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Valneva Receives First Marketing Authorization for IXCHIQ® in a Chikungunya Endemic Country

Saint Herblain (France), April 14, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company today announced that the Brazilian Health Regulatory Agency (ANVISA) has granted marketing authorization to its single-dose vaccine IXCHIQ® for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older. The ANVISA decision marks the world's first approval of a chikungunya vaccine in an endemic country. Part of Valneva's endemic country strategy, this endeavor is supported by the Coalition for Epidemic Preparedness Innovations (CEPI)[1], with co-funding from the European Union (EU), and Instituto Butantan[2] to support broader access to a chikungunya vaccine in low-and-middle-income countries (LMICs).

IXCHIQ® is the world's first licensed chikungunya vaccine available to address this significant unmet medical need. In addition to Brazil, IXCHIQ® is approved for the prevention of disease caused by the chikungunya virus in people aged 12 years and older in the EU, and in people aged 18 years and older in the United States (U.S.)[3], Canada[4] and the United Kingdom (U.K.)[5]. Label extension applications to adolescents were submitted in the U.S., Canada and the U.K.

This important approval primarily enables initiation of large-scale clinical trials of IXCHIQ® in Brazil, including the committed Phase 4 clinical trials supporting IXCHIQ®'s approval by the U.S. Food and Drug Administration (FDA) and the European Commission to generate additional data on vaccine effectiveness. CEPI is providing funding support to these trials.

ANVISA continues to review VLA1555, the chikungunya vaccine candidate which, if approved, will be locally manufactured and distributed by Instituto Butantan pursuant to its collaboration with Valneva. Potential approval is anticipated in mid-2025. Instituto Butantan is committed to providing a locally manufactured vaccine at an affordable price in Latin America and selected LMICs.

Valneva and Instituto Butantan are working together to ensure fast access to its chikungunya vaccines for the Brazilian market and other countries in the region as quickly as possible. The Americas saw nearly 300,000 chikungunya cases and 300 deaths attributed to the virus between January and July 2023, totaling more than 720,000 cases since 2020[6]. Brazil has reported the highest number of cases, with over 1 million total between January 2019 and July 2024[6].

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "This approval marks a crucial milestone toward making our chikungunya vaccine available to LMICs where the disease is endemic. The ongoing outbreak in Brazil underscores the fact that containing chikungunya is an international public health priority. Our vaccine is particularly well suited for LMICs, where vaccine access is often limited, due to its ability to induce a robust, long-lasting antibody response in both

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[1] *CEPI awards up to US$23.4 million to Valneva for late-stage development of a single-dose chikungunya vaccine - Valneva*
[2] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries - Valneva*
[3] *Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[4] *Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[5] *Valneva Receives Marketing Authorization in the UK for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[6] *Vaccines on the table as chikungunya outbreak intensifies in India - BlueDot*

younger and older adults with a single vaccination. We would like to thank our partners CEPI and Instituto Butantan for helping us address this urgent medical need by accelerating further access to our highly differentiated vaccine."

Dr. Esper Kallás, Director of Instituto Butantan added, "The approval of the chikungunya vaccine is a great victory for Brazil, where over 150,000 people suffer from the disease every year. It is an honor for Butantan to be able to contribute to ensuring that this vaccine reaches the population that needs it the most."

Dr. Richard Hatchett, Chief Executive Officer of the Coalition for Epidemic Preparedness Innovations (CEPI), commented, "As we confront the ongoing challenges posed by chikungunya, today marks a significant step forward in our collective efforts to expand access to an important vaccine to not only benefit the travelers' market but also populations in need in outbreak-affected countries, like Brazil. ANVISA's marketing authorization of the vaccine offers new hope in the fight against the debilitating disease and allows us to make headway in our goal to protect the tens of thousands in the country who suffer from chikungunya each year. Brazil's approval is testament to the power of collaboration, innovation and determination and should help set the world up for additional approvals in other endemic regions in the near future."

Supported by CEPI and the EU's Horizon program, Valneva remains focused on expanding the vaccine's access in LMICs. In December 2024, Valneva announced a new partnership with the Serum Institute of India (SII), the world's largest manufacturer of vaccines by number of doses, enabling supply of the vaccine in Asia[7].

Additionally, as part of the CEPI and EU support, Valneva is conducting a Phase 2 trial in children aged 1 to 11 years in the Dominican Republic and Honduras, for which it reported positive results in January 2025. The trial is intended to support a pivotal Phase 3 study in children, which the Company expects to initiate in the fourth quarter of 2025, with the objective to extend the product label to this age group. Valneva is also expected to evaluate the vaccine in pregnant women in countries affected by chikungunya outbreaks, like Brazil[8].

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[9].

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

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[7] *Valneva Successfully Expands Access to Asia for its Chikungunya Vaccine with Serum Institute of India - Valneva*

[8] *CEPI expands partnership with Valneva with $41.3 million to support broader access to world's first Chikungunya vaccine | CEPI*

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

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

[11] *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.*

continue to spread geographically. As such, the World Health Organization (WHO) has highlighted chikungunya as a major public health problem.[12]

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 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.

About Instituto Butantan

Instituto Butantan is the main producer of immunobiological products and vaccines in Brazil. Instituto Butantan carries out scientific missions domestically and abroad through the Pan American Health Organization, the World Health Organization, UNICEF and the United Nations. The Institute is an affiliate of the São Paulo State Secretariat of Health and cooperates with the Brazilian Ministry of Health for the improvement of overall health in Brazil. It acts in partnership with various universities and entities such as the Bill & Melinda Gates Foundation for the achievement of its institutional objectives. For more information please visit the Institute website at www.butantan.gov.br or contact the press office at (+55 11) 2627-9606 / 9428 or email to imprensa@butantan.gov.br

About CEPI

CEPI was launched in 2017 as an innovative partnership between public, private, philanthropic and civil organizations. Its mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. CEPI has supported the development of more than 50 vaccine candidates or platform technologies against multiple known high-risk pathogens or a future Disease X. Central to CEPI's pandemic-beating five-year plan for 2022-2026 is the '100 Days Mission' to compress the time taken to develop safe, effective, globally accessible vaccines against new threats to just 100 days.

Learn more at CEPI.net. Follow us on X (@CEPIvaccines), LinkedIn and Facebook.

About Horizon Europe

Horizon Europe — #HorizonEU — is the European Union's flagship Research and Innovation programme, part of the EU-long-term Multiannual Financial Framework (MFF) with a budget of €95,5 billion to spend over a seven-year period (2021-2027). Under Horizon Europe, health research will

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

be supported with the aim to find new ways to keep people healthy, prevent diseases, develop better diagnostics and more effective therapies, use personalised medicine approaches to improve healthcare and wellbeing, and take up innovative health technologies, such as digital ones.

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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 business partnerships and the progress, timing, results and completion of technology transfer and regulatory approvals in additional markets. 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.