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Valneva Announces FDA's Decision to Suspend License of Chikungunya Vaccine IXCHIQ® In the U.S.

Saint Herblain (France), August 25, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the United States Food and Drug Administration (FDA) has suspended the license for IXCHIQ®, citing four new reports of serious adverse events (SAEs) consistent with chikungunya-like illness. The suspension of the license is effective immediately and requires Valneva to stop shipping and selling of IXCHIQ® in the United States.

The suspension follows the FDA's decision on August 6, 2025[1] to remove its recommended pause[2] in the use of IXCHIQ® in individuals 60 years of age and older based on a thorough investigation of reported SAEs, primarily among elderly individuals with multiple underlying health conditions. The sudden subsequent decision to suspend IXCHIQ® is based on updated VAERS data (Vaccine Adverse Event Reporting System), which now includes four additional SAEs that occurred outside the United States. Of the four reported cases, three occurred in individuals aged 70 to 82 years, including one hospitalization of an 82-year-old individual who was discharged after two days; the remaining case occurred in a 55-year-old individual. Valneva believes all cases describe symptoms consistent with those previously reported during clinical trials and post marketing experience, particularly among the elderly individuals for whom the vaccine's Prescribing Information (PI) includes warnings and precautions. Valneva is continuing to investigate these cases in detail and if warranted will pursue further steps in connection with FDA's decision in accordance with applicable statutory procedures.

Valneva is committed to upholding the highest safety standards and will continue to engage proactively with health authorities in all territories where IXCHIQ® is licensed.

Thomas Lingelbach, Valneva's Chief Executive Officer, commented, "As we determine potential next steps, and as the clear threat of chikungunya continues to escalate globally, Valneva remains fully committed to maintaining access to our vaccine as a global health tool for addressing and preventing outbreaks of this devastating illness. We aim to continue providing IXCHIQ® to all countries where the product is licensed and continue our efforts with our partners to accelerate vaccine access in low-and-middle-income chikungunya-endemic countries – especially in response to any current or future chikungunya outbreaks, ensuring the vaccine reaches those most in need."

Valneva is evaluating the potential financial impact of a permanent withdrawal of the IXCHIQ® license in the United States but is not modifying its revenue guidance at this time. Sales of IXCHIQ® contributed €7.5 million to the Company's €91 million total product sales in the first half of 2025, a significant portion of which was the result of one-time delivery of vaccine doses to combat the chikungunya outbreak in La Reunion.

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[1] *https://valneva.com/press-release/valneva-announces-lifting-of-fdas-temporary-pause-on-use-of-chikungunya-vaccine-ixchiq-in-elderly-with-updates-to-the-prescribing-information/*

[2] *https://valneva.com/press-release/valneva-provides-update-on-recommended-use-of-ixchiq-by-elderly-individuals-in-the-united-states/*

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[3].

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[4]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[5] and the economic impact is considered to be significant. The medical and economic 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.[6]

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.

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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 and the impact of regulatory decisions on revenue guidance. 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

[3] https://jvi.asm.org/content/jvi/88/20/11644.full.pdf
[4] https://cmr.asm.org/content/31/1/e00104-16
[5] *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.*
[6] *Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)*

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 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.