician Society of El Salvador.

The tetravalent vaccine of Sanofi Pasteur was approved on February 5th, 2016 in El Salvador to provide protection against all four types of dengue for people 9 to 45 years of age. A summary of the efficacy profile of the vaccine in study participants 9 years of age and older showed that the Sanofi Pasteur dengue vaccine prevents 65.6% of all dengue cases with higher efficacy up to 80% against hospitalizations due to dengue and 93% protection against severe dengue cases, including dengue hemorrhagic fever that can cause death.1

Sixty percent of dengue cases in El Salvador are reported in individuals older than 9 years of age, who represent a highly mobile and socially-active segment of the community with the potential to contribute significantly to spread of the disease throughout the country.2

Dengue incidence has risen sharply in El Salvador in the last decade, reaching more than 50,000 suspected cases in 2015 with an incidence rate of approximately 800 cases per 100,000 inhabitants. Last year, El Salvador experienced its second largest outbreak of dengue since 1995.3
In April 2016, the Strategic Advisory Group of Experts (SAGE) on immunization to the World Health Organization (WHO) positively endorsed use of Dengvaxia® in highly endemic countries and recommended that these countries consider introducing the dengue vaccine as part of an integrated disease prevention plan to reduce their dengue burden.\(^4\) The WHO has set the objectives of reducing dengue mortality by dengue by 50% and morbidity by 25% by 2020 in the endemic countries.\(^5\)

**The Global Burden of Dengue**

According to the WHO, dengue is the fastest-growing mosquito-transmitted disease in the world, causing around 400 million infections every year. Over the last 50 years, the dengue has spread from a handful over countries to 128 countries today, home to almost half of the world’s population or 3.9 billion individuals. During this same period, the incidence of this disease has increased 30 times.\(^6\)

Even though dengue affects people of all ages and lifestyles, the greatest number of dengue cases worldwide occurs in individuals 9 years of age and older, who represent a highly mobilized and actively social segment of the community, capable of significantly contributing to the spread of the disease.\(^7,8\)

**About Sanofi Pasteur New Dengue Vaccine**

Sanofi Pasteur Dengue Vaccine is registered in Mexico, the Philippines, Brazil, 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.\(^9\)

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.\(^10\)

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 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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