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Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15

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- *Approximately 6,000 participants 5 years of age and older will be enrolled in Lyme disease-endemic regions in Europe and the U.S.*

NEW YORK & SAINT-HERBLAIN, France--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) today announced the initiation of a Phase 3 clinical study, Vaccine Against Lyme for Outdoor Recreationists (VALOR) (NCT05477524), to investigate the efficacy, safety and immunogenicity of their investigational Lyme disease vaccine candidate, VLA15.

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“With increasing global rates of Lyme disease, providing a new option for people to help protect themselves from the disease is more important than ever,” said Annaliesa Anderson, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer. “We hope that the data generated from the Phase 3 study will further support the positive evidence for VLA15 to date, and we are looking forward to collaborating with the research sites across the U.S. and Europe on this important trial."

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, “We are extremely pleased to reach this important milestone in the development of VLA15. Lyme disease continues to spread, representing a high unmet medical need that impacts the lives of many in the Northern Hemisphere. We look forward to further investigating the VLA15 candidate in Phase 3, which will take us a step closer to potentially bringing this vaccine to both adults and children who would benefit from it.”

The randomized, placebo-controlled, Phase 3 VALOR study is planned to enroll approximately 6,000 participants 5 years of age and older. The study is being conducted at up to 50 sites located in areas where Lyme disease is highly endemic, including Finland, Germany, the Netherlands, Poland, Sweden and the United States. Participants will receive three doses of VLA15 180 µg or saline placebo as a primary vaccination series followed by one booster dose of VLA15 or saline placebo (1:1 ratio).

Data from the Phase 2 studies continue to demonstrate strong immunogenicity in adults as well as in children, with acceptable safety and tolerability profiles in both study populations.[1,2] Pending successful completion of the Phase 3 study, Pfizer could potentially submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) in 2025.

As per the terms of the collaboration agreement between Pfizer and Valneva, Pfizer will make a $25 million milestone payment to Valneva upon initiation of the Phase 3 study.

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 a surface protein 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 the *Borrelia burgdorferisensu lato* species that are prevalent in North America and Europe. VLA15 has demonstrated a strong immune response and satisfactory safety profile in pre-clinical and clinical studies so far. Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15, with updates to the terms within this agreement made in June 2022.[3,4] The terms of the collaboration agreement include a $25 million milestone payment made to Valneva upon Pfizer's initiation of the Phase 3 study. The program was granted Fast Track designation by the U.S. FDA in July 2017.[5]

About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia burgdorferi* bacteria transmitted to humans by infected *Ixodes* ticks.[6] It is considered the most common vector-borne illness in the Northern Hemisphere.[7] While the true incidence of Lyme disease is unknown, it is estimated to annually affect approximately 476,000 people in the United States and 130,000 people in Europe.[8,9] Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called *Erythema migrans* or more nonspecific 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.[9] The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens.[8]

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.

Pfizer Disclosure Notice

The information contained in this release is as of August 8, 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, a Phase 3 clinical trial and the timing of potential regulatory submissions, 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, including uncertainties relating to the time needed to accrue cases in the Phase 3 trial, 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; whether our collaboration with Valneva will be successful; uncertainties regarding 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.

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.

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.

[Category: Research]

References

1. Valneva. Valneva Pfizer Report Positive Phase 2 Pediatric Data for Lyme Vaccine Candidate. April 2022. Available at: https://valneva.com/press-release/valneva-and-pfizer-report-positive-phase-2-pediatric-data-for-lyme-disease-vaccine-candidate/ Accessed: July 2022.
2. Valneva. Valneva Pfizer Report Positive Phase 2 Data for Lyme Disease Vaccine Candidate. February 2022. Available at: https://valneva.com/press-release/valneva-and-pfizer-report-further-positive-phase-2-data-for-lyme-disease-vaccine-candidate/ Accessed: July 2022.
3. Valneva. Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15. April 2020. Available at: https://valneva.com/press-release/valneva-and-pfizer-announce-collaboration-to-co-develop-and-commercialize-lyme-disease-vaccine-vla15/ Accessed: July 2022 .
4. Valneva. Valneva and Pfizer Enter into Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15. June 2022. Available at: https://valneva.com/press-release/valneva-and-pfizer-enter-into-an-equity-subscription-agreement-and-update-terms-of-collaboration-agreement-for-lyme-disease-vaccine-candidate-vla15/ Accessed: July 2022.
5. Valneva. Valneva Receives FDA Fast track Designation for its Lyme Disease Vaccine Candidate VLA15. July 2017. Available at: https://valneva.com/press-release/valneva-receives-fda-fast-track-designation-for-its-lyme-disease-vaccine-candidate-vla15/ Accessed: July 2022.
6. Stanek G, Wormser GP, Gray J, et al. Lyme borreliosis. Lancet. 2012; 4;379(9814):461-73
7. Gern L, Falco RC. Lyme disease. Rev Sci Tech. 2000 Apr;19(1):121-35.
8. Center for Disease Control and Prevention. Lyme Disease. Data and Surveillance. April 2021. Available at: https://www.cdc.gov/lyme/datasurveillance/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fly Accessed July 2022.
9. Sykes RA, et al. An estimate of Lyme borreliosis incidence in Western Europe. Journal of Public Health 2017; 39(1): 74-81
10. Center for Disease Control and Prevention. Lyme Disease. Signs and Symptoms of Untreated Lyme disease. January 2021. Available at: https://www.cdc.gov/lyme/signs_symptoms/index.html Accessed July 2022.

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