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Valneva Announces Publication of its Chikungunya Vaccine Candidate Phase 3 Data in *The Lancet*

Saint-Herblain (France), June 13, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announces that the Company's pivotal Phase 3 data for its single-shot chikungunya vaccine candidate, VLA1553, have been published in *The Lancet* , the world's leading peer-reviewed medical journal.

The article, titled "Safety and immunogenicity of a single-shot live-attenuated chikungunya vaccine: a double-blind, multicenter, randomized, placebo-controlled phase 3 trial" provides a detailed analysis of the Phase 3 results showing that VLA1553 demonstrated a very high seroresponse rate of 98.9% in participants 28 days after receiving the single administration. This immunogenicity profile was similar in both younger and older adults, and 96% of participants maintained seroresponse six months after vaccination. VLA1553 was generally safe and equally well tolerated in younger and older adults. The Lancet Paper can be accessed via the following link: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00641-4/fulltext.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "This publication in the Lancet underlines the strength of VLA1553's scientific approach and is consistent with the quality of our pivotal Phase 3 study. We are pleased that more detailed results on our single-shot chikungunya vaccine candidate are now available to the scientific and broader public health communities."

Valneva reported final pivotal Phase 3 data in March 2022[1], final lot-to-lot consistency results in May 2022[2] and positive twelve-month persistence data in December 2022[3]. A clinical study of VLA1553 in adolescents is ongoing in Brazil[4], for which Valneva reported enrollment and vaccination completion in February 2023[5].

VLA1553 is currently the only chikungunya vaccine candidate worldwide for which regulatory review processes are underway. A Biologic License Application (BLA) is currently under priority review[6] by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) review goal date at the end of August 2023, and a regulatory application has also been filed with Health Canada. If approved, VLA1553 could become the first licensed chikungunya vaccine available to address this unmet medical need.

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 72-92% of humans after four to seven days following the mosquito bite. While mortality with CHIKV is low, morbidity is high, and the global market for vaccines against chikungunya is estimated to exceed $500

[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 Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[4] *Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva*
[5] *Valneva Completes Enrollment for Adolescent Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate - Valneva*
[6] *FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva*

million annually by 2032[7]. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. 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[8]. As of July 2022, more than three million cases have been reported in the Americas[9] 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. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

About VLA1553

VLA1553 is a live-attenuated, single dose investigational vaccine candidate targeting the chikungunya virus, which has spread to over 110 countries[10]. 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 2022[11], final lot-to-lot consistency results in May 2022[12] and positive twelve-month persistence data in December 2022[13].

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 VLA1553[14]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[15], which provides funding of up to $24.6 million with support from the European Union's Horizon 2020 program.

VLA1553 received FDA Fast Track, Breakthrough Therapy designations and Priority Review in 2018, 2021 and 2023, respectively. VLA1553 was also granted PRIority MEdicine (PRIME) designation by the European Medicines Agency (EMA) in 2020.

About Valneva SE

We are a specialty vaccine company focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases. We take a highly specialized and targeted approach to vaccine development by focusing on vaccine solutions addressing unmet medical needs to ensure we can make a difference to peoples' lives. We apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, and our established

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[7] *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
[8] *https://www.who.int/news-room/fact-sheets/detail/chikungunya*
[9] *PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas (Cumulative Cases 2018-2022 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 25 Jul 2022.*
[10] *https://www.who.int/news-room/fact-sheets/detail/chikungunya*
[11] *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate*
[12] *Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate*
[13] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[14] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
[15] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*

vaccine development capabilities, to develop vaccines against diseases which are not yet vaccine-preventable, or for which there are limited effective treatment options. Today, we are leveraging our expertise and capabilities to rapidly advance a broad range of vaccines into and through the clinic, including candidates against the chikungunya virus and Lyme disease.

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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.