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Valneva's Chikungunya Vaccine IXCHIQ® Now Authorized in Canada for Individuals Aged 12 and Older

Saint Herblain (France), August 18, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that Health Canada has granted marketing authorization for its single-dose vaccine, IXCHIQ®, for the prevention of disease caused by the chikungunya virus in individuals aged 12 years and older. This announcement adds to the adult marketing authorization already received in Canada[1] and complements the adolescent label extension received in Europe in April 2025[2].

In addition to the adolescent data, Health Canada's label extension application included IXCHIQ®'s antibody persistence data, which show that the vaccine's immune response was sustained for 24 months by 97% of participants and was equally durable in younger and older adults[3].

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, said, "This approval marks another major milestone for our vaccine as chikungunya continues to pose a significant risk to people living in or traveling to endemic regions. Ensuring our vaccine is accessible to all age groups is especially important. We await further regulatory decisions from other countries where broader access will help to provide protection and lessen the burden of this potentially debilitating illness which continues to spread into previously unaffected areas."

IXCHIQ® became the world's first approved chikungunya vaccine in an endemic country earlier this year when the Brazilian Health Regulatory Agency (ANVISA) granted marketing authorization in adults.[4]

Chikungunya is becoming an increasingly prominent public health issue, with recent outbreaks in Brazil, India, and China[5]. Valneva's partnership with The Coalition for Epidemic Preparedness Innovations (CEPI), supported by the European Union's Horizon Europe programme, supports broader access to IXCHIQ® in Low- and Middle-Income Countries (LMICs)[6].

Dr. Richard Hatchett, Chief Executive Officer of the Coalition for Epidemic Preparedness Innovations (CEPI), commented, "As outbreaks of chikungunya surge around the world, expanding access to vaccines is more important than ever. This approval could help to accelerate licensure of IXCHIQ® in this age group in other regions, including areas where the disease is endemic."

Health Canada's label extension is based on positive six-month adolescent Phase 3 data which the Company reported in May 2024[7]. These data showed that a single-dose vaccination with IXCHIQ® induces a high and sustained immune response in 99.1% of adolescents, and that the vaccine was generally well tolerated. *The Lancet Infectious Diseases,* a world leading infectious diseases journal,

[1] Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ®
[2] Valneva's Chikungunya Vaccine IXCHIQ® Now Authorized in EU for Adolescents Aged 12 and Above
[3] Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ®
[4] Valneva Receives First Marketing Authorization for IXCHIQ® in a Chikungunya Endemic Country
[5] Chikungunya in China
[6] CEPI expands partnership with Valneva with $41.3 million to support broader access to world's first Chikungunya vaccine
[7] Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine

published an article in January 2025 showing that the vaccine was generally safe and well tolerated in adolescents aged 12 to 17 years 28 days after a single injection, regardless of previous CHIKV infection.

About Chikungunya

Chikungunya virus (CHIKV) is a mosquito-borne viral disease spread by the bites of infected Aedesmosquitoes 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[8]. 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 Americas3. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[9] 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[10].

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. 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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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

[8] Reemergence of Chikungunya Virus
[9] Vaccine and Therapeutic Options To Control Chikungunya Virus
[10] Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)

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.