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Valneva Submits Label Extension Application for its Chikungunya Vaccine, IXCHIQ®, to the U.S. FDA

To potentially include adolescents and antibody persistence up to two years

Saint Herblain (France), November 26, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that it has submitted a label extension application to the U.S. Food and Drug Administration (FDA) to potentially extend the use of its chikungunya vaccine IXCHIQ®, which is currently approved in adults, to adolescents aged 12 to 17 years. The application also includes adding the two-year antibody persistence data to the product label, which is a key differentiator for IXCHIQ®. This FDA application follows the submission of label extension applications to the European Medicines Agency (EMA) and Health Canada two months ago[1].

These label extension applications are based on positive adolescent Phase 3 data, which the Company reported in May 2024[2]. These data showed that a single-dose vaccination with IXCHIQ® induces a high and sustained immune response in 99.1% of adolescents, and that the vaccine was generally well tolerated. *The Lancet Infectious Diseases,* a world leading infectious diseases journal, also recently published an article showing that the vaccine was well tolerated in adolescents aged 12 to 17 years 28 days after a single injection, regardless of previous CHIKV infection.

In addition to the adolescent data, the U.S. and Canadian label extension applications included IXCHIQ®'s long-term antibody persistence data, which showed that the vaccine's immune response was sustained by 97% of participants after 24 months and was equally durable in younger and older adults[3]. These persistence data were already included in the initial EMA filing. The Company expects to publish 36-month persistence data in the coming weeks.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "Given the substantial risk that chikungunya presents to individuals residing in or traveling to endemic regions, it's imperative to ensure the vaccine is available to all age groups. This broader accessibility would certainly help provide protection and mitigate the burden of this debilitating illness which is currently spreading in areas that were previously unaffected. The long-term durability of the immune response from a single shot is also extremely important, especially for endemic countries where access to immunization can be difficult."

IXCHIQ® is the world's first and only licensed chikungunya vaccine available to address this significant unmet medical need. The vaccine is currently approved in the U.S.[4], Europe[5], and Canada[6] for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older. It was launched in the U.S. at the beginning of March 2024, following adoption of the

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[1] *Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ®, to EMA and Health Canada - Valneva*
[2] *Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine - Valneva*
[3] *Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva*
[4] *Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[5] *Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[6] *Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*

U.S. Advisory Committee on Immunization Practices (ACIP)'s recommendations by the U.S. Centers for Disease Control and Prevention (CDC), and launches in France and Canada are underway.

In addition to ramping up sales, Valneva is focused on expanding the vaccine's label and access. The Company expects a marketing authorization in Brazil before the end of the year and expanded its partnership with The Coalition for Epidemic Preparedness Innovations (CEPI) earlier this year[7] to support broader access to the vaccine in Low and Middle-Income Countries (LMICs), post-marketing trials and potential label extensions in children, adolescents and pregnant women. CEPI will provide Valneva up to $41.3 million of additional funding over the next five years, with support from the European Union's (EU) Horizon Europe program.

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.[8]

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.[9] Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[10] 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.[11]

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, including the world's first and only chikungunya vaccine, as well as certain third-party 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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[7] *CEPI Expands Partnership with Valneva with a $41.3 Million Grant to Support Broader Access to the World's First Chikungunya Vaccine - Valneva*

[8] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*

[9] *https://cmr.asm.org/content/31/1/e00104-16*

[10] *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.*

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

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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 the progress, timing, results and completion of research, development and clinical trials for product candidates, to regulatory approval of product candidates and 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, 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.