VALNEVA SE
Campus Bio-Ouest | 6, Rue Alain Bombard
44800 Saint-Herblain, *France*

Valneva Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial

Saint-Herblain (France), April 12, 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 pivotal Phase 3 trial, VLA1553-301, of its single-shot chikungunya vaccine candidate, VLA1553. 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) [1].

A total of 4,131 adults aged 18 or above have been recruited across 44 sites in the US for the pivotal Phase 3 trial, VLA1553-301, which was launched in September 2020[2]. If the trial results are positive, the trial is expected to support VLA1553's licensure.

The primary endpoint of the double-blinded, placebo-controlled study is to demonstrate safety and immunogenicity 28 days after a single-shot vaccination with VLA1553 including a subset of participants (immunogenicity subset) tested for sero-protection based on an immunological surrogate agreed with the Food and Drug Administration (FDA). Participants will be followed for six months in the pivotal trial. On April 1st 2021, Valneva also initiated an antibody persistence trial, VLA1553-303, that will follow the immunogenicity subset for a period of five years.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "We are extremely pleased to have reached this important milestone despite the ongoing COVID-19 pandemic affecting many people worldwide and creating challenges for recruitment into clinical trials. Chikungunya virus is a major, growing public health threat and we are looking forward to our top line data in mid-2021. We would like to thank everyone involved, we could not have achieved this important milestone without hard work and dedication".

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

[1] *https://priorityreviewvoucher.org/*
[2] *Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553*
[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.*

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 targeting the chikungunya virus, which has spread to more than 100 countries. VLA1553 is a live-attenuated, single dose vaccine candidate for protection against chikungunya disease. It has been designed by deleting a part of the chikungunya virus genome. To Valneva's knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials and the Company believes that it is differentiated from other clinical stage chikungunya vaccine candidates since VLA1553 is the only candidate that targets long-term protection with a single administration.

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. These results were sustained after 12 months. Based on these results and Valneva's discussions with regulators, VLA1553 has advanced 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 trial VLA1553-301

VLA1553-301 Phase 3 trial was initiated in September 2020 and Valneva has now completed enrollment for this trial. Valneva expects to report topline data in mid-2021. VLA1553-301 is a prospective, double-blinded, multicenter, randomized, pivotal Phase 3 trial comprising 4,131 participants aged 18 years or above. Lyophilized VLA1553 or placebo were administered as a single intramuscular immunization. The primary objective of the trial is to evaluate the immunogenicity and safety of the final dose of VLA1553 28 days following a single immunization. Safety data collection and immunogenicity will continue to be assessed until Month 6; further long-term follow up is planned. Additional information, including a detailed description of the trial design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04546724).

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

About Phase 3 trial VLA1553-303
VLA1553-303 is a prospective, multicenter, Phase 3 antibody persistence trial. Up to 375 participants vaccinated with VLA1553 in the pivotal trial VLA1553-301 will be enrolled in this follow-up trial. The primary objective is to evaluate persistence of antibodies annually for five years after a single immunization.
Additional information, including a detailed description of the trial 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, 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.

Valneva Investor and Media Contacts
Laetitia Bachelot-Fontaine
Director Investor Relations & Corporate Communications
M +33 (0)6 4516 7099
investors@valneva.com

Dan Sharp
Government & Public Affairs Manager
T +44-(0)7436-244309
communications@valneva.com

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, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. 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. 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 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.