

## Dengvaxia<sup>®</sup> vaccine approved for prevention of dengue in Europe

**Paris, France - December 19, 2018** - The European Commission has granted marketing authorization for Dengvaxia<sup>®</sup>, Sanofi's dengue vaccine. The marketing authorization follows the October 18, 2018, recommendation by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) to approve use of the dengue vaccine in European endemic areas.

Dengue fever is a mosquito-borne infection that people can get up to 4 times in a lifetime. Dengue is also known as 'break-bone fever' since it can cause debilitating disease marked by prolonged episodes of high fever and severe joint pain. An 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.

Dengvaxia<sup>®</sup> will be available in Europe to prevent dengue disease in individuals 9-45 years of age with a documented prior dengue infection and who are living in endemic areas.

*"In some of the European overseas territories where dengue recurs regularly, people who have had a dengue infection previously are at risk of being infected with the virus again,"* explains Dr. Su-Peing Ng, Global Medical Head at Sanofi Pasteur, the vaccine unit of Sanofi. *"As the second infection with dengue tends to be more severe than the first, it is important to be able to offer these people a vaccine that could help protect them against subsequent dengue infections."*

According to the WHO, the global incidence of dengue has grown rapidly in recent decades and it now threatens half of the world's population living in 128 countries.<sup>i</sup> Dengue is endemic in several European territories located in tropical and sub-tropical climates prone to outbreaks of the disease particularly during the rainy season.<sup>ii</sup> Earlier this year, dengue outbreaks in La Reunion resulted in more than 6,000 people being made ill by the virus, which is spread by a day-

biting mosquito that often lives in people's homes. During past outbreaks of dengue in Guadeloupe and Martinique, more than 40,000 people reportedly contracted the fever.<sup>iii,iv</sup>

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 from large-scale clinical safety and efficacy investigations.

Dengvaxia<sup>®</sup> is approved for use in several endemic countries in Latin America and Asia where reducing the human and economic burden of dengue is critical. The vaccine is currently under priority review by the US Food and Drug Administration (FDA) as it would be considered a significant medical advance in the prevention of dengue, which is considered an unmet medical need by the FDA.

#### About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We 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 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, expectations for the transfer of our American Depositary Shares (ADS) listing and the stock exchange on*

*which our ADSs will be listed, as well as those risks and uncertainties 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*

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<sup>i</sup> 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.

<sup>ii</sup> San Martin 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.

<sup>iii</sup> 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

<sup>iv</sup> <http://invs.santepubliquefrance.fr/Publications-et-outils/Points-epidemiologiques/Tous-les-numeros/Ocean-Indien/2018/Surveillance-de-la-dengue-a-la-Reunion.-Point-epidemiologique-au-30-octobre-2018>