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Health Canada Accepts Valneva's Chikungunya Vaccine License Application for Review

Saint-Herblain (France), August 29, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that Health Canada has completed screening validation of the Company's regulatory application for marketing approval of its single-shot chikungunya vaccine candidate VLA1553 in persons aged 18 years and above, and has determined that the New Drug Submission (NDS) application is sufficiently complete to permit a substantive review. Based on Health Canada's performance standard to process an NDS application, the Company believes the regulatory review could be completed by mid-2024.

This is the second regulatory application for VLA1553 filed by Valneva, and the Company intends to make additional regulatory submissions in 2023. A Biologic License Application (BLA) is currently under priority review[1] by the U.S. Food and Drug Administration (FDA)[2].

VLA1553 is currently the only chikungunya vaccine candidate worldwide for which regulatory review processes are underway and, if approved, it could become the first licensed chikungunya vaccine available to address this unmet medical need. It would also represent the third vaccine Valneva[3] has brought from early R&D to approval.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, "Chikungunya represents a major threat for people traveling to or living in areas where chikungunya virus and the mosquitos that transmit it are present, including popular destinations for U.S. and Canadian travelers. This threat continues to grow as shown by the recent epidemiological alert issued by the Pan American Health Organization (PAHO)[4]. No vaccine or specific treatments are currently available for this debilitating disease, and we will continue to work diligently to make VLA1553 available in different territories as quickly as possible."

The regulatory submissions with Health Canada and the FDA follow final pivotal Phase 3 data in March 2022[5], final lot-to-lot consistency results in May 2022[6] and positive twelve-month persistence data in December 2022[7]. The Company's pivotal Phase 3 results were published in the Lancet in June 2023.

A clinical study of VLA1553 in adolescents aged 12 to 17 years is ongoing in Brazil[8], for which Valneva reported initial Phase 3 safety data in adolescents yesterday[9]. This study, conducted by Valneva's partner Instituto Butantan and funded by the Coalition for Epidemic Preparedness Innovations (CEPI), is intended to support label extension in this age group following a potential initial regulatory approval in adults from the FDA. The study is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in endemic populations, as well as regulatory submission in Europe.

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[1] *FDA Accepts Valneva's Chikungunya Vaccine License Application for Priority Review - Valneva*
[2] *Valneva Announces PDUFA Date Extension for Chikungunya Virus Vaccine Candidate - Valneva*
[3] *This statement refers to Valneva and its predecessor Intercell*
[4] *https://www.paho.org/en/documents/epidemiological-alert-chikungunya-increase-region-americas*
[5] Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
[6] Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate
[7] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[8] *Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva*
[9] Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate - Valneva

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

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 up to 97% 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[10]. 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[11]. As of July 2022, more than three million cases have been reported in the Americas[12] 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[13]. 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[14], final lot-to-lot consistency results in May 2022[15] and positive twelve-month persistence data in December 2022[16].

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[17]. The collaboration falls within the framework of the

[10] *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
[11] *https://www.who.int/news-room/fact-sheets/detail/chikungunya*
[12] *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.*
[13] *https://www.who.int/news-room/fact-sheets/detail/chikungunya*
[14] *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate*
[15] *Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate*
[16] *Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva*
[17] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*

agreement signed between CEPI and Valneva in July 2019[18], 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
Valneva is a specialty vaccine company focused on the development, manufacturing 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 commercialize three vaccines and to rapidly advance a broad range of vaccine candidates 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

[18] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*

publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.