

## Valneva Provides Update Following European Medicines Agency Announcement on Use of IXCHIQ® in Elderly

**Saint Herblain (France), May, 07 2025** – [Valneva SE](#) (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the European Medicines Agency (EMA) has started a review of Valneva's single-dose live attenuated chikungunya vaccine IXCHIQ® based on reports of serious adverse events (SAEs) in elderly people. As a temporary measure, while this review is ongoing, EMA has suspended the use of the vaccine for individuals over 65 years old. EMA has maintained current recommendations for IXCHIQ® for people from 12 to 64 years of age.

The decision was taken following a plenary meeting of the Pharmacovigilance Risk Assessment Committee (PRAC) on May 5, 2025 and is based on reports of 17 SAEs worldwide (including two deaths) in elderly people with significant underlying medical conditions and/or co-medications. To date, over 40,000 doses of IXCHIQ® have been used worldwide.

Additionally, EMA highlighted that the exact cause of these serious adverse events and their relationship with the vaccine have not yet been determined and is reminding healthcare professionals that IXCHIQ® must not be given to people whose immune system is weakened because of disease or medical treatments, as stated in IXCHIQ®'s Summary of Product Characteristics (SmPC).

Valneva previously reported on changes to recommendations for use of IXCHIQ® in the U.S.<sup>1</sup> and France<sup>2</sup>. On April 16, 2025, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommended a precaution related to the use of Valneva's chikungunya vaccine IXCHIQ® in persons aged 65 and over.

On April 25, 2025, within the framework of the ongoing vaccination campaign initiated in La Réunion at the beginning of April prioritizing people aged 65 and older with comorbidities<sup>3</sup>, France's national public health agency, the Haute Autorité de Santé (HAS), suspended its recommendation for use of the vaccine in that age range pending further investigation. The vaccination campaign is maintained for people aged 18 to 64 years of age.<sup>4</sup>

**Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, said:** "We are deeply concerned by the reports of adverse events experienced by elderly individuals. Valneva remains committed to upholding the highest safety standards and respects the precautionary measures taken by authorities as investigations continue. The Company will continue to monitor all reported serious adverse events and fully cooperate with health authorities while also actively exploring a potential update to the product's indication."

The Company continues to see a positive risk-benefit in the vast majority of people with potential exposure to the disease.

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<sup>1</sup> [Valneva Provides Update on ACIP Recommendation for its Chikungunya Vaccine IXCHIQ® Among U.S. Travelers](#)

<sup>2</sup> [Valneva Provides Update on Recommendation for Use of Its Chikungunya Vaccine by French Authorities](#)

<sup>3</sup> [Valneva Responds to French Government's Call for Vaccine Supply of IXCHIQ® against Chikungunya Outbreak in La Réunion](#)

<sup>4</sup> [Valneva Provides Update on Recommendation for Use of Its Chikungunya Vaccine by French Authorities](#)



### 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<sup>5</sup>.

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<sup>6</sup>. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas<sup>7</sup> 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.<sup>8</sup>

### 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 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](http://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

<sup>5</sup> <https://jvi.asm.org/content/jvi/88/20/11644.full.pdf>

<sup>6</sup> <https://cmr.asm.org/content/31/1/e00104-16>

<sup>7</sup> 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.

<sup>8</sup> [Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas \(who.int\)](https://www.who.int/news-room/fact-sheets/detail/chikungunya)

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.

