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Valneva Initiates Phase I Clinical Study to Evaluate Its Single-Shot Vaccine Candidate against Chikungunya

Lyon (France), March 13, 2018 – Valneva SE, a fully integrated commercial stage biotech company focused on developing innovative, lifesaving vaccines, today announced the initiation of a Phase I clinical trial in the U.S. to evaluate the safety and immunogenicity of VLA1553, its live-attenuated vaccine candidate against Chikungunya.

The Phase I clinical trial is a randomized, observer-blinded, dose-escalation, multi-center study. It will investigate three different dose levels of VLA1553 in approximately 120 healthy adults vaccinated with a single-shot immunization.

The trial design includes the investigation of antibody persistence and an additional vaccination using the highest dose of VLA1553 at 6 and 12 months. This re-vaccination will serve as an intrinsic human viral challenge, aiming to demonstrate that subjects are protected from vaccine-induced viremia thereby indicating potential efficacy of VLA1553 early in clinical development.

First data from the trial are expected to be available early 2019.

Wolfgang Bender, MD, PhD, Chief Medical Officer of Valneva commented "*We are proud to contribute to the ongoing global efforts to develop effective prevention against the increasing threat to public health caused by the Chikungunya virus. We have developed a sophisticated Phase I design with the intent to provide us with an early indication of competitive advantage that we anticipate for our vaccine candidate.*"

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[1]. 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 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 Americas[2] and the economic impact is considered to be significant (e.g. Columbia outbreak 2014: $73.6m[3]). The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to further spread geographically.

[1] *WHO, PAHO*
[2] *PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)*
[3] *Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015*

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 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 travellers, military personnel and individuals at risk living in endemic regions. The global market for vaccines against Chikungunya is estimated at up to €500 million annually[4].

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 strains[5].

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 challenge[6]. 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 fully integrated, commercial stage biotech company focused on developing innovative life-saving vaccines.

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 proprietary 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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[4] *Company estimate support by an independent market study*
[5] *Hallengärd et al. 2013 J. Virology 88: 2858-2866*
[6] *Roques et al. 2017JCI Insight 2 (6): e83527*

Valneva 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 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. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.