Ixchiq® (Chikungunya vaccine, live) – FDA and CDC recommend pause in use in 60 years and older

- On May 9, 2025, The FDA and the CDC recommended a pause in the use of Valneva's Ixchiq (Chikungunya vaccine, live) in individuals 60 years of age and older while the Agencies investigate postmarketing reports of serious adverse events, including neurologic and cardiac events, in individuals who have received the vaccine.

- As of May 7, 2025, 17 serious adverse events, including two that resulted in death, have been reported in individuals 62 through 89 years of age who received Ixchiq during postmarketing use globally.

    - Six of these reports have been from the U.S.
    - Most of the adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) have been in individuals with underlying chronic medical conditions.
    - Adverse events reported to VAERS may not be causally related to vaccination.

- Ixchiq is a vaccine indicated 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.

- The FDA-approved Prescribing Information includes a warning to inform that the vaccine may cause severe or prolonged chikungunya-like adverse reactions.

    - During the clinical studies, severe chikungunya-like adverse reactions that prevented daily activity and/or required medical intervention occurred in 1.6% of Ixchiq recipients and none of the placebo recipients.

- The FDA will conduct an updated benefit-risk assessment for the use of Ixchiq in individuals 60 years of age and older. In addition, the FDA and CDC will continue the evaluation of postmarketing safety reports for Ixchiq.

- The FDA and CDC will update the public when the Agencies complete their evaluation of this safety issue.

- Until the evaluation is complete, individuals 60 years and older should not receive Ixchiq.