Ixchiq® (chikungunya vaccine, live) – New vaccine approval

- On November 9, 2023, the FDA announced the approval of Valneva's Ixchiq (chikungunya vaccine, live), for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV.
    - This indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory studies.
- CHIKV is primarily transmitted to people through the bite of an infected mosquito. The highest risk of infection is in tropical and subtropical regions of Africa, Southeast Asia, and parts of the Americas where chikungunya virus-carrying mosquitos are endemic. However, CHIKV has spread to new geographical areas causing a rise in global prevalence of the disease.
    - At least 5 million cases of CHIKV infection have been reported during the past 15 years.
- The efficacy of Ixchiq was established based on an evaluation of seroresponse defined as an anti-CHIKV neutralizing antibody level above a threshold ($\mu PRNT_{50}$ titer ≥ 150). This threshold was derived from a non-human primate model.
    - The seroresponse rate 28 days post-vaccination was 98.9% (95% CI: 96.7, 99.8). The seroresponse rate at 180 days was 96.3% (95% CI: 93.1, 98.3).
- Ixchiq is contraindicated in individuals:
    - Who are immunodeficient or immunosuppressed due to disease or medical therapy
    - With a history of a severe allergic reaction to any component of the vaccine.
- Warnings and precautions for Ixchiq include management of acute allergic reactions; risk of severe or prolonged chikungunya-like adverse reactions; potential for vertical transmission of vaccine virus and fetal/neonatal adverse reactions; syncope; and limitation of vaccine effectiveness.
- The most common solicited injection site reaction (> 10%) with Ixchiq use was tenderness. The most common solicited systemic adverse reactions (> 10%) were headache, fatigue, myalgia, arthralgia, fever, and nausea.
- Ixchiq is administered as a single dose (approximately 0.5 mL) by intramuscular injection.
- Valneva plans to launch Ixchiq early next year. Ixchiq will be available as a solution for injection (0.5 mL after reconstitution).