

## Valneva to Present its Chikungunya Vaccine Candidate at the ASTMH 2021 Annual Meeting

**Saint-Herblain (France), November 15, 2021** – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced it will present its Chikungunya vaccine candidate, VLA1553, on November 18 and 19, 2021 during the American Society of Tropical Medicine & Hygiene (ASTMH) 2021 Annual Meeting.

Valneva's Chief Medical Officer, Juan Carlos Jaramillo, MD, will present on Friday, November 19 at 2:15pm ET, "Chikungunya: Phase 3 Clinical Development of a Single-shot Live-attenuated Vaccine" and Martina Schneider, PhD, Clinical Strategy Manager at Valneva, will present a poster abstract entitled "Chikungunya: Safety up to Day 29 of Phase 3 Clinical Development of a Single-shot Live-attenuated Vaccine" on Thursday, November 18 from 11:00 to 12:30pm ET.

At the beginning of August 2021, Valneva announced positive topline results for the Phase 3 pivotal trial of VLA1553. The vaccine candidate induced protective CHIKV neutralizing antibody titers in 98.5% of trial participants after a single vaccination and was well tolerated across all age groups<sup>1</sup>.

TropMed21, the ASTMH 2021 Annual Meeting, is the premier international forum for the exchange of scientific advances in tropical medicine, hygiene and global health and will be 100% virtual this year. For more information and to register for the conference, please visit <https://www.astmh.org/annual-meeting>.

### About VLA1553

VLA1553 is a live-attenuated, single dose vaccine candidate targeting the chikungunya virus, which has spread to more than 100 countries. It has been designed by deleting a part of the chikungunya virus genome.

In September 2020, Valneva initiated the pivotal Phase 3 clinical trial, VLA1553-301, in the United States. 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 98.5% 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 potential FDA 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. The majority of solicited adverse events were mild or moderate and resolved within 3 days. 1.6% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of trial participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia (seen in more than 20% of

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<sup>1</sup> [Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate](#)

subjects). The local tolerability profile showed that approximately 15% of participants experienced solicited local adverse events.

Additionally, VLA1553 was 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.

VLA1553-301 will continue towards final analysis including the 6-month safety data. The Company expects to report final trial results in early 2022.

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<sup>2</sup>.

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<sup>3</sup>. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019<sup>4</sup>, 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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### **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, and to 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,"

<sup>2</sup> *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*

<sup>3</sup> *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*

<sup>4</sup> *CEPI awards up to \$23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*

“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.

