Our STN: BL 125777/138

BIOLOGICS LICENSE
VOLUNTARY REVOCATION
/RELEASE OF POSTMARKETING
REQUIREMENTS and COMMITMENT
January 29, 2026

Valneva Austria GmbH
Attention: Shailesh Dewasthaly, Ph.D.
Campus Vienna Biocenter 3
Vienna, Vienna
Austria

Dear Dr. Dewasthaly:

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Chikungunya Vaccine, Live (IXCHIQ).

We also refer to your letter received January 20, 2026, notifying us that your company Valneva Austria GmbH, which was issued U.S. License No. 1909, has requested voluntary revocation under 21 CFR 601.5(a) of the biologics license for the above product.

Therefore, under the provisions of 21 CFR 601.5(a), approval to manufacture and market Chikungunya Vaccine, Live (IXCHIQ) is hereby revoked, effective this date.

Any pending submissions are now considered closed.

All of your open postmarketing requirements and commitment for this revoked product have been released.

STN: BL 125777/0

PMR #1 To conduct an observational study with a test-negative, case-control design to assess the effectiveness of IXCHIQ vaccination in the prevention of symptomatic, laboratory confirmed chikungunya after a single vaccination with IXCHIQ in the adolescent and adult population (12 years of age and older) in endemic areas of Brazil.

PMR #2 To conduct a pragmatic randomized controlled trial to assess the effectiveness and safety of IXCHIQ vaccination in the prevention of symptomatic, laboratory confirmed chikungunya after a single vaccination with IXCHIQ in adults in an endemic country.

PMR #3 Deferred pediatric study under PREA (VLA1553-321) to evaluate safety and immunogenicity of IXCHIQ in adolescents 12 to <18 years of age.

PMR #4 Deferred pediatric study under PREA (VLA1553-221) to evaluate dose-finding safety and immunogenicity of IXCHIQ in children 1 to <12 years of age.

PMR #5 Deferred pediatric study under PREA (VLA1553-322) to evaluate safety and immunogenicity of IXCHIQ in children 1 to <12 years of age.

PMR #6 Deferred pediatric study under PREA (VLA1553-222) to evaluate dose-finding safety and immunogenicity of IXCHIQ in neonates and infants <1 year of age.

PMR #7 Deferred pediatric study (VLA1553-323) to evaluate safety and immunogenicity of IXCHIQ in neonates and infants <1 year of age.

PMR #8 To conduct a pragmatic randomized controlled trial to assess the effectiveness and safety of IXCHIQ vaccination in the prevention of symptomatic, laboratory confirmed chikungunya after a single vaccination with IXCHIQ in adults and possibly adolescents in an endemic country. This individual-level randomized, observer-blind, controlled trial conducted across multiple centers in an endemic country will evaluate severe chikungunya-like adverse reactions (including typical and atypical presentations and cases that result in hospitalization) and prolonged arthralgia in at least 10,000 individuals vaccinated with IXCHIQ.

PMC #9 Observational study to evaluate the safety of live-attenuated chikungunya virus vaccine (IXCHIQ) in pregnant women aged 18-45 years exposed to the vaccine. This prospective, observational registry study of pregnant women residing in Brazil will compare maternal and infant outcomes of at least 90 women exposed to IXCHIQ prior to or during pregnancy to a group of pregnant women who have not been exposed to IXCHIQ.

We recommend that a copy of this letter be available for review at the time of Food and Drug Administration inspections.

If you have any questions, please contact the Regulatory Project Manager, Georgeta Crivat, Ph.D., by email (Georgeta.Crivat@fda.hhs.gov).

Sincerely,

/s/

Digitally signed by DAVID C. KASLOW -S
Date: 2026.01.29 15:05:38 -05'00'

David C. Kaslow, MD
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

cc: US Agent, Adam Friedman