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Valneva Provides Update on Chikungunya Vaccine IXCHIQ®

- Company voluntarily withdraws IXCHIQ BLA and IND in the U.S.
- Continuing review of global product opportunity according to medical need and commercial attractiveness

Saint Herblain (France), January 19, 2026 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the Company has decided to voluntarily withdraw the biologics license application (BLA) and Investigational New Drug (IND) application for its chikungunya vaccine, IXCHIQ®, in the United States, following suspension of the license by the U.S. Food and Drug Administration (FDA) in August 2025. The Company had been awaiting further information with respect to its formal response to the vaccine license suspension. Valneva was recently informed of the FDA's further decision to now place the Investigational New Drug (IND) on clinical hold pending an investigation of a newly reported foreign Serious Adverse Event (SAE).

There are currently no clinical studies involving IXCHIQ® that are actively vaccinating participants, and the Company intends to move forward with its planned post-marketing clinical activities, subject to further discussions with relevant regulatory authorities.

The SAE occurred outside of the U.S. and involved a younger adult who received three concomitant vaccines, including IXCHIQ®. Based on the information made available to Valneva, which the Company submitted to the U.S. Vaccine Adverse Event Reporting System (VAERS) as well as to all other pharmacovigilance systems in accordance with the products license, the case may be plausibly related to IXCHIQ® vaccination, but causality has not been determined. The Company is actively seeking additional information to further characterize the case.

Valneva is committed to upholding the highest safety standards, and the Company continues to engage proactively with health authorities in all territories where IXCHIQ® is licensed, including Europe, Canada, the United Kingdom and Brazil. While IXCHIQ® is currently focused on travelers to regions where the virus is endemic, such as tropical and subtropical areas in Asia, Africa, and the Americas, and persons for whom vaccination is medically justified based on risk in accordance with the approved label and vaccination guidance, the Company continues to believe that IXCHIQ®'s benefit-risk profile also remains favorable for people living in the endemic and outbreak settings, where IXCHIQ® may be uniquely positioned as a highly durable single-shot vaccine.

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[1].
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[2]. Between 2013 and 2023, more than 3.7 million cases were reported in

[1] https://jvi.asm.org/content/jvi/88/20/11644.full.pdf
[2] https://cmr.asm.org/content/31/1/e00104-16

the Americas[3] 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.[4]

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 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, regulatory review, sales, and safety 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

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[3] *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.*

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

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.