

## Valneva to Present on Lyme and Chikungunya Vaccine Candidates at the 19<sup>th</sup> World Vaccine Congress

**Saint Herblain (France), April 9, 2019** – Valneva SE (“Valneva” or “the Company”), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, announced today it will present on its Lyme disease and chikungunya vaccine candidates on April 16th, 2019 at the 19th World Vaccine Congress in Washington, D.C.

Valneva’s Chief Executive Officer, Thomas Lingelbach, will provide an update and discuss next steps for VLA15, the Company’s vaccine candidate against Lyme disease. Lyme is the most commonly occurring vector borne illness in the Northern Hemisphere with an estimated 300,000 Americans contracting the disease each year<sup>1</sup>. VLA15 has been shortlisted in the “Best Prophylactic Vaccine” category of the 2019 Vaccine Industry Excellence (ViE) Awards, held in conjunction with the World Vaccine Congress each year.

Valneva’s Chief Medical Officer, Dr. Wolfgang Bender, will also present on the Phase 1 development of the Company’s chikungunya vaccine candidate, VLA1553. He will also discuss next steps for the potential single-shot vaccine.

Valneva, a gold sponsor of the event, will have a display in the exhibit area at booth #318.

### Presentation Details

Event: The World Vaccine Congress 2019, Washington, D.C.

Venue: Renaissance Washington D.C. Downtown Hotel

Date: Tuesday, April 16, 2019

Time: 11:40 a.m. EDT for the chikungunya presentation; 2:40 p.m. EDT for the Lyme presentation

### About VLA15

Valneva’s vaccine candidate, VLA15, is currently the only active vaccine program in clinical development against Lyme disease. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017<sup>2</sup> and Valneva reported final Phase 1 data and positive initial booster data in January 2019<sup>3</sup>. VLA15 showed a favorable safety profile and was immunogenic in all doses and formulations tested with good OspA-specific IgG antibody responses against all OspA serotypes.

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<sup>1</sup> As estimated by the CDC, <https://www.cdc.gov/lyme/stats/humancases.html>

<sup>2</sup> <https://www.valneva.com/en/investors-media/news/2017#270>

<sup>3</sup> <https://www.valneva.com/en/investors-media/news/2019#309>



VLA15 is a multivalent, protein subunit vaccine that targets the outer surface protein A (OspA) of *Borrelia*. It is designed for prophylactic, active immunization against Lyme disease aiming for protection against the majority of human pathogenic *Borrelia* species. VLA15 is designed to confer protection by raising antibodies that prevent *Borrelia* from migrating from ticks to humans after a bite. The safety profile is expected to be similar to other vaccines using the same technology that have been approved for active immunization in adults and children.

The target population includes individuals at risk above 2 years of age living in endemic areas, people planning to travel to endemic areas to pursue outdoor activities and people at risk who have a history of Lyme disease (as infection with *Borrelia* does not confer protective immunity against all pathogenic *Borrelia* species).

Vaccination with OspA was already proven to work in the 1990s and VLA15 pre-clinical data showed that the vaccine has the potential to provide protection against the majority of the *Borrelia* species pathogenic for humans<sup>4</sup>.

### **About VLA1553**

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate for protection against chikungunya and was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in December 2018<sup>5</sup>. The vaccine candidate 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 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 annually<sup>6</sup>.

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<sup>7</sup>.

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<sup>8</sup>. 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 various vaccines in development including a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France,

<sup>4</sup> <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0113294>

<sup>5</sup> <https://www.valneva.com/en/investors-media/news/2018#304>

<sup>6</sup> *Company estimate support by an independent market study*

<sup>7</sup> *Hallengård et al. 2013 J. Virology 88: 2858-2866*

<sup>8</sup> *Roques et al. 2017JCI Insight 2 (6): e83527*

Canada and the U.S. with approximately 480 employees. More information is available at [www.valneva.com](http://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 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.