

Valneva Reports Positive Six-Month Antibody Persistence and Safety Phase 2 Results in Children for its Single-Shot Chikungunya Vaccine IXCHIQ®

- IXCHIQ® was well tolerated by children aged one to eleven years regardless of the dose or previous chikungunya infection (CHIKV)
- Antibody levels remained high after six months in both dose groups, although more robust with the full dose
- Six-month data confirm full dose selection for pivotal Phase 3 trial

Saint-Herblain (France), June 5, 2025 – [Valneva SE](#) (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced positive six-month antibody persistence and safety data 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 first quarter of 2026, with the objective of extending the product label to this age group.

Trial VLA1553-221's six-month results were in line with the initial data the Company reported for this trial in January 2025¹. A full dose (licensed IXCHIQ® formulation and presentation) elicited a more robust immune response in children aged one to eleven years at Day 15 and Day 180 post vaccination compared to a half dose. Overall, the immunological response profile was in line with what was previously observed in adults and adolescents²³⁴⁵⁶⁷.

The strong immune response was confirmed in CHIKV-naïve children with a 96.5% seroresponse rate (full dose) at Day 180. VLA1553 was well tolerated in children aged one to eleven years regardless of the dose or previous CHIKV infection. No safety concerns were identified.

The comparability of the VLA1553 doses tested in terms of safety and tolerability, along with the more pronounced immune response of the full dose observed for all age groups tested in children up to Day 180 post-vaccination, support the selection of the full dose for use in this population.

¹ [Valneva Reports Positive Phase 2 Results in Children for its Chikungunya Vaccine and Announces Phase 3 Dose Decision - Valneva](#)

² [Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

³ [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

⁴ [Lancet Paper: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(23\)00641-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00641-4/fulltext)

⁵ [Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

⁶ [Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

⁷ [Lancet Paper: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(24\)00458-4/abstract](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00458-4/abstract)

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, “The six months persistence and safety data in children are aligned with the robust antibody response and safety profile we reported in adolescents 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 protection from a single shot. This is especially important in Low- and Middle-Income countries (LMICs) where access to vaccines is often limited.”

Brazil has reported the highest number of chikungunya cases worldwide, with over one million cases between January 2019 and July 2024⁸, 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 travelers⁹. Additionally, two outbreaks are ongoing on the French islands of La Reunion and Mayotte¹⁰.

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 years¹¹.

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 Americas¹². Between 2013 and 2023, more than 3.7 million cases were reported in the Americas¹³ 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.¹⁴

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](https://clinicaltrials.gov/ct2/show/study/NCT06106581)).

⁸ <https://bluedot.global/vaccines-on-the-table-as-chikungunya-outbreak-intensifies-in-india/>

⁹ <https://wwwnc.cdc.gov/travel/notices/level2/chikungunya-telangana-india>

¹⁰ <https://www.who.int/emergencies/disease-outbreak-news/item/2025-DON567>

¹¹ <https://jvi.asm.org/content/jvi/88/20/11644.full.pdf>

¹² <https://cmr.asm.org/content/31/1/e00104-16>

¹³ 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.

¹⁴ [Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas \(who.int\)](https://www.who.int/publications-detail/Geographical-expansion-of-cases-of-dengue-and-chikungunya-beyond-the-historical-areas-of-transmission-in-the-Region-of-the-Americas)

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 use and regulatory 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 or new adverse events, 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.

