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Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate

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

This BLA submission follows final pivotal Phase 3 data reported in March 2022[1] and final lot-to-lot consistency results reported in May 2022[2]. A clinical study of VLA1553 in adolescents is ongoing in Brazil[3], which may support future regulatory submissions in this group if VLA1553 is approved in adults.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, "This is an extremely important milestone for our VLA1553 program and we are very proud to be the first company worldwide that has begun submission of a BLA for a chikungunya vaccine candidate. Chikungunya is a major public health threat that continues to grow, and no vaccine or specific treatments are currently available for this debilitating disease. We will continue to work assiduously to bring VLA1553 to market as soon as possible."

Valneva is currently targeting the end of 2022 for completion of the BLA submission. Once all portions of the application have been submitted and if the filing is accepted, the FDA will determine priority review eligibility and the action date which the FDA will target to complete its evaluation.

This rolling BLA submission is part of the accelerated approval pathway agreed upon with the FDA in 2020[4]. 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 first 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. 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 million annually by 2032[5]. 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

[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 End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study*
[5] *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*

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 July 2022, more than three million cases have been reported in the Americas[6] 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 120 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 2022[7] and final lot-to-lot consistency results in May 2022[8].

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[9]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[10], 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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[6] *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.*
[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*

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 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.