UPDATE ON LICENSURE OF LIVE ATTENUATED CHIKUNGUNYA VACCINE

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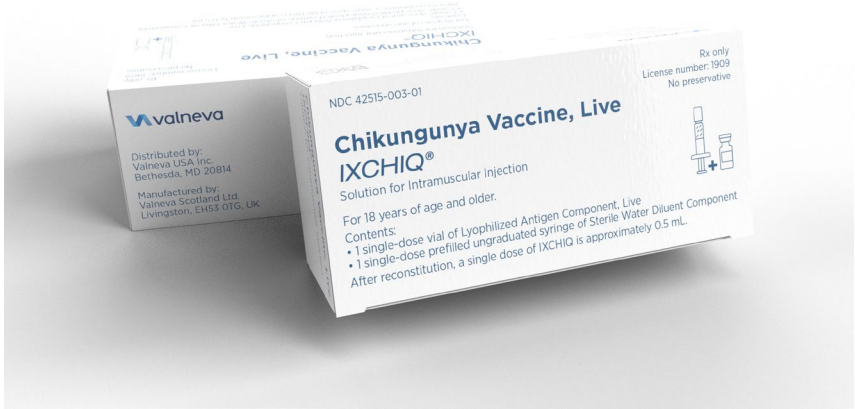
Key points from FDA licensure and package insert

- Vaccine approved on November 9, 2023 and named IXCHIQ
- Indicated for individuals at increased risk of exposure to chikungunya virus
- Single dose primary schedule and for use in individuals aged ≥18 years



Contraindications

- Immunocompromised individuals
- Individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of IXCHIQ

Warnings and precautions in package insert

- Vaccine may cause severe or prolonged chikungunya-like adverse reactions
- Vaccine viremia occurs in the first week following vaccination and no data on risk of vertical transmission to fetus or neonate

Licensure through accelerated approval pathway

- Tradition approval would have been challenging and clinical development would likely have been delayed
  - Chikungunya outbreaks unpredictable and duration can be relatively short
  - No established immunologic correlate of protection

- Accelerated approval pathway endorsed at FDA VRBAC* meeting, 2019
  - FDA can grant for products for serious conditions that fill unmet medical need
  - Effectiveness demonstrated by controlled clinical trials showing vaccine has effect on surrogate endpoint reasonably likely to predict clinical benefit
  - Marker of protection for chikungunya vaccine based on neutralizing antibody titer estimated from validated non-human primate model
  - Post-licensure requirement for controlled trials to confirm the clinical benefit

*Vaccines and Related Biological Products Advisory Committee

Required post-marketing studies

- Vaccine effectiveness case-control study in persons aged ≥12 years, Brazil
  - Plan to initiate by March 2026, complete by March 2028
- Pragmatic randomized controlled trial for effectiveness and safety in adults in endemic area
  - Plan to initiate by Oct 2025, complete by Jul 2029