**VALNEVA SE**
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# Valneva's Chikungunya Vaccine IXCHIQ® Now Authorized in EU for Adolescents Aged 12 and Above

**With this extension, IXCHIQ®, the first vaccine against the chikungunya virus (CHIKV), is now available for administration for individuals 12 years of age and older in the European Union (EU).**

**Saint Herblain (France), April 1, 2025** – 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 12 years of age and older. This label extension complements the adult marketing authorization in Europe Valneva received in July 2024[1]. With this approval, IXCHIQ® becomes available in the market for adolescents in the EU, Norway, Liechtenstein and Iceland.

IXCHIQ® is the world's first licensed chikungunya vaccine available to address this significant unmet medical need. In addition to its approval in adolescents and adults in the EU, it is approved in the United States (U.S.)[2], Canada[3] and the United Kingdom (U.K.)[4] for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older. Similar label extension applications to adolescents were also submitted in the U.S., Canada and the U.K.

**Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva**, said, "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 adolescent approval marks a crucial milestone toward introducing a more robust preventative solution against chikungunya in the EU. Broader accessibility will help provide protection and mitigate the burden of this debilitating illness, which is continuing to spread in areas that were previously unaffected."

Chikungunya has become an increasingly pressing public health issue, with outbreaks currently ongoing in India, Brazil and the French Island of La Réunion. Valneva announced last week that it has responded to the French government's call for supply of IXCHIQ® in La Réunion and that it will provide 40,000 doses to the Island's wholesalers, with an option to provide more[5].

**Dr. Richard Hatchett, Chief Executive Officer of the Coalition for Epidemic Preparedness Innovations (CEPI),** commented, "Cases of chikungunya are increasing around the world, making populations of all ages vulnerable to the disease's long-term debilitating effects, such as prolonged joint plan and inflammation. EC's marketing authorization for use of IXCHIQ® in adolescents in the

[1] *Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ®*
[2] *Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[3] *Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[4] *Valneva Receives Marketing Authorization in the UK for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[5] *Valneva Responds to French Government's Call for Vaccine Supply of IXCHIQ® against Chikungunya Outbreak in La Réunion - Valneva*

EU is an important steppingstone that could help accelerate the approval of the vaccine in this age group in other regions, including areas where the disease is endemic."

The EC adolescent marketing authorization is supported by positive six-month adolescent Phase 3 data which Valneva reported in May 2024[6]. These data, collected through a study in Brazil funded by CEPI and the EU's Horizon Program, showed that a single-dose vaccination with IXCHIQ® induces a high immune response in 99.1% of adolescents, and that the vaccine was generally well tolerated[7]. Valneva recently announced that this immune response was sustained in 98.3% of adolescents one-year after single vaccination[8]. These results reaffirm the strong and persistent immune response with only one dose already seen in adults[9]. The Lancet Infectious Diseases, a world leading infectious diseases journal, also published an article[10] showing that the vaccine was generally safe and well tolerated in adolescents 12 to 17 years of age 28 days after a single injection, regardless of previous CHIKV infection.

Valneva is focused on expanding the vaccine's label and access. In the third quarter of 2024, the Company expanded its partnership with CEPI[11], with support from the EU's Horizon Europe program, through a $41.3 million grant to advance broader access to the vaccine in Low- and Middle-Income Countries (LMICs), post-marketing studies and research to support potential label extensions in children, adolescents and pregnant women.

Within the framework of this partnership, in December 2024, Valneva 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, 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[12].

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

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[6] *Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine*
[7] *Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine*
[8] *Valneva Reports High Sustained Immune Response in Adolescents One Year After Single Vaccination with its Chikungunya Vaccine - Valneva*
[9] *Valneva Reports Positive Three-Year Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva*
[10] *Safety and immunogenicity of a live-attenuated chikungunya virus vaccine in endemic areas of Brazil: interim results of a double-blind, randomised, placebo-controlled phase 3 trial in adolescents*
[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] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*
[13] *https://cmr.asm.org/content/31/1/e00104-16*

the Americas[14] 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.[15]

**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 tetravalent 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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**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

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[14] *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.*

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

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 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.