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# Valneva Provides Update on Recommendation for Use of Its Chikungunya Vaccine by French Authorities

**Saint Herblain (France), April 26, 2025** – <u>Valneva SE</u> (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that France's national public health agency, the Haute Autorité de Santé (HAS), has updated its recommendation for use of Valneva's single-dose chikungunya vaccine IXCHIQ<sup>®</sup> for the prevention of disease caused by the chikungunya virus (CHIKV) following reports of serious adverse events (SAEs) in elderly people with comorbidities during the ongoing vaccination campaign in La Reunion and Mayotte. Valneva has been responding to the French government's call for vaccine supply of IXCHIQ<sup>®</sup> in La Reunion<sup>1</sup> as the island is going through a major chikungunya outbreak with ~ 40,000 confirmed cases since the beginning of 2025<sup>2</sup>.

The authorities initially prioritized vaccination of adults aged 65 and over, especially those with comorbidities. On April 25, the French health authorities decided to suspend the use of IXCHIQ<sup>®</sup> in persons aged 65 years and older pending further investigation. This is a response to an ongoing investigation of three cases of SAEs resulting in hospitalization, including one death, after vaccination with IXCHIQ<sup>®</sup> among people in La Reunion. The three individuals who were hospitalized were over 80 years old and had pre-existing comorbidities<sup>3</sup>. These SAEs were reported through the pharmacovigilance system set up by the French health authorities, and causality has not been definitively established. The HAS maintains its current recommendation for IXCHIQ<sup>®</sup> for people aged 18 to 64 years old as part of the ongoing vaccination campaign.

Valneva is also actively working with regulators on next steps.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "Valneva is committed to the highest standards of safety and agrees on the importance of continuing the stringent safety surveillance protocols that are in place. We appreciate the precautionary decision of the authorities while investigations remain ongoing and in the context of the active vaccination campaign. We continue to encourage providers to assess the benefit/risk of vaccination based on the individual's medical history, while we are working on a potential update of the product's indication."

To date, Valneva has supplied 40,000 doses of IXCHIQ<sup>®</sup> to La Reunion.

# 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>4</sup>.

<sup>&</sup>lt;sup>3</sup>Les autorités sanitaires retirent les personnes de 65 ans et plus des cibles de la campagne de vaccination contre le chikungunya avec le vaccin IXCHIQ à La Réunion et à Mayotte - Ministère du Travail, de la Santé, des Solidarités et des Familles *https://wi.com.acr/control/wi/99/20/11644.full.pdf* 





<sup>&</sup>lt;sup>1</sup> <u>Valneva Responds to French Government's Call for Vaccine Supply of IXCHIQ® against Chikungunya Outbreak in La Réunion -</u> <u>Valneva</u>

<sup>&</sup>lt;sup>2</sup> <u>https://www.lareunion.ars.sante.fr/index.php/chikungunya-la-reunion-semaine-du-7-au-13-avril-</u>

<sup>2025#:~:</sup>text=L'%C3%A9pid%C3%A9mie%20de%20chikungunya%20se,hospitalisations%20sont%20en%20l%C3%A9g%C3%A8re%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<sup>5</sup>. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas<sup>6</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>7</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.

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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

<sup>&</sup>lt;sup>6</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>7</sup> Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)



<sup>&</sup>lt;sup>5</sup> https://cmr.asm.org/content/31/1/e00104-16



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.

