

Valneva Completes BLA Submission to U.S. FDA for its Single-Shot Chikungunya Vaccine Candidate

Saint-Herblain (France), December 23, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announces that it has completed rolling submission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for its single-shot chikungunya vaccine candidate, VLA1553. Valneva is seeking approval of its investigational chikungunya vaccine in persons aged 18 years and above.

This BLA application follows final pivotal Phase 3 data reported in March 2022¹ and final lot-to-lot consistency results reported in May 2022². A clinical study of VLA1553 in adolescents is ongoing in Brazil³, which may support future regulatory submissions in this group if VLA1553 is initially approved in adults. The Company also recently reported positive antibody persistence data with a 99% seroresponse rate 12 months after a single-dose vaccination⁴.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, “The completion of our BLA submission is extremely important as it takes us a step closer to potentially bringing a preventative solution to fight this debilitating disease. Chikungunya is a major public health threat transmitted to humans by infected mosquitoes, and no vaccine or specific treatments for the disease are currently available. If the FDA approves the submission, our goal is to provide a tool to help curtail this growing, unmet medical need.”

The FDA will now review the filing for acceptance, determine priority review eligibility and the action date which it targets to complete its evaluation. The program received FDA Fast Track and Breakthrough Therapy designations in 2018 and 2021, respectively. VLA1553 was also granted Priority Medicine (PRIME) designation by the European Medicines Agency (EMA) in 2020, and Valneva plans to make regulatory submissions for VLA1553 in Europe in the second half of 2023.

About Chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a *Togaviridae* virus, transmitted by *Aedes* mosquitoes. 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. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat. As of September 2020, there were more than 3 million reported cases in the Americas⁵ 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. Infection leads to symptomatic disease in up to 97% of humans after three to seven days following the mosquito bite. While mortality with CHIKV is low, morbidity is high. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. It is estimated that over three quarters of the world’s population live in areas at-risk

¹ [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

² [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate](#)

³ [Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva](#)

⁴ [Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva](#)

⁵ PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas. <https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html>. Last accessed 13 Oct 2020.



of CHIKV transmission⁶. High risk areas of infection are places where chikungunya virus-carrying mosquitos are currently endemic, including the Americas, parts of Africa, and Southeast Asia.

About VLA1553

VLA1553 is a live-attenuated, single dose investigational vaccine candidate targeting the chikungunya virus, which has spread to over 100 countries. It has been designed by deleting a part of the chikungunya virus genome.

Valneva reported final data from the pivotal Phase 3 trial of VLA1553 in March 2022⁷ and final lot-to-lot consistency results in May 2022⁸.

If approved, VLA1553 would expand Valneva's existing commercial vaccines portfolio and as such, Valneva intends to commercialize this vaccine, leveraging its existing manufacturing and commercial operations.

To make VLA1553 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 VLA1553⁹. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019¹⁰, which provides funding of up to \$23.4 million with support from the European Union's Horizon 2020 program.

About Valneva SE

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

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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 regulatory approval of VLA1553, timing and plans for clinical programs and

⁶ CDC 2022, Puntasecca CJ 2021

⁷ [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#)

⁸ [Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate](#)

⁹ [Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries](#)

¹⁰ [CEPI awards up to \\$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine](#)



product candidates and revenue forecasts. 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 indicative of future results. 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 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 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, the ability to obtain or maintain patent or other proprietary intellectual property protection and the impact of the COVID-19 pandemic. 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 the information in this press release as of the date hereof 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.

