

## Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate

**Saint Herblain (France), May 25, 2022** – [Valneva SE](#) (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced the successful completion of the lot-to-lot Phase 3 trial of its single-shot chikungunya vaccine candidate, VLA1553. The final analysis included six-month follow-up data and confirmed the topline results reported in December 2021.

The VLA1553-302 trial met its primary endpoint, demonstrating that three consecutively manufactured vaccine lots elicited equivalent immune responses measured by neutralizing antibody titer GMT ratios on Day 29 after vaccination.

The trial included 408 participants aged 18 to 45 years. The safety profile shown in study VLA1553-302 was similar to the Phase 3 trial, VLA1553-301<sup>1</sup>. With a 96.0% seroprotection rate at Day 180, the immunogenicity profile from study VLA1553-301 was also confirmed.

**Juan Carlos Jaramillo, Chief Medical Officer of Valneva commented,** “We are extremely pleased that the final lot-to lot data confirmed the previously reported topline results. We have now all necessary clinical data to support submission with the US Food and Drug Administration (FDA), which we plan to start later this year. Chikungunya is a major, growing and unmet public health threat, yet no vaccine or specific treatment is currently available to prevent this debilitating disease. We will continue to work assiduously to bring VLA1553 to market as soon as possible.”

Valneva’s chikungunya program was awarded Breakthrough Therapy Designation by the US FDA in July 2021. This milestone followed the US FDA’s Fast Track designation and the European Medicines Agency (EMA)’s PRIME designation which the Company received in December 2018 and in October 2020, respectively. The sponsor of the first chikungunya vaccine Biologics License Application (BLA) to be approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV)<sup>2</sup>.

### 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 4 to 7 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. 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 100 countries. As of September 2020, there were more than 3 million reported cases in the Americas<sup>3</sup> and the

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

<sup>2</sup> <https://priorityreviewvoucher.org/>

<sup>3</sup> 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.

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 designed to target the chikungunya virus. It has been designed by deleting a part of the chikungunya virus genome. In March 2022, Valneva announced successful completion of the Phase 3 pivotal trial of VLA1553<sup>4</sup>. The final six-month analysis confirmed the very high level of seroprotection reported from this trial in August 2021. In this double-blind, multi-center, randomized Phase 3 clinical trial, 4,115 participants aged 18 years and above were randomized 3:1 into two groups to receive either 0.5mL of VLA1553 or a placebo. The trial met its primary endpoint, inducing protective CHIKV neutralizing antibody titers in 98.9% of participants 28 days after receiving a single shot (264 of 268 subjects from the per-protocol subgroup tested for immunogenicity, 95% CI: 96.2-99.6). The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a submission for approval of VLA1553 under the accelerated approval pathway. VLA1553 was highly immunogenic, with a GMT of approximately 3,270.

VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board, or DSMB, continuously monitored the study and identified no safety concerns. Solicited adverse events were observed, the majority of which were mild or moderate and resolved within 3 days.

Additionally, VLA1553 was shown in the Phase 3 pivotal trial to be highly immunogenic in elderly study participants, who achieved equally high seroprotection rates and neutralizing antibody titers as younger adults, as well as an equally good safety profile.

VLA1553 would expand Valneva's existing travel vaccine portfolio and as such, Valneva intends to commercialize this vaccine, if approved, leveraging its existing manufacturing and commercial operations. The global market for chikungunya vaccines is estimated to exceed \$500 million annually by 2032<sup>5</sup>.

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<sup>6</sup>. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019<sup>7</sup>, which provides funding of up to \$23.4 million with support from the European Union's Horizon 2020 program.

### **About Phase 3 study VLA1553-302**

The VLA1553-302 clinical lot-to-lot consistency study is a prospective, multicenter, randomized, pivotal Phase 3 study including 408 participants aged 18 to 45 years. Lyophilized VLA1553 were administered as a single intramuscular immunization. Equivalence of immune responses was determined based on neutralizing antibody titers. The primary objective of the study was to evaluate a pair-wise comparison of the 95% Confidence Interval (CI) on the ratio of GMTs on

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<sup>4</sup> *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate – Valneva*

<sup>5</sup> *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*

<sup>6</sup> *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*

<sup>7</sup> *CEPI awards up to \$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*

Day 29 after vaccination in the three vaccine lots. The two-sided 95% CI on the GMT ratio should be within 0.67 and 1.5 in order to demonstrate consistency.

Study volunteers were followed for six months after vaccination. Additional information, including a detailed description of the study design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: [NCT04786444](https://clinicaltrials.gov/ct2/show/study/NCT04786444)).

### **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, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. It then applies its deep understanding of vaccine science, including its expertise across multiple vaccine modalities, as well as its established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. Valneva has leveraged its expertise and capabilities to successfully commercialize two wholly owned vaccines and rapidly advance multiple vaccine candidates into late-stage clinical development, including candidates against Lyme disease (partnered with Pfizer), 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 the progress, timing, results and completion of research, development and clinical trials for investigational product candidates and estimates for future performance. 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 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



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