**VALNEVA SE**
Campus Bio-Ouest | 6, Rue Alain Bombard
44800 Saint-Herblain, *France*

# Valneva Announces Removal of FDA-Recommended Pause on Use of Chikungunya Vaccine IXCHIQ® in Elderly and Updates to the Prescribing Information

**Saint Herblain (France), August 7, 2025** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the FDA has removed its recommended pause in the use of IXCHIQ® in individuals 60 years of age and older and has approved updates to the Prescribing Information (PI) for IXCHIQ®. IXCHIQ® remains indicated in the United States for the prevention of disease caused by the Chikungunya Virus (CHIKV) in individuals 18 years of age and older who are at high risk of exposure to CHIKV.

The FDA decision follows the announcement in July by the European Medicines Agency (EMA)[1] which recommended the lifting of temporary restrictions in elderly people after the conclusion of a thorough review of IXCHIQ® by its safety committee (PRAC).

The PI has been updated to reflect reports of Serious Adverse Events, primarily among elderly individuals with multiple underlying health conditions, following a mass vaccination campaign in La Réunion in response to a severe chikungunya outbreak.

The FDA noted that for most U.S. travelers the risk of exposure to CHIKV is low and therefore, the product is not advisable for most of them. IXCHIQ® should be given when there is a significant risk of chikungunya infection and only after careful consideration of the benefits and risks. Healthcare professionals are reminded that IXCHIQ® is contraindicated in individuals with weakened immune systems due to disease or immunosuppressive treatments, as stated in IXCHIQ®'s product label in the U.S., Europe and other territories.

Furthermore, the product's Warnings and Precaution section has been expanded to reflect the SAE profile observed, especially in people above 65 years of age and older with one or more chronic medical conditions.

Ongoing FDA reviews are progressing regarding potential extension of IXCHIQ®'s label to adolescents and inclusion of additional persistence data.

**About Chikungunya**
Chikungunya virus (CHIKV) is a mosquito-borne viral disease spread by the bites of infected *Aedes* mosquitoes which causes fever, severe joint and muscle pain, headache, nausea, fatigue and rash. Joint pain is often debilitating and can persist for weeks to years[2].
In 2004, the disease began to spread quickly, causing large-scale outbreaks around the world. Since the re-emergence of the virus, CHIKV has now been identified in over 110 countries in Asia, Africa, Europe and the Americas[3]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[4] and the economic impact is considered to be significant. The medical and economic

---

[1] *Ixchiq: temporary restriction on vaccinating people 65 years and older to be lifted | European Medicines Agency (EMA)*
[2] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*
[3] *https://cmr.asm.org/content/31/1/e00104-16*
[4] *PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas (Cumulative Cases 2018-2023 and Cases per year 2013-2017). https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 01 Aug 2023.*

burden is expected to grow with climate change as the mosquito vectors that transmit the disease continue to spread geographically. As such, the World Health Organization (WHO) has highlighted chikungunya as a major public health problem.[5]

**About Valneva SE**

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions.

We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market three proprietary travel vaccines.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, the world's most clinically advanced tetravalent Shigella vaccine candidate, as well as vaccine candidates against the Zika virus and other global public health threats. More information is available at www.valneva.com.

**Media and Investor Relations Contacts**


Laetitia Bachelot-Fontaine
VP Global Communications & European Investor Relations
M +33 (0)6 4516 7099
laetitia.bachelot-fontaine@valneva.com

Joshua Drumm, Ph.D.
VP Global Investor Relations
M +001 917 815 4520
joshua.drumm@valneva.com


**Forward-Looking Statements**

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to use and regulatory review of existing products. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be sustained in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties and delays involved in the development and manufacture of vaccines, unexpected clinical trial results or new adverse events, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made in this press release will in fact be realized. Valneva is providing this information as of the date of this press

[5] *Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)*

release and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.