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Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ®

- *Primary endpoint met with 97% seroresponse rate 24 months after a single vaccination*
- *Antibody levels remained high and well above the seroresponse threshold, further supporting the anticipated long-term durability of the immune response*
- *No safety concerns identified in long-term follow up*

Saint-Herblain (France), December 4, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported positive antibody persistence data twenty-four months after vaccination with a single dose of its chikungunya vaccine IXCHIQ®, further supporting the anticipated long-term durability of the immune response and in line with positive twelve-month persistence data the Company reported in December 2022[1]. These persistence data are intended to supplement the existing approval by U.S. FDA and ongoing regulatory approval processes.

97% of the 316 healthy adults still enrolled in the trial retained neutralizing antibody titers above the seroresponse threshold[2] twenty-four months after the single-dose vaccination. The persistence of antibodies in older adults aged 65 and above was as robust as in younger adults, and even slightly higher in terms of geometric mean titers (GMTs) and seroconversion rates (SRRs). This outcome underscores the vaccine's potential to offer strong and lasting protection against chikungunya across different age groups. These results follow completion of the pivotal Phase 3 study published in the *Lancet*[3] in which a seroresponse rate of 96% six months after a single vaccination[1] was reported.

Study VLA1553-303 collected long-term safety by following any Adverse Event of Special Interest (AESI) from the preceding study and collecting new-onset SAEs. No safety concerns were identified for the duration of the 24-month follow-up and, as reported in the 12-months data analysis, no AESI was ongoing when participants were enrolled in the trial.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, “We are very pleased about these twenty-four-month data which confirm IXCHIQ®'s ability to induce a robust, long-lasting antibody response in both younger and older adults with a single vaccination. Being the world's first approved vaccine against chikungunya, each positive outcome further strengthens the defense against this significant and expanding public health threat.”

Valneva was granted U.S. FDA approval[4] for its chikungunya vaccine IXCHIQ® in November 2023[5]. Two marketing applications are currently under review by EMA and Health Canada with potential approvals in mid-2024. A clinical study in adolescents is also ongoing in Brazil for which the Company reported positive pivotal Phase 3 data in November 2023[6]. This study is

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[1] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[2] *A neutralizing antibody titer of ≥150 determined by µPRNT$_{50}$, i.e. the antibody level agreed with regulators as endpoint under the accelerated approval pathway.*
[3] *Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in The Lancet*
[4] *Valneva Announces U.S. FDA Approval of World’s First Chikungunya Vaccine, IXCHIQ® - Valneva*
[5] *Valneva Announces U.S. FDA Approval of World’s First Chikungunya Vaccine, IXCHIQ® - Valneva*
[6] *Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva*

intended to support label extension in this age group and licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations.

About Chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. Infection leads to symptomatic disease in up to 97% of humans after four to seven days following the mosquito bite[7]. While mortality with CHIKV is low, morbidity is high, and the global market for vaccines against chikungunya is estimated to exceed $500 million annually by 2032[8]. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The high-risk areas of infection for travelers are places where chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia, and the virus has spread to more than 110 countries[9]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[10] and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread geographically. Before IXCHIQ®, there were no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

About IXCHIQ®

In the U.S., IXCHIQ® is a live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. As for all products approved under FDA's accelerated approval pathway, continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory studies.

IXCHIQ® (chikungunya virus, live) Solution for Intramuscular Injection

Indication

IXCHIQ® is a vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years and older who are at increased risk of exposure to CHIKV. This indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody titers. Continued approval for this vaccine is contingent upon verification and description of clinical benefit in confirmatory studies.

IMPORTANT SAFETY INFORMATION ABOUT IXCHIQ® – Please consult the full prescribing information for all the labeled safety information.

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7 Staples, J.E. Hills, S.L. Powers, A.M. "Chikungunya." In CDC Yellow Book 2020: Health Information for International Travel, by Centers for Disease Control and Prevention. New York: Oxford University Press, 2020

8 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

9 https://www.who.int/news-room/fact-sheets/detail/chikungunya

10 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.

Contraindications
IXCHIQ® should not be given to individuals who have a weakened immune system due to medications used for hematologic and solid tumors, on chemotherapy, history of congenital immunodeficiency, long-term immunosuppressive therapy, or patients with HIV infection who are severely immunocompromised.

Individuals with a history of a severe allergic reaction to any component of the vaccine.

Warnings
Appropriate medical treatment used to manage immediate allergic reactions must be available in the event an acute anaphylactic reaction following administration of IXCHIQ® or any vaccine.

Vaccination with IXCHIQ® may cause severe or prolonged chikungunya-like adverse reactions. Severe chikungunya-like adverse reactions that prevented daily activity and/or required medical intervention occurred in 1.6% of 3,082 IXCHIQ® recipients and no placebo recipients. Fourteen IXCHIQ® recipients had prolonged (duration at least 30 days) chikungunya-like adverse reactions.

Infection of pregnant individuals with wild-type chikungunya virus can result **in intra-partum transmission and potentially fatal neonatal complications.** IXCHIQ® should be administered during pregnancy only after an individual risk-benefit assessment, considering maternal risk of chikungunya infection and gestational age.

Fainting can occur with administration of IXCHIQ®. Procedures should be in place to avoid injury from fainting.

IXCHIQ® may not protect all individuals who receive the vaccine.

Adverse Reactions
The most common injection site reaction (>10%) was tenderness (11%) and the most common systemic adverse reactions (>10%) were headache (31%), fatigue (29%), myalgia (24%), arthralgia (17%), fever (13%) and nausea (11%).

Use in Specific Populations

Pregnancy

There are no adequate and well-controlled studies of IXCHIQ® in pregnant individuals, and human data available from clinical trials with IXCHIQ® are insufficient to establish the presence or absence of vaccine-associated risk during pregnancy.

Please click here for full Prescribing Information for IXCHIQ®.

About Phase 3 trial VLA1553-303
VLA1553-303 is a single-arm, open label Phase 3 trial evaluating antibody persistence in 363 participants aged 18 years or above who were immunized with VLA1553 during the pivotal trial VLA1553-301. The primary objective of the trial is to evaluate the persistence of antibodies annually from one to five years after the single immunization with VLA1553. Study VLA1553-303 collected long-term safety by following-up any Adverse Event of Special Interest (AESI) from the preceding clinical study and collecting new-onset SAE up to two years. When participants joined the follow-up study, no AESI was ongoing.
Additional information, including a detailed description of the trial design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04546724).

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 two proprietary travel vaccines as well as certain third-party vaccines leveraging our established commercial infrastructure.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the world's first vaccine against the chikungunya virus and the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, as well as vaccine candidates against the Zika virus and other global public health threats.

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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 during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.