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Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ®

Saint Herblain (France), July 1, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the European Commission (EC) has granted marketing authorization in Europe for Valneva's single-dose vaccine, IXCHIQ®, for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older. The approval was unanimously endorsed by Member States following a stringent assessment by the European Medicines Agency (EMA)[1]. The EC decision marks the third approval the Company has received for IXCHIQ® following approval from the U.S. Food and Drug Administration (FDA) in November 2023 and Health Canada last month[2]. The Company expects to deliver the first doses in Europe in the fourth quarter of 2024.

IXCHIQ® is the world's only licensed chikungunya vaccine available to address this unmet medical need. In accordance with the International Recognition Procedure (IRP)[3], Valneva has also submitted a Marketing Authorization Application (MAA) to the UK Medicines and Healthcare products Regulatory Agency (MHRA). An additional marketing authorization application is under review by the Brazilian Health Regulatory Agency (ANVISA) to make the vaccine available in certain Low- and Middle-Income Countries (LMIC), with potential approval in 2024.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "The EC approval marks a crucial milestone toward making this vaccine available to as many European citizens as possible. In recent years, climate change has caused the Aedes mosquito, a known carrier of chikungunya and dengue viruses, to spread to areas in Europe that were previously unaffected. It is critical to provide a vaccine solution not only to European travelers going to endemic chikungunya areas, such as South America or Africa, but also to the local European populations experiencing invasive mosquito attacks. We would like to thank our partner, CEPI, for supporting us in this endeavor."

Dr. Richard Hatchett, Chief Executive Officer of the Coalition for Epidemic Preparedness Innovations (CEPI), commented, "Supported by CEPI and EU funding, IXCHIQ is the world's first vaccine offering protection against the debilitating Chikungunya virus. The EU's rapid approval of the vaccine, following recommendation by the European Medicines Agency, is a historic moment to help protect the lives and livelihoods of European populations against Chikungunya outbreaks, which are becoming more frequent and widespread in the region. But the fight is not over – as a matter of priority CEPI is working with Valneva and the EU to expand access to the vaccine to those living in endemic countries who are greatest risk from the disease."

The EC marketing authorization follows the European Medicines Agency's (EMA) positive opinion a month ago[4] and is supported by data from the pivotal Phase 3 study which were published in The

[1] *Commission authorises Chikungunya vaccine (europa.eu)*
[2] *Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[3] *International Recognition Procedure - GOV.UK (www.gov.uk)*
[4] *Valneva Receives EMA's Positive CHMP Opinion for its Chikungunya Vaccine - Valneva*

Lancet, and showed a 98.9% seroresponse rate at 28 days with a single vaccination. This immune response was sustained for 24 months by 97% of participants and was equally durable in younger and older adults[5]. Last month, Valneva reported further positive pivotal data in adolescents six months after a single vaccination, which are intended to support filing for potential label extension for use in adolescents aged 12 to 17 years[6]. The data are also expected to support licensure of IXCHIQ® in Brazil, which would be the first potential approval for use in an endemic population.

Valneva partnered with CEPI[7] and Instituto Butantan in Brazil[8] to make the vaccine more accessible to LMIC. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[9], which provides funding of up to $24.6 million with support from the European Union's Horizon 2020 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 pain, muscle pain, headache, nausea, fatigue and rash. Joint pain is often debilitating and can persist for weeks to years.[10]

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.[11] Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[12] 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.[13]

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

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[5] *Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva*
[6] *Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine - Valneva*
[7] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*
[8] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
[9] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*
[10] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*
[11] *https://cmr.asm.org/content/31/1/e00104-16*
[12] *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.*
[13] *Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)*

development, which is partnered with Pfizer, 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 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.