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

Saint Herblain (France), February 5, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization in the United Kingdom (UK) for the world's first and only chikungunya vaccine, IXCHIQ®. The single-dose vaccine is indicated for active immunization for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older. The vaccine is manufactured at Valneva's leading vaccine production site in Livingston, Scotland.

The approval is based on IXCHIQ®'s final pivotal Phase 3 data, published in The Lancet, which included more than 4,000 participants and demonstrated that a single dose of the live-attenuated IXCHIQ® vaccine induces a rapid and strong immune response. Data has since shown this response can be maintained for at least three years in both younger and older adults[1].

The UK approval marks the fourth regulatory approval Valneva has received for its single-shot chikungunya vaccine. The vaccine is currently approved in the United States (U.S.)[2], Europe[3] and Canada[4] in adults 18 years of age and older. Valneva expects to receive marketing approval in Brazil in the first quarter of 2025, which would represent the first approval in an endemic country. Valneva submitted label extension applications to the U.S. Food and Drug Administration (FDA)[5], the European Medicines Agency (EMA) and Health Canada[6] to potentially extend the use of IXCHIQ® to adolescents aged 12 to 17 years. The Company now also plans to submit a label extension application to MHRA.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "This latest approval is a further recognition of IXCHIQ®'s strong product profile and the medical need for a chikungunya vaccine. Travelers from the UK consistently rank among India's largest tourist groups given cultural ties and shared history. With the current outbreak in India, it is critical to ensure UK travelers have access to this vaccine, not only for their protection when travelling to India or other chikungunya endemic countries but also to prevent potential chikungunya transmission when returning to the UK. Considering the significant risk chikungunya poses to individuals living in or traveling to endemic areas, it's crucial to ensure that the vaccine is accessible to people of all ages and capable of potentially offering long-term protection from a single shot."

In 2023, 920,000 UK travellers visited India[7], which recorded the second highest number of chikungunya cases worldwide over five years, with 370,000 cases reported between January 2019

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[1] *Valneva Reports Positive Three-Year Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva*
[2] *Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[3] *Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[4] *Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[5] *Valneva Submits Label Extension Application for its Chikungunya Vaccine, IXCHIQ®, to the U.S. FDA - Valneva*
[6] *Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ®, to EMA and Health Canada - Valneva*
[7] *United Kingdom Becomes Third Largest Tourism Source Market for India - Travel And Tour World*

and July 2024[8]. The number of cases in India is rapidly increasing due to the current outbreak in the Indian states of Maharashtra and Telangana, for which the U.S. Centers for Disease Control and Prevention (CDC) issued a travel notice after identifying higher-than-expected numbers of chikungunya cases in returning travelers[9].

Dr. Richard Hatchett, Chief Executive Officer of the Coalition for Epidemic Preparedness Innovations (CEPI), supporting late-stage development and broader access to the vaccine**,** commented, "In a warming world, mosquito-borne diseases like chikungunya are causing more frequent and severe outbreaks around the world, so it is vital that we keep people safe from this debilitating illness. Today's MHRA approval of Valneva's IXCHIQ® vaccine is an important step forward in protecting UK citizens travelling to affected countries – but the fight is not over. Our work now focusses on expanding access to vaccine doses, at an affordable price, in those endemic regions. As a major investor in CEPI, the UK Government is providing vital support to advance this goal, helping to make the vaccine accessible to those in Low- and Middle- Income Countries (LMICs) who are most at risk from the disease, while also protecting their own population."

Valneva entered a partnership with CEPI in 2019[10], with support from the European Union (EU) Horizon program, to support late-stage development of IXCHIQ® and expand access to the vaccine for at-risk populations in affected countries. Valneva and CEPI expanded their partnership in the third quarter of 2024[11], with support from the EU, through a $41.3 million grant to advance broader access to the vaccine in LMICs, including outbreak-affected countries, post-marketing studies and research to support potential label extensions in children, adolescents and pregnant women.

Within the framework of this partnership, Valneva recently announced the signing of an exclusive license agreement with the Serum Institute of India (SII), the world's largest manufacturer of vaccines by number of doses[12], enabling the supply of the vaccine in Asia, with a commitment to priority supply of the chikungunya vaccine at an affordable price to public health markets in LMICs. This new agreement complements the license agreement Valneva signed in 2021 with Instituto Butantan in Brazil for the development, manufacturing and marketing of a local chikungunya vaccine at an affordable price for distribution in Latin American countries and selected LMICs affected by the disease.

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[13].

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

[8] https://bluedot.global/vaccines-on-the-table-as-chikungunya-outbreak-intensifies-in-india/
[9] https://wwwnc.cdc.gov/travel/notices/level2/chikungunya-telangana-india
[10] *CEPI awards up to US$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine | CEPI*
[11] *CEPI Expands Partnership with Valneva with a $41.3 Million Grant to Support Broader Access to the World's First Chikungunya Vaccine - Valneva*
[12] *Valneva Successfully Expands Access to Asia for its Chikungunya Vaccine with Serum Institute of India - Valneva*
[13] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*
[14] *https://cmr.asm.org/content/31/1/e00104-16*

the Americas[15] 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.[16]

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.

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 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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[15] *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.*

[16] *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.