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Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate

- *Primary endpoint met with 99% seroresponse rate 12 months after single-dose vaccination*
- *Antibody levels remained stable from month 6 to month 12*
- *No safety concern identified during follow-up, confirming the safety profile observed in earlier studies*
- *Valneva currently on track to complete rolling submission for Biologics License Application (BLA) with U.S. Food and Drug Administration (FDA) by end of 2022*

Saint-Herblain (France), December 5, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported positive antibody persistence data twelve months after vaccination with a single dose of its chikungunya vaccine candidate, VLA1553.

Following positive immunogenicity and safety data for Phase 3 study VLA1553-301 in March 2022[1], Valneva set up a dedicated antibody persistence trial (VLA1553-303) to monitor a subset of participants for a period of at least five years and confirm the anticipated long-term durability of the antibody response after a single vaccination.

The antibody persistence trial enrolled 363 healthy adult participants and followed them from month 6 after vaccination to month 12. 99% of participants retained neutralizing antibody titers above the seroresponse threshold of 150[2] 12 months after the single-dose vaccination. These antibody levels confirm the antibody persistence profile observed in an earlier study[3]. The antibody persistence was similar in older adults aged ≥65 years, who retained neutralizing antibody titers comparable to younger adults throughout the follow-up. These results follow completion of the pivotal study VLA1553-301, for which a seroresponse rate of 96% six months after vaccination[1] was reported. The study will continue to monitor antibody persistence on an annual basis.

No safety concerns were identified for the duration of the follow-up study, confirming the safety profile observed in previous studies.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "We are excited about these twelve-month data which are in line with what we saw from our previous read out at month 6, and strengthen the possibilities of inducing a long-lasting antibody response with our chikungunya vaccine candidate. We are looking forward to completing the BLA rolling submission to the FDA and potentially to changing people's lives. If our investigational vaccine is approved, we are confident that it can help address this major, growing and unmet public health threat."

Valneva expects to finalize its BLA submission with the FDA by the end of 2022. Once completed, and if the FDA accepts the filing, the FDA will determine priority review eligibility

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[1] Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate - Valneva
[2] *A neutralizing antibody titer of ≥150 determined by μPRNT$_{50}$, i.e. the antibody level agreed with regulators as endpoint under the accelerated approval pathway.*
[3] Valneva Reports Excellent Final Phase 1 Results for its Chikungunya Vaccine Candidate, Confirms Plans - Valneva

along with the action due date upon which it will complete its evaluation. 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 EMA in 2020. Valneva currently plans to make additional regulatory submissions for VLA1553 in 2023. Valneva also initiated a Phase 3 trial in adolescents conducted in Brazil by Instituto Butantan to support the label extension in this age group following a potential initial regulatory approval.

About Chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a *Togaviridae* virus, transmitted by *Aedes* mosquitoes. 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. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat. As of September 2020, there were more than 3 million reported cases in the Americas[4] 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. Infection leads to symptomatic disease in up to 97% of humans after three to seven 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. It is estimated that over three quarters of the world's population live in areas at-risk of CHIKV transmission[5]. High risk areas of infection are places where chikungunya virus-carrying mosquitos are currently endemic, including the Americas, parts of Africa, and Southeast Asia.

About VLA1553

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

VLA1553 would expand Valneva's existing commercial vaccines 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[6].

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[7]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[8], which provides funding of up to $23.4 million with support from the European Union's Horizon 2020 program.

About Phase 3 trial VLA1553-303

VLA1553-303 is a single-arm, open label Phase 3 trial evaluating antibody persistence in 363 participants aged 18 years or above who were immunized with VLA1553 during the pivotal trial

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[4] *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.*

[5] *CDC 2022, Puntasecca CJ 2021*

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

[7] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*

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

VLA1553-301. The primary objective of the trial is to evaluate the persistence of antibodies annually from 1 to 5 years after the single immunization with VLA1553. Study VLA1553-303 collected long-term safety by following-up any Adverse Event of Special Interest (AESI) from the preceding study and collecting new-onset SAE. When participants joined the follow-up study, no AESI was ongoing.
Additional information, including a detailed description of the trial design, eligibility criteria and investigator sites, is available at ClinicalTrials.gov (Identifier: NCT04546724).

About Valneva SE
Valneva is a specialty vaccine company focused on the development, production 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 Lyme disease and the chikungunya virus.

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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, clinical trials, and regulatory review of VLA1553. 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.