

Valneva Announces Publication in The Lancet of Complete Phase 1 Data for its Single-Shot Chikungunya Vaccine Candidate

Saint-Herblain (France), June 2, 2020 – [Valneva SE](#) (“Valneva” or “the Company”), a specialty vaccine company, announced today the publication of full data from the Phase 1 clinical trial of its chikungunya vaccine candidate, VLA1553, in the peer-reviewed medical journal *The Lancet Infectious Diseases*.

[The Lancet paper](#) provides a detailed analysis of final Phase 1 results and supports the continued clinical development of VLA1553.

Wolfgang Bender, Ph.D., M.D., Chief Medical Officer of Valneva, commented, “We reported excellent Phase 1 results¹ for our single-shot chikungunya vaccine and we’re pleased that these important results are now fully available to the broader infectious disease community. Millions of people have been affected by chikungunya and our objective is to help address this ongoing public health crisis as soon as we can.”

Valneva has previously reported the successful outcome of its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA)² in February 2020 and is now preparing to initiate Phase 3 clinical studies in the U.S. later this year.

About Chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a *Togaviridae* virus, transmitted by *Aedes* mosquitoes. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea and rash, potentially developing into long-term, serious health impairments. Chikungunya virus causes clinical illness in 72-92% of infected humans around 4 to 7 days after an infected mosquito bite. Complications resulting from the disease include visual, neurological, heart and gastrointestinal manifestations; fatalities have been reported (case fatality rates of 0.1% to 4.9% from epidemics)³ in elderly patients at higher risk. Chikungunya outbreaks have been reported in Asia, Africa, the Americas and recently (2017) in Europe. As of 2017, there have been more than one million reported cases in the Americas⁴ and the economic impact is considered to be significant (e.g., 2014 Colombia outbreak: \$73.6 million⁵). The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to further spread geographically. There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

¹ [Valneva Reports Excellent Final Phase 1 Results for its Chikungunya Vaccine Candidate, Confirms Plans](#)

² [Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study](#)

³ WHO, PAHO

⁴ PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)

⁵ Cardona-Ospina et al. 2015, *Trans R Soc Trop Med Hyg* 109:793-802.

About Valneva's vaccine candidate VLA1553

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate for protection against chikungunya. It was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in December 2018⁶.

The vaccine candidate is designed for prophylactic, active, single-dose immunization against chikungunya in humans over one year old. The vaccine targets long-lasting protection and an anticipated safety profile similar to licensed vaccines for active immunization in adults and children. The target population segments are travelers, military personnel and individuals at risk living in endemic regions. The global market for vaccines against chikungunya is estimated to exceed \$500 million annually, including a traveler vaccine market potential of ~\$250 million⁷. VLA1553 is based on an infectious clone (CHIKV LR2006-OPY1) attenuated by deleting a major part of the gene encoding the non-structural replicase complex protein nsP3, aiming for protection against various chikungunya virus outbreak phylogroups and strains⁸.

About Valneva SE

Valneva is a specialty vaccine company focused on prevention against diseases with major unmet needs. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has various vaccines in development including unique vaccines against Lyme disease and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the U.S. with over 500 employees. For more information, visit www.valneva.com and follow the company on [LinkedIn](#).

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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 and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. 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 their 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

⁶ [Valneva Awarded FDA Fast Track Designation for Chikungunya vaccine candidate](#)

⁷ *Company estimate supported by an independent market study*

⁸ *Hallengård et al. 2013, J. Virology 88:2858-2866.*

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. 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.