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Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate

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Saint-Herblain (France) and New York, NY, July 19, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, and Pfizer Inc. (NYSE: PFE), today announced that they have completed recruitment for the Phase 2 trial, VLA15-221, of Lyme disease vaccine candidate, VLA15. The trial builds on previous positive Phase 2 trials and includes both adult and pediatric participants with the aim to support acceleration of the vaccine candidate's pediatric program.

A total of 625 participants, 5 to 65 years of age, have been randomized in the Phase 2 trial to receive VLA15 at Month 0-2-6 or Month 0-6 (200 volunteers each) or placebo at Month 0-2-6 (200 volunteers). The main safety and immunogenicity readout will be performed approximately one month after completion of the primary vaccination schedule (i.e. at Month 7). The objective of the trial is to show safety and immunogenicity down to 5 years of age and to evaluate the optimal vaccination schedule for use in Phase 3.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, *"This recruitment completion represents another important milestone in the development of VLA15. If successful, this trial could enable the inclusion of a pediatric population in the Phase 3 trial. Lyme disease continues to be a major concern and is prevalent in children[1], it is therefore extremely important for us to potentially offer a vaccine that could protect both adults and children as rapidly as we can. We'd like to thank everyone involved in the trials for their contributions to keep the development moving forward and on track."*

"Given the medical importance of Lyme disease, its possible long term impact, and the known mechanism of vaccine protection, the development of a multivalent vaccine for prevention of 6 serotypes of Borrelia has the potential to address a great unmet need," said **Kathrin Jansen, PhD, Senior Vice President and Head of Pfizer Vaccine Research and Development.** *"We are pleased that the Phase 2 trial has reached full recruitment and look forward to what we hope will be a successful conclusion of the study."*

Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15[2]. Positive top-line results have already been reported for two Phase 2 clinical trials of VLA15 in over 800 healthy adults. Topline results for VLA15-221 are expected in the first half of 2022.

About VLA15
VLA15 is the only active Lyme disease vaccine candidate in clinical development today, and covers six serotypes that are prevalent in North America and Europe. 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. 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[3].
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.

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 enrolls a pediatric population aged 5 years and older.
A total of 625 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). Vaccinees receive VLA15 at a dose of 180µg, which was selected based on data generated in the two previous Phase 2 studies. The main safety and immunogenicity readout (Primary Endpoint analysis) will be performed at Month 7, when peak antibody titers are anticipated. A subset of participants will receive a booster dose of VLA15 or placebo at Month 18 (Booster Phase) and will be followed for three additional years to monitor antibody persistence.
VLA15 is tested as an alum-adjuvanted formulation and administered intramuscularly. The study is conducted at sites which are located in areas where Lyme disease is endemic and has enrolled volunteers with a cleared past infection with *Borrelia burgdorferias* well as *Borrelia burgdorferi* naïve volunteers.

About Lyme Disease
Lyme disease is a systemic infection caused by *Borrelia burgdorferi* bacteria transmitted to humans by infected Ixodes ticks[4]. 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[5], and there are at least a further 200,000 cases in Europe annually[6]. 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[7].

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. We take a highly specialized and targeted approach to vaccine development, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. We then apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, as well as our established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. We have leveraged our 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 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 March 8, 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 start, 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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[1] CDC: Lyme disease, reported cases by age group, United States, 2019
[2] Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15
[3] Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15
[4] Stanek et al. 2012, The Lancet 379:461–473
[5] Source: https://www.cdc.gov/lyme/stats/humancases.html
[6] 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
[7] 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/