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Valneva Reports High Sustained Immune Response in Adolescents One Year After Single Vaccination with its Chikungunya Vaccine

Saint-Herblain (France), January 20, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported further positive Phase 3 data in adolescents for its single-shot chikungunya virus (CHIKV) vaccine, IXCHIQ®, which showed a sustained 98.3% sero-response rate one-year after single vaccination. These results support and strengthen the pivotal data previously reported for adolescents (12 to 17 years old) which supported filing for potential label extension to this age group in the U.S.[1], Europe, and Canada[2]. Data from this trial are also expected to support licensure of IXCHIQ® in Brazil, which would be the first potential approval for use in endemic populations.

The one-year VLA1553-321 data showed that a single-dose vaccination induced a high, sustained immune response in an immunogenicity subset of participants who were CHIKV negative at baseline, with a seroresponse rate of 98.3% (232 out of 236 participants) one year after vaccination (Day 360) compared to 99.1% (232 out of 234 participants) after six month[3] (Day 180) and 98.8% (248 out of 251 participants) 28 days[4,5] after vaccination. The results complement the long-term persistence data previously reported for adults[6], confirming a strong and long-lasting antibody response to the vaccine.

Geometric mean antibody titers (GMTs) consistently surpassed the seroresponse threshold defined with the U.S. Food and Drug Administration (FDA)[7] as the surrogate of protection in baseline seronegative participants who received a single dose of the vaccine.

Additionally, the one-year data confirmed that a single dose of the vaccine was generally well tolerated in adolescents. Throughout the trial, an Independent Data Safety Monitoring Board (IDSMB) consistently assessed safety data and found no safety issues.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "These additional adolescent data confirm IXCHIQ®'s ability to induce a robust, long-lasting antibody response in both younger people and adults with a single vaccination. 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 and has the potential to offer long-term protection, particularly in low- and middle-income countries (LMICs) where vaccine access is often limited. We are now looking forward to the first data in children which we expect to report imminently."

Conducted in collaboration with Instituto Butantan in Brazil and funded by the Coalition for Epidemic Preparedness Innovations (CEPI) with support from the European Union (EU)'s Horizon 2020 program, the VLA1553-321 trial represents the first clinical trial conducted in an endemic area and with individuals previously infected with CHIKV. This trial supported the submission of label extension applications to

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[1] *Valneva Submits Label Extension Application for its Chikungunya Vaccine, IXCHIQ®, to the U.S. FDA - Valneva*
[2] *Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ®, to EMA and Health Canada - Valneva*
[3] *Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine - Valneva*
[4] *Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate*
[5] *Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate*
[6] *Valneva Reports Positive Three-Year Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ® - Valneva*
[7] *Defined as µPRNT$_{50}$ antibody titer ≥ 150 agreed with the FDA as surrogate of protection to support accelerated approval*

the U.S. Food and Drug Administration (FDA)[8], the European Medicines Agency (EMA) and Health Canada[9] to potentially extend the use of IXCHIQ® to adolescents aged 12 to 17 years. Data from this trial may support regulatory approval of the vaccine in Brazil and other countries in Latin America.

Valneva expanded its partnership with CEPI, with support from the EU's Horizon Europe programme, in the third quarter of 2024[10] through a $41.3 million grant to advance broader access to the vaccine in LMICs, including outbreak-affected countries, post-marketing studies and potential label extensions in children, adolescents and pregnant women. Within the framework of this agreement, 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[11], 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.

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.[12], Europe[13], and Canada[14] for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older. In addition to Brazil, Valneva also expects to receive marketing approval in the United Kingdom in the first quarter of the year.

About Phase 3 Study VLA1553-321

VLA1553-321 is a prospective, double-blinded, multicenter, randomized, placebo-controlled pivotal Phase 3 trial conducted in 754 adolescents aged 12 to 17 years old in Brazil. The VLA1553-321 clinical trial was initiated in January 2022 and Valneva reported immunogenicity and safety data 28 days and six months after a single vaccination in 2023[15,16] and 2024[17], respectively. Valneva's chikungunya vaccine or placebo was administered as a single intramuscular immunization to participants who were randomized into two study groups at a 2:1 ratio. The primary objective was to evaluate the immunogenicity and safety of the adult dose of the vaccine in adolescents 28 days following a single vaccination. Secondary objectives of the trial included assessment of safety and immunogenicity up to twelve months following a single vaccination with the vaccine. Additional information, including a detailed description of the study design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04650399).

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[18].

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,

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[8] *Valneva Submits Label Extension Application for its Chikungunya Vaccine, IXCHIQ®, to the U.S. FDA - Valneva*
[9] *Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ®, to EMA and Health Canada - Valneva*
[10] *CEPI Expands Partnership with Valneva with a $41.3 Million Grant to Support Broader Access to the World's First Chikungunya Vaccine - Valneva*
[11] *Valneva Successfully Expands Access to Asia for its Chikungunya Vaccine with Serum Institute of India - Valneva*
[12] *Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[13] *Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[14] *Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[15] *Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate*
[16] *Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate*
[17] *Valneva Reports Further Positive Pivotal Phase 3 Data in Adolescents for its Single-Shot Chikungunya Vaccine - Valneva*
[18] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*

Europe and the Americas[19]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[20] 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.[21]

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.

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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 business partnerships and the progress, timing, results and completion of technology transfer and regulatory approvals in additional markets. 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

[19] https://cmr.asm.org/content/31/1/e00104-16
[20] *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.*
[21] *Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)*

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.