SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NYSE: SNY)

Sanofi receives positive CHMP opinion for dengue vaccine

Paris, France – October 19, 2018 – The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the marketing authorization of Sanofi's dengue vaccine, recommending its approval in Europe.

Dengue fever is a debilitating disease typically leading to prolonged fever and severe joint pain. Dengue infection can progress unpredictably to a life-threatening form of the disease called dengue haemorrhagic fever that often requires hospitalized care. Today, there is no specific treatment available for dengue disease.

> *"This is good news for people living in dengue-endemic parts of the European territories where frequent outbreaks could put them at risk of re-infection with another dengue virus serotype, which is often more severe than the first infection,"* said Su-Peing Ng, Global Medical Head at Sanofi Pasteur*. "Sanofi is committed to ensuring access to dengue vaccination as part of integrated prevention efforts to reduce the burden of this disease in endemic populations around the world."*

The indication for the dengue vaccine recommended by the CHMP is for use in prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in individuals 9 to 45 years of age with prior dengue virus infection and living in endemic areas. European Commission approval of the vaccine is expected in December 2018.

According to the WHO, the global incidence of dengue has grown rapidly in recent decades and it now puts at risk half of the world's population living in 128 countries.[i] Dengue is endemic in several European territories located in tropical and sub-tropical climates.[ii,iii,iv]

A person can get dengue more than once as there are four distinct virus serotypes circulating worldwide. Dengue infection is unique in that a secondary infection

tends to be worse than the first infection. Therefore, preventing dengue in individuals with a prior dengue infection has the potential to reduce the high human and economic costs of severe dengue.

The dengue vaccine has been evaluated in studies involving more than 40,000 people from 15 countries with up to six years of follow-up data from large-scale clinical safety and efficacy investigations.

The vaccine, known as Dengvaxia®, is currently licensed in 20 countries for the prevention of dengue.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We help prevent illness with vaccines, provide innovative treatments to fight pain, and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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Sanofi 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 regarding the clinical development of and potential marketing approvals for the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans", "will be" 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 of the product, 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 the product as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of the product, the absence of guarantee that the product if approved will be commercially successful, risks associated with intellectual property, future litigation, the future approval and commercial success of therapeutic alternatives, and volatile economic conditions, as well as those risks 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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

[i] Brady OJ, Gething PW, Bhatt S, Messina JP, Brownstein JS, Hoen AG et al. Refining the global spatial limits of dengue virus transmission by evidence-based consensus. PLoS Negl Trop Dis. 2012;6:e1760. doi:10.1371/journal.pntd.0001760.

[ii] San Martín JL et al. The Epidemiology of Dengue in the Americas Over the Last Three Decades: A Worrisome Reality. Am J Trop Med Hyg 2010; 82(1):128-35.

[iii] Larrieu S et al. Dengue outbreaks: a constant risk for Reunion Island. Results from a seroprevalence study among blood donors. Trans R Soc Trop Med Hyg 2014; 108(1):57-9

[iv] L'Azou M et al. Dengue seroprevalence in the French West Indies: a prospective study in adult blood donors. Am J Trop Med Hyg, 2015; 92(6):1137-40