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.¹ Dengue is endemic in several European territories located in tropical and subtropical climates.²,³,⁴

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
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