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Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15

- Phase 2 study VLA15-202 met its endpoints
- VLA15 generally safe across all dose and age groups tested
- Immunogenicity further increased in VLA15-202 compared to VLA15-201
    - Seroconversion Rates exceeded 90% across all serotypes, including in older adults (50-65 years)
- Functionality of antibodies was demonstrated across all serotypes using a Serum Bactericidal Assay

Saint-Herblain (France), October 20, 2020 – Valneva SE ("Valneva"), a specialty vaccine company focused on prevention of diseases with major unmet needs, today announced positive initial results for its second Phase 2 study (VLA15-202) of Lyme disease vaccine candidate VLA15.

Compared to study VLA15-201, study VLA15-202 investigated a vaccination schedule of Month 0-2-6 based on matching doses.

VLA15 was generally safe across all doses and age groups tested. The tolerability profile including fever rates was comparable to other lipidated recombinant vaccines or lipid containing formulations. As in VLA15-201, no related Serious Adverse Events (SAEs) were observed in any treatment group. Reactogenicity decreased following the first vaccination.

Compared to study VLA15-201, immunogenicity was further enhanced using a Month 0-2-6 schedule. SCRs (Seroconversion Rates), after completion of the primary vaccination series, showed similar responses and ranged from 93.8% [ST1] to 98.8% [ST2, ST4]. Antibody responses were comparable in the two dose groups tested.

The immunological response in older adults, one of the main target groups for a Lyme vaccine, is particularly encouraging, as already observed in VLA15-201.

Furthermore, results did not indicate that prior exposure to Borrelia spirochetes (sero-positivity) has an impact on immunogenicity or safety, also as observed in VLA15-201.

A Serum Bactericidal Assay (SBA), assessing the functional immune response against Lyme disease after vaccination with VLA15, was conducted for the first time and demonstrated functionality of antibodies against all OspA serotypes. Assays, such as SBAs, are commonly used to enable a potential prediction of vaccine efficacy via the measurement of vaccine-induced functional immune responses.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, *"We are extremely pleased with these results which showed an excellent immunological profile, further supported by additional positive data through the Serum Bactericidal Assay (SBA). With these encouraging data we are now well positioned to continue development. Lyme disease continues to be a high*

unmet medical need and our objective remains to work closely with Pfizer to offer a preventative solution as soon as possible."

VLA15-202 Day 208 safety and immunogenicity data support advancing the program with the Month 0-2-6 schedule. Valneva and Pfizer will finalize dosage analysis and prepare for the next development steps in the coming months.

About Phase 2 Clinical Study VLA15-202

VLA15-202, the second Phase 2 study, is a randomized, observer-blind, placebo controlled trial conducted in the US.

A total of 246 volunteers received 135 µg or 180 µg of VLA15 (approximately 100 subjects each) or placebo (approximately 50 subjects).

VLA15 was tested as alum adjuvanted formulation and was administered intramuscularly in three injections, given at Month 0, 2 and 6 (compared to Month 0, 1 and 2 in study VLA15-201).

Subjects are followed for 18 months, with the main immunogenicity readout at one month after completion of the primary vaccination series (primary endpoint). The study enrolled healthy adults 18 to 65 years of age.

Study centers are located in areas where Lyme disease is endemic; volunteers with a cleared past infection with *Borrelia burgdorferi*, the bacteria that cause Lyme disease, were also enrolled.

About VLA15

VLA15 is the only active Lyme disease vaccine in clinical development today, and covers six serotypes that are prevalent in North America and Europe. This investigational multivalent protein subunit vaccine targets the outer surface protein A (OspA) of Borrelia, an established mechanism of action for a Lyme disease vaccine. OspA is one of the most dominant surface proteins expressed by the bacteria when present in a tick. VLA15 has demonstrated strong immunogenicity and safety data in pre-clinical, Phase 1 and Phase 2studies. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[1].

Valneva and Pfizer announced a collaboration for VLA15's development and commercialization at the end of April 2020[2]. The two companies are working closely together on the next development steps.

About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks[3]. 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[4] are diagnosed with Lyme disease each year with at least a further 200,000 cases in Europe[5]. 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

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[1] *Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15*

[2] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*

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

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

[5] *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*

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[6].

About Valneva SE

Valneva is a specialty vaccine company focused on prevention of 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. Valneva has various vaccines in development including unique vaccines against Lyme disease, COVID-19 and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US 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 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.

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[6] *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/