Sanofi Pasteur Dengue Vaccine Approved in Costa Rica

- Costa Rica is 5th country in the world to approve the dengue vaccine, which was recently endorsed by the WHO SAGE recommendations supporting the safety, efficacy and public health value of the dengue vaccine in endemic countries -

- Vaccine needed to address precipitous rise of dengue in Costa Rica, with greater than 500% increase in incidence in 2016 already compared to last year’s numbers -

Costa Rica – 21st June, 2016 - Today Sanofi Pasteur, Sanofi’s vaccine division, announced that the National Ministry of Health of Costa Rica has approved Sanofi Pasteur’s tetravalent dengue vaccine, Dengvaxia®, to protect individuals 9 to 45 years of age living in endemic areas against all four serotypes of dengue.

This approval in Costa Rica is the fourth registration of the dengue vaccine in Latin America, and the fifth in the world. Sanofi Pasteur’s dengue vaccine has already been approved in Mexico, Brazil, El Salvador and the Philippines.

“Dengue is a disease that is beginning to hit us hard as a result of increased mobility and urbanization in the country. Already in 2016, we have recorded 7,711 cases of dengue at week 22 which is more than a 500% increase in incidence compared to last year,” said Jorge Martinez, Pediatrician Member of the Pediatrician Society of Costa Rica. “Approval of the dengue vaccine gives us access to critical prevention tool against dengue to curb further spread of this debilitating disease in our country.”

In April 2016, the Strategic Advisory Group of Experts (SAGE) on immunization to the World Health Organization (WHO) recommended endemic countries to consider introduction of Dengvaxia® as part of integrated disease prevention including vector control and community mobilization. The WHO has set the objectives of reducing mortality by dengue by 50% and morbidity by 25% by 2020 in the endemic countries.

“Dengue represents a growing and serious public health issue in many parts of the Americas with significant associated human and economic burden,” according to Cesar Mascareñas, Global Director of Medical Affairs for the Dengue Project, Sanofi Pasteur. “Approval of the dengue vaccine in Costa Rica will give the country’s healthcare providers access to the first clinical preventive tool against dengue, allowing them to better protect their patients against this threat.”

Public vaccinations against dengue began in the Philippines in April, with the goal of initiating the vaccination of 1 million fourth-grade students in highly-endemic regions of the country this year. Introduction of dengue vaccine in private and public immunization clinics in Brazil, Mexico and other countries in Central America are planned also to follow in coming months.

The global burden of dengue
According to the WHO, dengue is currently the fastest-growing mosquito-transmitted disease in the world, causing around 400 million infections every year. Over the last 50 years, dengue has spread; initially present in a handful of countries, it is now endemic in 128, inhabited by around 4 billion people. Also, the incidence of this disease has increased 30 times in this same period.
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 mobile and social segment of the community capable of contributing significantly to spread of the disease.\(^5\,^6\)

**About Sanofi Pasteur’s dengue vaccine**

Besides Costa Rica, Sanofi Pasteur’s dengue vaccine has also been registered in Brazil, Mexico, El Salvador and the Philippines to date. Both private and public vaccinations against dengue have been successfully introduced in the Philippines and are being planned in other approval countries. The regulatory review process for the vaccine is continuing in other countries where dengue is a public health priority.

Sanofi Pasteur’s dengue vaccine is the culmination of over two decades of scientific innovation and collaboration, as well as 25 clinical studies in over 15 countries around the world. More than 40,000 volunteers participated in the dengue vaccine clinical study program (phase I, II and III), of whom 29,000 volunteers received the vaccine.\(^7\,^8\)

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 27\(^{th}\), 2015, documenting the vaccine’s consistent efficacy and longer-term safety profile in a study population 9-16 years of age. In the pooled efficacy analysis in this age group, Sanofi Pasteur’s dengue vaccine was shown to reduce dengue caused by all four serotypes in two-thirds of the participants. Furthermore, this pooled analysis showed that Dengvaxia\(^\circledast\) prevented up to 93% of severe dengue cases and 8 out of 10 hospitalizations.\(^9\)

Sanofi Pasteur’s dengue vaccine is the first and only vaccine licensed for the prevention of dengue in the world. The first vaccine doses have already been produced and shipped to countries in Asia and Latin America; the full-scale production capacity of the dedicated vaccine facility in France is 100 million vaccine doses annually.

Additional information about Sanofi Pasteur’s dengue vaccine is available on the web in Spanish at [http://es.dengue.info/](http://es.dengue.info/) or at [www.dengue.info](http://www.dengue.info) (in English).

**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 provides 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](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 expected.
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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