Sanofi updates information on dengue vaccine

* New analysis of long-term Dengvaxia® data found differences in vaccine performance based on prior dengue infection
* Company will ask regulators to update product label to reflect new information

PARIS, FRANCE – November 29, 2017 – Sanofi will ask health authorities to update information provided to physicians and patients on its dengue vaccine Dengvaxia® in countries where it is approved. The request is based on a new analysis of long-term clinical trial data, which found differences in vaccine performance based on prior dengue infection.

Based on up to six years of clinical data, the new analysis evaluated long-term safety and efficacy of Dengvaxia in people who had been infected with dengue prior to vaccination and those who had not. The analysis confirmed that Dengvaxia provides persistent protective benefit against dengue fever in those who had prior infection. For those not previously infected by dengue virus, however, the analysis found that in the longer term, more cases of severe disease could occur following vaccination upon a subsequent dengue infection.

“These findings highlight the complex nature of dengue infection. We are working with health authorities to ensure that prescribers, vaccinators and patients are fully informed of the new findings, with the goal of enhancing the impact of Dengvaxia in dengue-endemic countries.” said Dr. Su-Peing Ng, Global Medical Head, Sanofi Pasteur.

About half of the world’s population lives in countries where four serotypes of dengue virus are in circulation. Every year an estimated 390 million dengue infections are reported. People can be infected with dengue up to four times in their lifetime and they can get severely ill after any of these infections. Surveillance data from some endemic countries indicate that between 70 and 90 percent of people will have been exposed to dengue at least once by the time they reach adolescence. There are many factors that can lead to severe dengue infection. However, the highest risk of getting more severe disease has
been observed in people infected for the second time by a different dengue virus.

Dengvaxia is currently indicated in most of the countries for individuals 9 years of age and older living in a dengue-endemic area. In this indicated population, Dengvaxia has been shown to prevent 93 percent of severe disease and 80 percent of hospitalizations due to dengue over the 25 month phase of the large-scale clinical studies conducted in 10 countries in Latin America and Asia where dengue is widespread.

**Proposed Label Update**

Based on the new analysis, Sanofi will propose that national regulatory agencies update the prescribing information, known as the label in many countries, requesting that healthcare professionals assess the likelihood of prior dengue infection in an individual before vaccinating. Vaccination should only be recommended when the potential benefits outweigh the potential risks (in countries with high burden of dengue disease). For individuals who have not been previously infected by dengue virus, vaccination should not be recommended.

The Sanofi label proposal will be reviewed by national regulatory agencies in each of the countries where the vaccine is registered or under registration. Following their review, each agency might amend the company proposed label.

**Financial Information**

Taking this information into account and expected future sales, Sanofi will record a charge reflecting depreciation of inventories as well as accelerated depreciation of some tangible and intangible assets in its fourth quarter results. The impact on the Business Net Income (BNI) is still under assessment but it is expected to be in the range of €100 million after tax. Despite this impact, Sanofi confirms the guidance provided on November 2nd of broadly stable Business EPS\(^{(1)}\) at CER in 2017 versus 2016, barring unforeseen major adverse events.

\(^{(1)}\) Business net income is a non-GAAP financial measure (see Appendix 8 of our November 2, 2017 financial release for a definition).

**About Dengue**

Dengue is a painful, debilitating mosquito-borne viral disease for which there is no treatment. Almost 4 billion people are living at risk of dengue and these people can be sickened by dengue not just once but as many as four times in their lifetimes.
Dengue hits hardest during rainy season outbreaks that spread rapidly in the urban growth centers of endemic countries. The World Health Organization has called on countries with dengue to employ an integrated approach to dengue prevention and management, with the aim of reducing deaths due to dengue by 50 percent and related disease and disability by 25 percent by 2020.