

## Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ®

**Saint-Herblain (France), November 10, 2023** – [Valneva SE](#) (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the U.S. Food and Drug Administration (FDA) has approved IXCHIQ®, Valneva's single-dose, live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. This indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody titers. Continued approval for this indication is contingent upon verification of clinical benefit in confirmatory studies.

The Company will hold an analyst call and a webcast at 3:00pm CET or 9:00am EDT on Monday, November 13, 2023. The link will be available on the Company's investor page. Please refer to this link [Investors - Valneva](#).

As sponsor of the first chikungunya vaccine approved in the U.S., Valneva has received a Priority Review Voucher (PRV) from the FDA, which it intends to monetize to help finance its research and development (R&D) programs.

With this U.S. approval, IXCHIQ® becomes the world's first licensed chikungunya vaccine available to address this unmet medical need and the third vaccine Valneva<sup>1</sup> has brought from early R&D to approval. Valneva reported final pivotal Phase 3 data for the vaccine in March 2022 showing a 98.9% seroresponse rate at 28 days with a single vaccination<sup>2</sup> and final lot-to-lot consistency results in May 2022<sup>3</sup>. IXCHIQ®-induced seroresponse was sustained over time with a 96.3% seroresponse rate six months post-vaccination<sup>2</sup>. Valneva will continue to evaluate antibody persistence for at least five years<sup>4</sup>. The Company's pivotal Phase 3 results were published in the [Lancet](#) in June 2023.

Every year, more than 60 million Americans travel to countries where mosquito-borne diseases are endemic<sup>5</sup>. Initially addressing the potential needs of U.S. travelers, IXCHIQ® fits seamlessly into Valneva's global established travel vaccines business, which includes vaccines against Japanese encephalitis and cholera/ETEC<sup>6</sup>, leveraging Valneva's existing commercial and industrial infrastructure, which has been augmented with this newest product.

Valneva plans to begin commercializing IXCHIQ® in the U.S. early next year while continuing to support the work towards an anticipated vote from the Advisory Committee on Immunization Practices (ACIP) at the end of February 2024.

**Thomas Lingelbach, Chief Executive Officer of Valneva**, said, "As a leading specialty vaccines company, we aim to deliver vaccines in areas of unmet medical need supporting our

<sup>1</sup> This statement refers to Valneva and its predecessor Intercell

<sup>2</sup> [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

<sup>3</sup> [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate](#)

<sup>4</sup> [Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate](#)

<sup>5</sup> <https://www.trade.gov/feature-article/us-citizen-international-outbound-travel-six-percent-2018>

<sup>6</sup> Indications differ by country – Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed; ETEC = Enterotoxigenic *Escherichia coli* (E. Coli) bacterium

vision to contribute to a world in which no one dies or suffers from a vaccine preventable disease. As such, today marks an important step forward in the prevention of chikungunya. I would like to personally express a huge thank you to everyone who helped make this possible. I would also like to recognize CEPI and Instituto Butantan for their collaboration in potentially bringing this product to low- and middle-income countries.”

**Dr. Richard Hatchett, Chief Executive Officer of the Coalition for Epidemic Preparedness Innovations (CEPI)**, commented, “The first-ever licensed chikungunya vaccine will play a crucial role in preventing the suffering caused by this debilitating disease. Climate change is intensifying the threat posed by chikungunya, which means safe and effective vaccines are needed now more than ever before. Through our partnership with Valneva and Instituto Butantan, CEPI – with support from the EU – will help to make this vaccine accessible to the people most affected by the virus in low- and middle-income countries. I am proud of our contribution and congratulate our partner Valneva on this historic achievement.”

**Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva**, added, “Today, it is estimated that more than 75% of the world's population lives in areas at risk of CHIKV transmission due to factors such as global warming and climate change<sup>7</sup>. Chikungunya has already spread to over 110 countries and is currently regarded as one of the most likely viral infections to emerge in new geographic areas. Morbidity is high with 43% of CHIKV patients suffering from chronic chikungunya where joint pain, fatigue, and potentially debilitating effects may last from months to years and can have substantial impact on daily activities<sup>7,8</sup>. As we are introducing IXCHIQ<sup>®</sup>, our objective is to make this vaccine available to the largest number of people that will benefit from it.”

Earlier this year, the Pan American Health Organization (PAHO) issued an epidemiological alert as the number of cases and deaths due to chikungunya continues to rise in the Americas<sup>9</sup>. Modeling now shows the problem may only worsen due to climate change. As the Earth's temperature continues to rise, vector habitats are likely to expand, which poses an immediate risk of outbreaks in warmer areas of the United States and Europe<sup>10</sup>.

A clinical study in adolescents, aged 12 to 17 years, is ongoing in Brazil<sup>11</sup> as part of an agreement signed between Instituto Butantan and Valneva in January 2021<sup>12</sup> to make the vaccine more accessible to Low- and Middle-Income Countries (LMIC). The study, funded by the Coalition for Epidemic Preparedness Innovations (CEPI), may support future regulatory submissions in this

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7 Puntasecca CJ, King CH, LaBeaud AD. "Measuring the global burden of chikungunya and Zika viruses: A systematic review." *PLOS Negl Trop Dis* 15, no. 3 (2021): e0009055.

8 Paixão, E. S., Rodrigues, L. C., Costa, M., Itaparica, M., Barreto, F., Gérardin, P., & Teixeira, M. G. "Chikungunya chronic disease: a systematic review and meta-analysis." *Transactions of the Royal Society of Tropical Medicine and Hygiene* 7, no. 112 (2018): 301-316

9 Pan American Health Organization / World Health Organization. *Epidemiological Alert: Chikungunya increase in the Region of the Americas*. 13 February 2023, Washington, D.C. PAHO / WHO. 2023 <https://www.paho.org/en/documents/epidemiological-alert-chikungunya-increase-region-americas> accessed August 2023

10 Rocklöv, J., Dubrow, R. *Climate change: an enduring challenge for vector-borne disease prevention and control*. *Nat Immunol* 21, 479–483 (2020). <https://doi.org/10.1038/s41590-020-0648-y>

11 *Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva*

12 *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*

age group as well as licensure of the vaccine in Brazil, which would be the first potential approval for use in an endemic region.

The study is also expected to support regulatory approval in Europe. Initial safety data from this trial were included in the submission to the European Medicines Agency (EMA) in October 2023<sup>13</sup>. The vaccine was granted Priority Medicine (PRIME) designation by EMA in 2020. A regulatory review is currently also underway with Health Canada.

### **About Chikungunya**

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. Infection leads to symptomatic disease in up to 97% of humans after four to seven days following the mosquito bite<sup>14</sup>. While mortality with CHIKV is low, morbidity is high, and the global market for vaccines against chikungunya is estimated to exceed \$500 million annually by 2032<sup>15</sup>. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The high-risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia, and the virus has spread to more than 110 countries<sup>16</sup>. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas<sup>17</sup> and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread geographically. Before IXCHIQ®, there were no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

### **About IXCHIQ®**

In the U.S., IXCHIQ® is a live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. As for all products approved under FDA's accelerated approval pathway, continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory studies.

## **IXCHIQ® (chikungunya virus, live) Solution for Intramuscular Injection**

### **Indication**

IXCHIQ® is a vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years and older who are at increased risk of exposure to CHIKV. This

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13 Valneva Submits Chikungunya Vaccine Marketing Application to EMA and Announces CHMP Accelerated Assessment

14 Staples, J.E., Hills, S.L., Powers, A.M. "Chikungunya." In *CDC Yellow Book 2020: Health Information for International Travel*, by Centers for Disease Control and Prevention. New York: Oxford University Press, 2020

15 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

16 <https://www.who.int/news-room/fact-sheets/detail/chikungunya>

17 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.

indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody titers. Continued approval for this vaccine is contingent upon verification and description of clinical benefit in confirmatory studies.

**IMPORTANT SAFETY INFORMATION ABOUT IXCHIQ<sup>®</sup>** – Please consult the full prescribing information for all the labeled safety information.

### **Contraindications**

IXCHIQ<sup>®</sup> should not be given to individuals who have a weakened immune system due to medications used for hematologic and solid tumors, on chemotherapy, history of congenital immunodeficiency, long-term immunosuppressive therapy, or patients with HIV infection who are severely immunocompromised.

Individuals with a history of a severe allergic reaction to any component of the vaccine.

### **Warnings**

**Appropriate medical treatment used to manage immediate allergic reactions** must be available in the event an acute anaphylactic reaction following administration of IXCHIQ<sup>®</sup> or any vaccine.

**Vaccination with IXCHIQ<sup>®</sup> may cause severe or prolonged chikungunya-like adverse reactions.** Severe chikungunya-like adverse reactions that prevented daily activity and/or required medical intervention occurred in 1.6% of 3,082 IXCHIQ<sup>®</sup> recipients and no placebo recipients. Fourteen IXCHIQ<sup>®</sup> recipients had prolonged (duration at least 30 days) chikungunya-like adverse reactions.

**Infection of pregnant individuals with wild-type chikungunya virus can result in intrapartum transmission and potentially fatal neonatal complications.** IXCHIQ<sup>®</sup> should be administered during pregnancy only after an individual risk-benefit assessment, considering maternal risk of chikungunya infection and gestational age.

Fainting can occur with administration of IXCHIQ<sup>®</sup>. Procedures should be in place to avoid injury from fainting.

**IXCHIQ<sup>®</sup> may not protect all individuals who receive the vaccine.**

### **Adverse Reactions**

The most common injection site reaction (>10%) was tenderness (11%) and the most common systemic adverse reactions (>10%) were headache (31%), fatigue (29%), myalgia (24%), arthralgia (17%), fever (13%) and nausea (11%).

## Use in Specific Populations

### Pregnancy

There are no adequate and well-controlled studies of IXCHIQ® in pregnant individuals, and human data available from clinical trials with IXCHIQ® are insufficient to establish the presence or absence of vaccine-associated risk during pregnancy.

Please [click here](#) for full Prescribing Information for IXCHIQ®.

### 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 two proprietary travel vaccines as well as certain third-party vaccines leveraging our established commercial infrastructure.

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, potentially the world's first vaccine against the chikungunya virus, as well as vaccine candidates against the Zika virus and other global public health threats.

### Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine  
VP Global Communications & European Investor Relations  
M +33 (0)6 4516 7099  
laetitia.bachelot-fontaine@valneva.com

Joshua Drumm, Ph.D.  
VP Global Investor Relations  
M +001 917 815 4520  
joshua.drumm@valneva.com

### 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 during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.