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Valneva Reports Positive Phase 2 Results in Children for its Chikungunya Vaccine and Announces Phase 3 Dose Decision

Saint-Herblain (France), January 22, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) today announced positive results for its Phase 2 clinical trial evaluating the safety and immunogenicity of two different dose levels of its single-shot chikungunya vaccine, IXCHIQ®, in 304 children. Partially funded by the Coalition for Epidemic Preparedness Innovations (CEPI), with support from the European Union, the trial is intended to support a pivotal Phase 3 study in children, which the Company expects to initiate in the fourth quarter of 2025, with the objective to extend the product label to this age group.

Trial VLA1553-221 met its primary endpoint, demonstrating that the vaccine was well tolerated by children aged one to eleven years regardless of the dose (half dose or full dose) or previous chikungunya infection (CHIKV), and, to a similar extent, to an active control MenACYW vaccine (Nimenrix®). Overall, the safety profile was consistent with the profile observed in Valneva's pivotal Phase 3 trials in adults and adolescents[1,2,3,4,5]. An independent Data Safety Monitoring Board (DSMB) rigorously monitored safety data throughout the trial and confirmed the absence of any safety concerns.

Valneva's vaccine was highly immunogenic in both dose groups. A full dose of the vaccine exhibited a more robust immune response compared to a half dose by providing protective antibody titers already at Day 15 and Day 29 post-vaccination, confirming the excellent immunogenicity previously observed in adults and adolescents[6,7,8,9,10].

The comparability of the full and half dose in post-vaccination safety and tolerability, along with the more pronounced immune response of the full dose observed for all age groups tested in children, confirm the suitability of the full dose for this population and led to the selection of this dose (licensed IXCHIQ® formulation and presentation) for the pivotal Phase 3 evaluation in participants aged one to eleven years.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "These first data in children are aligned with the robust antibody response and good safety profile we reported in both adolescents and adults after a single vaccination. Considering the significant risk chikungunya poses to individuals living in or traveling to endemic areas, it's crucial to ensure that the vaccine is accessible to people of all ages and capable of potentially offering long-term

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[1] https://valneva.com/press-release/valneva-announces-positive-phase-3-pivotal-results-for-its-single-shot-chikungunya-vaccine-candidate/
[2] https://valneva.com/press-release/valneva-successfully-completes-pivotal-phase-3-trial-of-single-shot-chikungunya-vaccine-candidate/
[3] *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00641-4/fulltext*
[4] https://valneva.com/press-release/valneva-reports-positive-pivotal-phase-3-immunogenicity-data-in-adolescents-for-its-single-shot-chikungunya-vaccine-candidate/
[5] https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00458-4/abstract
[6] https://valneva.com/press-release/valneva-announces-positive-phase-3-pivotal-results-for-its-single-shot-chikungunya-vaccine-candidate/
[7] https://valneva.com/press-release/valneva-successfully-completes-pivotal-phase-3-trial-of-single-shot-chikungunya-vaccine-candidate/
[8] *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00641-4/fulltext*
[9] https://valneva.com/press-release/valneva-reports-positive-pivotal-phase-3-immunogenicity-data-in-adolescents-for-its-single-shot-chikungunya-vaccine-candidate/
[10] https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00458-4/abstract

protection from a single shot. This is especially important in Low- and Middle-Income countries (LMICs) where access to vaccines is often limited."

IXCHIQ® is the world's first and only licensed chikungunya vaccine available to address this significant unmet medical need. It is currently approved in the U.S.[11], Europe[12], and Canada[13] in adults 18 years of age and older. Brazil has reported the highest number of chikungunya cases, with over one million cases between January 2019 and July 2024[14], followed by India with 370,000 cases during the same period. This number is rapidly increasing due to the current outbreak in the Indian states of Maharashtra and Telangana, for which the U.S. Centers for Disease Control and Prevention (CDC) issued a travel notice after identifying higher-than-expected numbers of chikungunya cases in returning travelers[15]. An active outbreak was recently declared on the French island La Reunion[16].

Valneva expects to receive marketing approval in Brazil and the United Kingdom (UK) in the first quarter of the year and submitted label extension applications to the U.S. Food and Drug Administration (FDA)[17], the European Medicines Agency (EMA) and Health Canada[18] in 2024 to potentially broaden the use of IXCHIQ® to adolescents aged 12 to 17 years. Earlier this week, the Company reported positive Phase 3 data in adolescents one year after a single vaccination, confirming the robust and long-lasting antibody response observed in adults[19].

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[20].

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[21]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[22] 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.[23]

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[11] *Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[12] *Valneva Receives Marketing Authorization in Europe for the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[13] *Valneva Announces Health Canada Approval of the World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
[14] https://bluedot.global/vaccines-on-the-table-as-chikungunya-outbreak-intensifies-in-india/
[15] https://wwwnc.cdc.gov/travel/notices/level2/chikungunya-telangana-india
[16] *https://www.lareunion.ars.sante.fr/point-sur-la-situation-du-chikungunya-la-reunion-2*
[17] *Valneva Submits Label Extension Application for its Chikungunya Vaccine, IXCHIQ®, to the U.S. FDA - Valneva*
[18] *Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ®, to EMA and Health Canada - Valneva*
[19] *Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva*
[20] *https://jvi.asm.org/content/jvi/88/20/11644.full.pdf*
[21] *https://cmr.asm.org/content/31/1/e00104-16*
[22] *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.*
[23] *Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)*

About Phase 2 Trial VLA1553-221

VLA1553-221 is a multi-center, randomized, observer-blinded, dose response Phase 2 clinical trial in 304 healthy children aged one to eleven years. The trial is performed at three trial sites in the Dominican Republic and Honduras. The primary and secondary objectives of the trial are to evaluate the safety and immunogenicity of two different dose levels of Valneva's single-shot chikungunya vaccine. Participants were randomized 2:2:1 to receive either a full dose (licensed IXCHIQ® formulation and presentation) or a half dose of the vaccine, or an active control (Nimenrix). Additional information, including a detailed description of the trial design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT06106581).

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.

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 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 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 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.