

Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate

Saint-Herblain (France), December 21, 2018 – Valneva SE (“Valneva”), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its chikungunya vaccine candidate, VLA1553.

Wolfgang Bender, MD, PhD, chief medical officer of Valneva, commented, “Chikungunya is a growing threat with unpredictable outbreaks and a serious impact on public health. Infection with the virus can cause serious symptoms and complications. The fast track designation will allow us to work closely with the FDA and to accelerate our efforts to develop a one dose solution for the prevention of this spreading disease.”

Fast Track designation is granted by the FDA to products under development for serious conditions that have the potential to fulfill an unmet medical need. Fast Track is designed to facilitate the clinical development and expedite the review of new drugs and vaccines with the intention of accelerating the availability of promising products on the market¹.

Valneva will release VLA1553’s initial Phase 1 data in the coming weeks.

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% to 92% of infected humans around four to seven days after an infected mosquito bite². 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)¹ in elderly patients, who are at a 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 Americas³ and the economic impact is considered to be significant (e.g. Colombia outbreak 2014: \$73.6m⁴). The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread further 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 monovalent, single dose, live-attenuated vaccine candidate for protection against chikungunya. It is designed for prophylactic, active, single-dose immunization against

¹ <https://www.fda.gov/forpatients/approvals/fast/ucm20041766.htm>

² WHO, PAHO

³ PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)

⁴ Cardona-Ospina et al., *Trans R Soc Trop Med Hyg* 2015

chikungunya in humans over one year old. The vaccine aims for 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 at up to €500 million annually⁵.

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 strains⁶.

In pre-clinical development, a single-vaccine shot was shown to be highly immunogenic in vaccinated Non-Human Primates (NHP) (*cynomolgus* macaques) and showed no signs of viremia after challenge⁷. In NHPs, VLA1553 induced a strong, long lasting (more than 300 days) neutralizing antibody response comparable to wild-type CHIKV infections combined with a good safety profile.

About Valneva SE

Valneva is a biotech company developing and commercializing vaccines for infectious 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 a robust pipeline of vaccines in development including a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 450 employees. More information is available at www.valneva.com.

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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

⁵ Company estimate support by an independent market study

⁶ Hallengård et al. 2013 J. Virology 88: 2858-2866

⁷ Roques et al. 2017JCI Insight 2 (6): e83527

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.