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Valneva to Host Symposium on COVID-19 and Chikungunya Vaccine Candidates at 31st European Congress of Clinical Microbiology & Infectious Diseases

Saint Herblain (France), July 5, 2021 –<u>Valneva SE</u> (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, announced today it will host a virtual symposium titled, "Developing new vaccines to protect against infectious diseases at home and abroad" on July 9, 2021 at 14:15 CEST at the 31st European Congress of Clinical Microbiology & Infectious Diseases (ECCMID).

The symposium will be chaired by Prof. Thea Kølsen Fischer, Danish epidemiologist and member of the WHO team investigating the origins of SARS-CoV-2, and Katrin Dubischar, VP Program Director Chikungunya Vaccine at Valneva.

Adam Finn, Principal investigator for Valneva's COVID-19 program, Professor of Paediatrics at the University of Bristol and Consultant at the Bristol Royal Hospital for Children, will discuss Phase 1/2 data of VLA2001, the only whole-virus, inactivated adjuvanted COVID-19 vaccine candidate in clinical trials in Europe.

Prof. Thomas Jelinek, renowned key opinion leader and Medical Director of Berlin Centre for Travel and Tropical Medicine, will present on chikungunya disease and results of the Phase 1 study of Valneva's single-shot chikungunya vaccine candidate VLA1553.

To attend the ECCMID conference and participate in Valneva's symposium, you can register <u>here</u>.

About VLA2001

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe. It is intended for active immunization of at-risk populations to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic and potentially later for routine vaccination including addressing new variants. VLA2001 may also be suited for boosting, as repeat booster vaccinations have been shown to work well with whole virus inactivated vaccines. VLA2001 is produced on Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO[®]. VLA2001 consists of inactivated whole virus particles of SARS-CoV-2 with high Sprotein density, in combination with two adjuvants, alum and CpG 1018. This adjuvant combination has consistently induced higher antibody levels in preclinical experiments than alum-only formulations and shown a shift of the immune response towards Th1. CpG 1018 adjuvant, supplied by Dynavax Technologies Corporation (Nasdaq: DVAX), is a component of the US FDA- and EMA-approved HEPLISAV-B® vaccine. The manufacturing process for VLA2001, which has already been upscaled to final industrial scale, includes inactivation with BPL to preserve the native structure of the S-protein. VLA2001 is expected to conform with standard cold chain requirements (2 degrees to 8 degrees Celsius).





About VLA1553

VLA1553 targets 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 currently the only chikungunya vaccine candidate in Phase 3 clinical trials 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. Antibody titers were sustained after 12 months. Based on these results and Valneva's discussions with regulators, VLA1553 has advanced directly 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 2018¹ and PRIME designation by the European Medicines Agency (EMA) in October 2020².

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 2032³.

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 VLA1553⁴. 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 million⁵.

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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 and 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," "may," "expects," "anticipates," "believes," "intends,"

⁵ CEPI awards up to US\$23.4 million to Valneva for late-stage development of a single-dose chikungunya vaccine



¹ Valneva PR: <u>Valneva Awarded FDA Fast Track Designation for Chikungunya vaccine candidate</u>

² Valneva's Chikungunya Vaccine Candidate Awarded EMA Prime Designation

³ VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

⁴ Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries



"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.

