Generic Name:
Dengue virus vaccine
Trade Name:
Dengvaxia
Company:
Sanofi Pasteur
Notes:

FDA has approved Dengvaxia, the first vaccine for prevention of dengue disease caused by all dengue virus serotypes (1, 2, 3, and 4) in people aged 9 through 16 years who have laboratory-confirmed previous dengue infection and who live in endemic areas. Dengvaxia is a live, attenuated vaccine that is administered as three separate injections, with the initial dose followed by two additional shots given 6 and 12 months later.

Dengue disease is the most common mosquito-borne viral disease in the world and is endemic in the U.S. territories of American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands. The first infection with dengue virus typically results in either no symptoms or a mild illness that can be mistaken for the flu or another viral infection. A subsequent infection can lead to severe dengue, including dengue hemorrhagic fever, a more severe form of the disease that can be fatal. Symptoms may include stomach pain, persistent vomiting, bleeding, confusion, and difficulty breathing. Approximately 95% of all severe/hospitalized cases of dengue are associated with second dengue virus infection. Because there are no specific drugs approved for treatment of dengue disease, care is limited to managing the symptoms.

Safety and effectiveness of the new vaccine were determined in three randomized, placebo-controlled studies involving approximately 35,000 individuals in dengue-endemic areas, including Puerto Rico, Latin America, and the Asia Pacific region. The vaccine was determined to be approximately 76% effective in preventing symptomatic, laboratory-confirmed dengue disease in individuals aged 9 through 16 years who previously had laboratory-confirmed dengue disease. Dengvaxia has already been approved in 19 countries and the European Union.

The most commonly reported adverse effects by those who received Dengvaxia were headache, muscle pain, joint pain, fatigue, injection-site pain, and low-grade fever. The frequency of adverse effects was similar across Dengvaxia and placebo recipients and tended to decrease after each subsequent dose of the vaccine.

Dengvaxia is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. This is because in people who have not been infected with dengue virus, Dengvaxia appears to act like a first dengue infection?without actually infecting the person with wild-type dengue virus?such that a subsequent infection can result in severe dengue disease. Health professionals should evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus. This can be assessed through a medical record of a previous laboratory-confirmed dengue infection or through serological testing prior to vaccination.

Medication Monitor Categories:
New Drug Approvals