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Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate

- Phase 2 study VLA15-221 planned to be initiated in Q1 2021, subject to regulatory approval
  - First clinical study of VLA15 that includes a pediatric population, aged 5-17 years
  - Study will include participants from 5-65 years of age and a reduced immunization schedule (Month 0-6 compared to Month 0-2-6)
  - The study will trigger a milestone payment, upon dosing of the first subject, from Pfizer to Valneva of $10 million
- Phase 3 pivotal efficacy trial is planned to commence in 2022

Saint-Herblain (France), December 2, 2020 – Valneva SE ("Valneva"), a specialty vaccine company focused on prevention of diseases with major unmet needs, today announced its plans to accelerate pediatric development of its Lyme vaccine candidate, VLA15, in collaboration with Pfizer Inc. (NYSE: PFE), with the planned initiation of study VLA15-221 in the first quarter of 2021, subject to regulatory approval.

VLA15-221 is planned as a randomized, observer-blind, placebo-controlled Phase 2 study. Currently, the study will include approximately 600 healthy participants (5-65 years of age) who will receive VLA15 at the dose of 180µg, which was selected based on recent data generated in the two ongoing Phase 2 studies.

If approved, it will be the first clinical study of VLA15 to enroll a pediatric population aged 5-17 years and will compare the three-dose vaccination schedule Month 0-2-6 with a reduced two-dose schedule of Month 0-6.

"*This will be an important study that we anticipate will provide evidence that the vaccine can be used in the populations that are at risk of the devastating consequences of Lyme disease, using a simplified schedule,"* said **Kathrin Jansen, Senior Vice President and Head of Pfizer Vaccine Research and Development.**

This study will complement the two ongoing Phase 2 studies VLA15-201 (initial positive data reported on 22nd July 2020[1]) and VLA15-202 (initial positive data reported on 20th October 2020[2]). Initial data from study VLA15-221 (primary endpoint) are expected by the second quarter of 2022. VLA15-221 will also investigate a booster dose of VLA15, administered one year following the 6 Month dose. All three Phase 2 trials are anticipated to support a Phase 3 pivotal efficacy trial including all main target populations for the Lyme vaccine candidate starting in 2022.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva commented "We believe that *including the pediatric population early on could provide support for the Phase 3 study to include all major target groups for our future Lyme vaccine candidate and may potentially support successful market access including respective recommendations. We are pleased that Pfizer and*

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

Valneva have decided to accelerate this development step while preparing for a potential Phase 3 start, expected in 2022."

Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop and commercialize VLA15.

Under the terms of the agreement, first subject, first dose in this study will trigger a milestone payment of $10 million from Pfizer to Valneva. The original Valneva plan, prior to the Pfizer agreement, assumed age de-escalation post-licensure. The Pfizer collaboration allows acceleration of pediatric development.

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 promising immunogenicity and safety data in pre-clinical and clinical studies so far. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[3].
Valneva and Pfizer announced a collaboration for VLA15's development and commercialization at the end of April 2020[4]. The two companies are working closely together on the next development steps.

About Clinical Study VLA15-221

VLA15-221 is a randomized, observer-blind, placebo controlled Phase 2 study. It is the first clinical study with VLA15 that will enroll a pediatric population aged 5 years and older.
A total of approximately 600 participants will receive VLA15 at two different immunization schedules (Month 0-2-6 or Month 0-6, 200 volunteers each) or placebo (Month 0-2-6, 200 volunteers). The main safety and immunogenicity readout (Primary Endpoint analysis) is anticipated at Month 7, where peak antibody titers are expected. A subset of participants will receive a booster dose of VLA15 or placebo at Month 18 (Booster Phase) and will be followed for three further years to monitor the antibody persistence.
VLA15 will be tested as an alum-adjuvanted formulation and administered intramuscularly. The study will be conducted at sites which are located in areas where Lyme disease is endemic and will enroll volunteers with a cleared past infection with *Borrelia burgdorferi*, the bacteria that cause Lyme disease, as well as *B. burgdorferi* naïve volunteers.

About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia* bacteria *burgdorferi* sensu lato transmitted to humans by infected *Ixodes* ticks[5]. 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[6] are diagnosed with Lyme disease each

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[3] *Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15*
[4] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[5] *Stanek et al. 2012, The Lancet 379:461–473*
[6] *As estimated by the CDC, https://www.cdc.gov/lyme/stats/humancases.html.*

year with at least a further 200,000 cases in Europe[7]. 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[8].

About Valneva SE

Valneva is a specialty vaccine company focused on prevention against diseases with major unmet needs. The Company has several vaccines in development including vaccines against Lyme disease, COVID-19 and chikungunya. 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. 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, design, data read-outs, anticipated results and completion of clinical trials for VLA15 and the expected milestone payment from Pfizer to Valneva. 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 future results. 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 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, the ability to obtain or maintain patent or other proprietary intellectual property protection and the impact of the COVID-19 pandemic. 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 this press release

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[7] 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

[8] 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/

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