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Valneva Announces Lifting of European Medicines Agency's Temporary Restriction on Use of Chikungunya Vaccine IXCHIQ® in Elderly

Saint Herblain (France), July, 11 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the European Medicines Agency (EMA) will lift the temporary restriction on vaccinating people aged 65 years and above after concluding a thorough review of Valneva's single-dose chikungunya vaccine IXCHIQ® by EMA's safety committee (PRAC).

The committee initiated its review at the beginning of May following the occurrence of serious side effects mainly in elderly people with several underlying medical conditions. In a press release published today on its website[1], EMA underlined that the vaccine is already contraindicated for people with a weakened immune system and concluded that, for people of all ages, IXCHIQ® should be given when there is a significant risk of chikungunya infection and after a careful consideration of the benefits and risks.

Additionally, EMA noted that while most serious side effects occurred in older people, IXCHIQ® is effective at triggering the production of antibodies against the chikungunya virus which may be of particular benefit for older people who are at increased risk of severe chikungunya disease.

IXCHIQ® was authorised in the European Union in June 2024[2] and, in March 2025, the European Commission granted a label extension in adolescents 12 years of age and older[3].

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[4].
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[5]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[6] 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.[7]

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[1] *Ixchiq: temporary restriction on vaccinating people 65 years and older to be lifted | European Medicines Agency (EMA)*
[2] *Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[3] *2025_02_28_IXCHIQ_Ado_Extension_CHMP_Positive_Opinion_PR_EN_Final.pdf*
[4] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*
[5] *https://cmr.asm.org/content/31/1/e00104-16*
[6] *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.*
[7] *Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)*

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. 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 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.