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Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate

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- ***Strong immunogenicity profile observed in study participants aged 5-17 years one month after the primary vaccination series***
- ***Safety profile observed in pediatric participants similar to previously reported data in adult participants***
- ***Pediatric population to be included in planned Phase 3 trial – expected to start in Q3 2022, subject to regulatory approval***

SAINT-HERBLAIN, France & NEW YORK--(BUSINESS WIRE)-- Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE) today reported positive Phase 2 pediatric data for their Lyme disease vaccine candidate, VLA15. Based on these new results, Valneva and Pfizer plan to proceed with inclusion of pediatric participants in their planned Phase 3 trial. The trial will evaluate VLA15 in adults and pediatric subjects 5 years of age and above and is expected to be initiated in the third quarter of 2022, subject to regulatory approval.

The Phase 2 trial, VLA15-221, is the first clinical study with VLA15 which enrolled a pediatric population (5-17 years old). It compared the immunogenicity and safety of VLA15 after administration of two (at months 0 and 6) or three (at months 0, 2 and 6) primary series doses in groups aged 5-11, 12-17 and 18-65 years. In pediatric participants (5-17 years old) who received VLA15 in either the two-dose schedule (N=93) or three-dose schedule (N=97), VLA15 was found to be more immunogenic than in adults with both vaccination schedules tested. These data build on the strong immunogenicity profile already reported for adult participants (18-65 years old) in February 2022[1]. Like in adults, the immunogenicity and safety data support a three-dose primary vaccination schedule in pediatric participants in the Phase 3 study.

The safety and tolerability profile observed in the 5- to 17-year age group was similar to the previously reported profile in adult participants. No vaccine-related serious adverse events (SAEs) were observed.

Valneva and Pfizer plan to submit these data for publication and presentation at a future scientific congress.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, “Lyme disease affects all age groups, but with their affinity for being active outdoors, the pediatric population is at the greatest risk of Lyme disease. These first pediatric results are therefore extremely important and support the inclusion of pediatric participants in our planned Phase 3 trial. In partnership with Pfizer, we are excited to further investigate our VLA15 vaccine candidate, which will hopefully help protect both adults and children against Lyme disease.”

Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer, said: “The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens. These positive pediatric data mark an important step forward in the ongoing development of VLA15, and we are excited to continue working with Valneva to potentially help protect both adults and

children from Lyme disease."

About VLA15
VLA15 is the only Lyme disease vaccine candidate currently 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. OspA is one of the most dominant surface proteins expressed by the bacteria when present in a tick. Blocking OspA inhibits the bacterium's ability to leave the tick and infect humans. The vaccine covers the six most common OspA serotypes expressed by *Borrelia burgdorferisensu lato* species that are prevalent in North America and Europe. VLA15 has demonstrated a strong immunogenicity and safety profile 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 entered into a collaboration agreement in April 2020 to co-develop VLA15[3].

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 which enrolled a pediatric population (5-17 years old).

585 healthy participants received VLA15 at two different immunization schedules (month 0-2-6 [N=190] or month 0-6 [N=187]) or three doses of placebo (month 0-2-6 [N=208]). Vaccine recipients received VLA15 at a dose of 180 µg, which was selected based on data generated in the two previous Phase 2 studies. The main safety and immunogenicity readout was performed one month after the primary vaccination series. 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 being conducted at U.S. sites located in areas where Lyme disease is endemic and has enrolled both volunteers with a cleared past infection with *Borrelia burgdorferi* as well as *Borrelia burgdorferi*-naïve volunteers.

About Lyme Disease
Lyme disease is a systemic infection caused by *Borreliaburgdorferi* bacteria transmitted to humans by infected *Ixodes* ticks[4]. It is considered the most common vector-borne illness in the Northern Hemisphere. While the true incidence of Lyme disease is unknown, it is estimated to annually affect approximately 476,000 people in the United States[5] and 130,000 people in Europe[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 geographic footprint of the disease 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. 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.

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 Disclosure Notice

The information contained in this release is as of April 26, 2022. 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 planned phase 3 clinical 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; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; 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, 2021 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.

References

[1] *Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate – Valneva*
[2] Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15
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[6] Sykes RA, et al. An estimate of Lyme borreliosis incidence in Western Europe. Journal of Public Health 2017; 39(1): 74-81
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