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Valneva Completes Recruitment for Phase 3 Lot-to-Lot Consistency Trial of its Chikungunya Vaccine Candidate

Saint Herblain (France), June 10, 2021 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, today announced that it has completed recruitment for the clinical lot-to-lot consistency Phase 3 trial of its single-shot chikungunya vaccine candidate, VLA1553. VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials at this time.

410 participants aged 18 to 45 years have been randomized in the Phase 3 trial VLA1553-302 and will be followed for a total of six months. The objective of the trial is to show manufacturing consistency of the vaccine by demonstrating that three consecutively manufactured lots elicit equivalent immune responses measured by neutralizing antibody titers on Day 29 after vaccination.

Juan Carlos Jaramillo, Chief Medical Officer of Valneva commented, "We are pleased to have reached this new recruitment milestone. We've now enrolled all participants for both our pivotal Phase 3 trial and lot-to-lot consistency trial so our VLA1553 program is progressing extremely well. Chikungunya virus is a major, growing public health threat and we are looking forward to our top line data this summer".

The lot-to-lot consistency Phase 3 trial runs in parallel to the ongoing, pivotal Phase 3 trial, VLA1553-301, for which the Company already announced recruitment completion in April 2021[1]. 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) [2].

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. As of September 2020, there were more than 3 million reported cases in the Americas[3] and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors

[1] *Valneva Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial*
[2] *https://priorityreviewvoucher.org/*
[3] *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.*

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 vaccine candidate for protection against the chikungunya which has spread to more than 100 countries. It has been designed by deleting a part of the chikungunya virus genome.

In the Phase 1 clinical trial of VLA1553, Valneva observed development of antibodies to chikungunya virus resulting in 100% seroconversion of the 120 healthy participants. Antibody titers were sustained after 12 months. Based on these results and Valneva's discussions with regulators, VLA1553 has advanced directly into Phase 3 clinical development. The Company has also received confirmation for its proposal to seek licensure under the accelerated approval pathway from the FDA. Under this pathway, Valneva plans to seek licensure of the vaccine based on a surrogate of protection agreed with the FDA that is reasonably likely to predict protection from chikungunya infection.

The program was granted Fast Track designation by the FDA in December 2018 and PRIME designation by the European Medicines Agency (EMA) in October 2020.

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 vaccines against chikungunya is estimated to exceed $500 million annually by 2032[4].

To make VLA1553 more accessible to Low and Middle Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement for the development, manufacturing and marketing of VLA1553. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019, which provides funding of up to $23.4 million.

About Phase 3 study VLA1553-302

VLA1553-302 clinical lot-to-lot consistency Phase 3 study is a prospective, multicenter, randomized, pivotal Phase 3 study including 410 participants aged 18 to 45 years. Lyophilized VLA1553 are administered as a single intramuscular immunization. Equivalence of immune responses will be determined based on neutralizing antibody titers. The primary objective of the study is to evaluate a pair-wise comparison of the 95% Confidence Interval (CI) on the ratio of GMTs on 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 will be followed for a total of six months and overall, the study is expected to last approximately eight months. Additional information, including a detailed description of the study design, eligibility criteria and investigator sites, will be published on ClinicalTrials.gov.

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. We take 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. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities,

[4] *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*

as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our 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 the progress, timing, results and completion of research, development and clinical trials for 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 update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.