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Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate

Saint-Herblain (France) and New York (United States), September 28, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE), today announced further positive Phase 2 results, including booster response, for Lyme disease vaccine candidate VLA15.

The Phase 2 study, VLA15-202, is evaluating the immunogenicity and safety of VLA15 in a Month 0-2-6 vaccination schedule. The study enrolled 246 healthy adults 18 to 65 years of age in the U.S. As announced in October 2020[1], the study met its primary endpoint of demonstrating that VLA15 was immunogenic across all dose groups tested and elicited high antibody responses across all serotypes (ST1 - ST6) at one month after completion of the primary vaccination series. Continued evaluation at Month 18 showed that antibody titers declined thereafter across all groups, remaining above baseline but confirming the need for a booster strategy.

VLA15 was safe and well-tolerated across all doses and age groups tested. No related Serious Adverse Events (SAEs) were observed in any treatment group.

Participants who received a complete primary vaccination series with 180 µg doses of VLA15, were invited to continue the study in a booster extension phase and were randomized to receive an additional 180 µg dose of VLA15 (N=39) or placebo (N=19) at Month 18.

VLA15's acceptable safety profile was confirmed through one-month post-booster. Administration of a booster dose elicited a strong anamnestic response yielding a 2.9-fold (ST3) to 4.2-fold (ST1, ST4) increase (Geometric Mean Fold Rise) in anti-OspA IgG antibody titers compared with titers observed after primary immunization. All participants seroconverted to anti-OspA IgG after the booster dose, meaning Seroconversion Rates (SCRs) were 100% for all OspA serotypes. SCR was defined as the rate of subjects that changed from seronegative at baseline to seropositive. Additionally, subjects who were seropositive at baseline needed to show at least a 4-fold increase in anti-OspA IgG compared to baseline titer. Functionality of elicited antibodies was demonstrated by Serum Bactericidal activity Assays, leading to SCRs ranging from 86.8% (ST2) to 100.0% (ST3) after the booster. The study is continuing to monitor persistence of antibody responses.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, commented, "Lyme disease represents a high unmet medical need which impacts the lives of millions of people in the Northern Hemisphere. We are excited by these additional Phase 2 results, which we believe take us a step closer to making a major contribution against this severe disease, subject to regulatory approval."

"The prevalence and geographic reach of Lyme disease is growing, underscoring the major medical need for vaccination against the disease," adds **Kathrin Jansen, PhD, Senior Vice President and Head of Pfizer Vaccine Research and Development**. "These positive results of the Phase 2 VLA15-202 study represent another important milestone in the development of VLA15,

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

and we look forward to continue our development efforts in our quest to potentially protect people from Lyme disease in the future."

About VLA15

VLA15 is the only active Lyme disease vaccine candidate in clinical development. This investigational multivalent protein subunit vaccine uses an established mechanism of action for a Lyme disease vaccine that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacteria that cause Lyme disease, and covers the six OspA serotypes that are prevalent in North America and Europe. 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 and clinical studies so far. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[2].

Valneva and Pfizer announced a collaboration for VLA15's development and commercialization at the end of April 2020. The two companies are working closely together on the next development steps and are planning for a Phase 3 trial in 2022.

About Phase 2 Clinical Study VLA15-202

VLA15-202 is a randomized, observer-blind, placebo controlled trial conducted in the US.
A total of 246 healthy volunteers 18 to 65 years of age received 135 µg (N=97), or 180 µg (N=98) of VLA15 or placebo (N=51)).

VLA15 was tested as alum adjuvanted formulation and was administered intramuscularly at Month 0-2-6.

Participants were followed for an additional 12 months, with the primary immunogenicity readout at one month after completion of the primary vaccination series (Primary Endpoint). A subset of participants who received a complete primary vaccination series in the 180 µg dose level VLA15 group, were invited to continue the study into a booster phase and were randomized to receive an additional 180 µg dose of VLA15 (N=39) or placebo (N=19) at Month 18.

Study centers are located in areas where Lyme disease is endemic; volunteers with a prior history of Lyme disease were also enrolled.

About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia burgdorferi* 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 476,000 Americans are diagnosed and treated for Lyme disease each year[4], and there are at least a further 200,000 cases in Europe annually[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

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

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

[4] *Source: 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*

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[6].

About Valneva SE
Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

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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, results and completion of research, development and clinical trials for product candidates and estimates for future performance. In addition, even if

[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/*

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 sustained 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. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. 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.

Pfizer Forward-Looking Statements

The information contained in this release is as of September 28, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a Lyme disease vaccine candidate, VLA15, and a collaboration between Pfizer and Valneva for VLA15, including their potential benefits and a potential phase 3 trial, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for VLA15; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether VLA15 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VLA15; the impact of COVID-19 on Pfizer’s business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of

which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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