Dengvaxia® (dengue tetravalent vaccine, live) – New drug approval

- On May 1, 2019, the FDA announced the approval of Sanofi Pasteur's Dengvaxia (dengue tetravalent vaccine, live), for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4. Dengvaxia is approved for use in individuals 9 through 16 years of age with laboratory confirmed previous dengue infection and living in endemic areas.

    - Dengvaxia is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. Those not previously infected are at increased risk for severe dengue disease when vaccinated and subsequently infected with dengue virus. Previous dengue infection can be assessed through a medical record of a previous laboratory-confirmed dengue infection or through serological testing prior to vaccination.
    - The safety and effectiveness of Dengvaxia have not been established in individuals living in dengue non-endemic areas who travel to dengue endemic areas.

- The Centers for Disease Control and Prevention estimates more than one-third of the world's population is living in areas at risk for infection by dengue virus which causes dengue fever, a leading cause of illness among people living in the tropics and subtropics. 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.

    - There are no specific drugs approved for the treatment of dengue disease, and therefore care is limited to the management of symptoms.

- Although dengue cases are rare in the continental U.S., the disease is regularly found in American Samoa, Puerto Rico, Guam, the U.S. Virgin Islands, as well as Latin America, Southeast Asia and the Pacific islands.

- The efficacy of Dengvaxia was evaluated in two, observer-blind studies. Study 1 (N = 20,869) was conducted in individuals 9 through 16 years of age in four Latin American countries and Puerto Rico; and study 2 (N = 10,275) was conducted in individuals 2 through 14 years of age in five Asia-Pacific countries. Patients were randomized to Dengvaxia or placebo and were monitored for symptomatic virologically-confirmed dengue (VCD) starting at day 0. Per protocol vaccine efficacy was assessed beginning 28 days after the third vaccination for 12 months.

    - For each study, in prespecified vaccine efficacy analyses including the full age range of patients enrolled, the pre-specified criterion for demonstrating efficacy of Dengvaxia against VCD due to any dengue virus serotype and irrespective of previous dengue virus infection, was met (lower bound of 95% CI for vaccine efficacy > 25%).

- Dengvaxia is contraindicated in patients with a history of severe allergic reaction to a previous dose of Dengvaxia or to any component of Dengvaxia, and in immunocompromised patients.

- Warnings and precautions of Dengvaxia include increased risk of severe dengue disease following Dengvaxia in persons not previously infected with dengue virus; management of acute allergic reactions; limitations of vaccine effectiveness; and syncope.

- The most frequently reported adverse reactions regardless of the dengue serostatus prior to vaccination with Dengvaxia were headache (40%), injection site pain (32%), malaise (25%), asthenia (25%) and myalgia (29%).

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- The recommended dosing schedule for Dengvaxia is three doses (0.5 mL each) administered subcutaneously 6 months apart (at month 0, 6, and 12).

- Sanofi Pasteur's launch plans for Dengvaxia are pending. Dengvaxia will be available as a suspension for injection (0.5 mL) (supplied as a lyophilized powder to be reconstituted with the supplied diluent).