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# Valneva Completes Recruitment for Phase 2 Studies of its Lyme Disease Vaccine Candidate VLA15

**Saint-Herblain (France), September 30, 2019** – Valneva SE ("Valneva" or "the Company"), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, today announced that it has completed patient recruitment of the Phase 2 studies for its Lyme disease vaccine candidate, VLA15.

A total of 819 subjects have been recruited for Phase 2 development in two ongoing studies. The results of these studies, comprising immunogenicity and safety data, will support the dose and vaccination schedule to be used in Phase 3.

Study VLA15-201 includes 573 subjects across nine sites in Europe and the U.S. Study VLA15-202 includes 246 subjects across five sites in the U.S. In both studies, dosage levels of 135µg and 180µg of VLA15 are used and administered either at Day 1, Month 1 and Month 2 (VLA15-201) or at Day 1, Month 2 and Month 6 (VLA15-202).

**Wolfgang Bender, MD, PhD, Chief Medical Officer of Valneva**, commented, "*We are extremely pleased that all Phase 2 subjects have been recruited as planned and on target. We are making great progress in developing our Lyme disease vaccine candidate with the aim of addressing this significant unmet medical need. I would also like to thank our internal teams as well as our CROs and study sites for their dedication and commitment to achieve the subject recruitment on time. We are looking forward to our initial Phase 2 results in mid 2020."*

**About the Phase 2 Clinical Study VLA15-201**
VLA15-201 is the first of two planned, parallel Phase 2 studies. It is a randomized, observer-blind, placebo controlled trial conducted at trial sites in the U.S. and Europe.
In the run-in Phase, 120 subjects received one of three dosage levels of VLA15, or placebo. Following review of safety data by an independent Data Safety Monitoring Board, 453 subjects in the main study phase now receive one of two selected dose levels of VLA15, or placebo.
VLA15 is tested as an alum adjuvanted formulation and administered intramuscularly in three injections, given one month apart at Days 1, 29 and 57. Subjects will be followed for one year, with the main immunogenicity readout one month after the third immunization on Day 85 (primary endpoint). The study has enrolled healthy adults 18 to 65 years of age. Study centers are located in areas where Lyme disease is endemic; subjects with a cleared past infection with *Borrelia burgdorferi*, the bacteria that cause Lyme disease, were also enrolled.

**About the Phase 2 Clinical Study VLA15-202**
VLA15-202 is the second of two planned Phase 2 studies. It is a randomized, observer-blind, placebo controlled trial conducted at trial sites in the US.
246 subjects receive one of two dosage levels of VLA15 or placebo.
VLA15 is tested as alum adjuvanted formulations with 135µg and 180µg dosage levels and administered intramuscularly in three injections, given at Days 1, 57 and 180. Subjects will be followed for 18 months, with the main immunogenicity readout on Day 208 (primary endpoint). The study has enrolled healthy adults 18 to 65 years of age. Study centers are located in areas

where Lyme disease is endemic; subjects with a cleared past infection with *Borrelia burgdorferi*, the bacteria that cause Lyme disease, were also enrolled.

**About Lyme Disease**

Lyme disease is a systemic infection caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks[1]. It is considered the most common vector borne illness in the Northern Hemisphere. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 300,000 Americans[2] are diagnosed with Lyme disease each year with at least a further 200,000 cases in Europe[3]. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called *Erythema migrans* or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system. The medical need for vaccination against Lyme disease is steadily increasing as the disease footprint widens[4].

**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[5] .

Valneva reported final Phase 1 data demonstrating VLA15's favorable safety profile and immunogenicity in all doses and formulations tested, with good OspA-specific IgG antibody responses against all OspA serotypes. In addition, VLA15 elicited an excellent anamnestic response following a booster vaccination in a time window of 12 to 15 months after initial primary immunization[6]. As part of the ongoing Phase 2, two higher, alum-adjuvanted formulations have been selected for further development[7].

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 in Europe and the US. 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 lipidated protein based vaccines that are 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 proven to work in the 1990s

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[1] *Stanek et al. 2012, The Lancet 379:461–473*

[2] *As estimated by the CDC, https://www.cdc.gov/lyme/stats/humancases.html.*

[3] *Estimated from available national data. Number largely underestimated based on WHO Europe Lyme Report as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed; ECDC tick-borne-diseases-meeting-report*

[4] *New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017 https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/*

[5] *https://valneva.com/press-release/valneva-receives-fda-fast-track-designation-for-its-lyme-disease-vaccine-candidate-vla15/*

[6] *https://valneva.com/press-release/valneva-reports-positive-initial-booster-data-and-final-phase-1-data-for-its-lyme-disease-vaccine-candidate/*

[7] *https://valneva.com/press-release/valneva-reports-successful-outcome-of-phase-2-run-in-for-its-lyme-disease-vaccine-candidate/*

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[8].

**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, Canada and the US with over 480 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 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.

[8] *http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0113294.*