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Valneva Reports Positive Three-Year Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ®

- *Antibody levels remained high at 96% seroresponse in line with the two-year persistence data*
- *This long-lasting antibody persistence was comparable in older (65+) and younger adults*

Saint-Herblain (France), December 3, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported positive antibody persistence data three years after vaccination with a single dose of its chikungunya vaccine IXCHIQ®. The results are in line with Valneva's expectations for this vaccine, confirming a strong and long-lasting antibody persistence across all age groups investigated. The three-year persistence data are also in line with positive twelve-month and two-year persistence data the Company reported in December 2022[1] and 2023[2], respectively.

Among the 278 healthy adults still enrolled in the trial, 96% maintained neutralizing antibody titers well above the seroresponse threshold[3] three years after the single-dose vaccination. The primary endpoint was therefore met. Persistence of antibodies in older adults (age 65+) in terms of geometric mean titers (GMTs) and seroresponse rates (SRRs) was comparable to younger adults (18-64 years of age).

Study VLA1553-303, which has received funding support from the Coalition for Epidemic Preparedness Innovations (CEPI) and the European Union's (EU) Horizon Europe program, also collected long-term safety data by following any ongoing Adverse Event of Special Interest (AESI) from the preceding study and collecting new-onset Serious Adverse Events (SAEs). The latest analysis does not include a further safety evaluation since safety data collection was concluded at two years after vaccination according to the Clinical Trial Protocol. No safety concerns were reported or identified during the two-year follow-up and no AESI were ongoing at the time of participant enrollment in the trial.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "We are extremely pleased about these three-year data which further highlight IXCHIQ®'s differentiated product profile and ability to induce a robust, long-lasting antibody response in both younger and older adults with a single vaccination. Whether you are a traveler or live in an endemic region, the potential for long-term protection against a mosquito-borne disease with a single dose is crucial, particularly in low- and middle-income countries where vaccine access is often limited."

IXCHIQ® is the world's first and only licensed chikungunya vaccine available to address this significant unmet medical need. The vaccine is currently approved in the U.S.[4], Europe[5], and Canada[6] for the prevention of disease caused by the chikungunya virus in individuals 18 years

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[1] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[2] *Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva*
[3] *A neutralizing antibody titer of ≥150 determined by $\mu PRNT_{50}$, i.e. the antibody level agreed with regulators as endpoint under the accelerated approval pathway.*
[4] *Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[5] *Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[6] *Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*

of age and older. Valneva recently submitted label extensions applications to the U.S. Food and Drug Administration (FDA)[7], the European Medicines Agency (EMA) and Health Canada[8] to potentially extend the use of its chikungunya vaccine IXCHIQ® to adolescents aged 12 to 17 years. In addition to the adolescent data, the U.S. and Canadian label extension applications included IXCHIQ®'s two-year antibody persistence data for potential addition to the product label. These persistence data were already included in the initial EMA filing.

The vaccine was launched in the U.S. at the beginning of March 2024, following adoption of the U.S. Advisory Committee on Immunization Practices (ACIP)'s recommendations by the U.S. Centers for Disease Control and Prevention (CDC) and launches in France and Canada are currently underway.

In addition to ramping up sales, Valneva is focused on expanding the vaccine's label and access. The Company expects a marketing authorization in Brazil before the end of the year and expanded its partnership with CEPI earlier this year[9] to support broader access to the vaccine in Low and Middle-Income Countries (LMICs) including outbreak-affected countries, post-marketing trials and potential label extensions in children and adolescents. CEPI is providing Valneva up to $41.3 million of additional funding over the next five years, with support from the EU's Horizon Europe program.

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.[10]

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.[11] Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[12] 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.[13]

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.

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[7] *Valneva Submits Label Extension Application for its Chikungunya Vaccine, IXCHIQ®, to the U.S. FDA - Valneva*
[8] *Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ®, to EMA and Health Canada - Valneva*
[9] *CEPI Expands Partnership with Valneva with a $41.3 Million Grant to Support Broader Access to the World's First Chikungunya Vaccine - Valneva*
[10] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*
[11] *https://cmr.asm.org/content/31/1/e00104-16*
[12] *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.*
[13] *Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)*

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.

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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.