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Valneva Vaccinates First Participant in Pediatric Trial of Single-Shot Chikungunya Vaccine

Saint-Herblain (France), January 10, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) today announced that the first participant has been vaccinated in the Phase 2 clinical trial evaluating the safety and Immunogenicity in children of two different dose levels of Valneva's single-shot chikungunya vaccine. The Company reported positive pivotal Phase 3 data in adolescents two months ago confirming the immunogenicity and safety profile observed in adults[1].

There is currently no approved chikungunya vaccine for children and Valneva's vaccine IXCHIQ® is currently the only licensed chikungunya vaccine[2] to address this unmet medical need in adults aged 18 years and older who are at increased risk of exposure to the virus. Once available, the Phase 2 pediatric data are intended to support a Phase 3 pivotal study in children with the objective to extend the label in this age group following initial regulatory approvals in adults and possibly in adolescents.

The multicenter, prospective, randomized, observer-blinded, Phase 2 clinical trial is planned to enroll approximately 300 healthy children one to eleven years of age at three trial sites in the Dominican Republic and Honduras. Following a safety run-in phase, participants will be randomized to receive either a full dose formulation of the vaccine (120 participants), a half dose formulation (120 participants) or a control vaccine (60 participants).

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "This pediatric trial is extremely important. Given the significant threat that chikungunya poses to individuals living in or traveling to endemic areas, it is crucial to make the vaccine accessible to all age groups. By doing so, we can broaden the protection against and reduce the impact of this debilitating disease."

Valneva was granted approval from the U.S. Food and Drug Administration (FDA) for its chikungunya vaccine IXCHIQ® in November 2023[3]. Three marketing applications are currently under review by the European Medicines Agency, Health Canada and the Brazilian Health Regulatory Agency (Anvisa) with potential approvals in 2024.

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[4]. 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[5]. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia.

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[1] Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva
[2] Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva
[3] Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva
4 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
5 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

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[6]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[7] 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.

To make the vaccine more accessible to Low- and Middle-Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement in January 2021 for the development, manufacturing and marketing of VLA1553[8]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[9], which provides funding of up to $23.4 million with support from the European Union's Horizon 2020 program.

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.

Please click here for full Prescribing Information for IXCHIQ®.

About Phase 2 Trial VLA1553-221

VLA1553-221 is a multi-center, randomized, observer-blinded, dose response Phase 2 clinical trial in approximately 300 healthy children aged one to eleven years. The trial will be performed at three trial sites in the Dominican Republic and potentially 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. 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.

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

7 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.

8 Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries

9 CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

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.