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Pfizer and Valneva Complete Recruitment for Phase 3 VALOR Trial for Lyme Disease Vaccine Candidate, VLA15

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- *9,437* participants enrolled at sites across the U.S., Europe and Canada in areas where Lyme disease is endemic*
- *Trial conclusion expected by year-end 2025*
- *Pfizer aims to submit regulatory filings in the U.S. and Europe in 2026*

New York, NY, and Saint-Herblain (France), December 4, 2023 – Pfizer Inc. (NYSE: PFE) and Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) today announced that they have completed recruitment for the Phase 3 trial Vaccine Against Lyme for Outdoor Recreationists (VALOR) (NCT05477524) for Lyme disease vaccine candidate VLA15. The trial builds on previous positive Phase 1 and 2 trial results and includes both adult and pediatric participants, with the aim to confirm the efficacy, safety, lot consistency, and immunogenicity of VLA15.

“We are pleased that the Phase 3 trial recruitment is complete. Lyme disease is the most prevalent vector-borne infectious disease in the United States and Europe, can sometimes even lead to long lasting consequences,” said **Annaliesa Anderson, Ph.D., Senior Vice President and Head Vaccine Research and Development, Pfizer**. “If approved, a vaccine could prevent the disease and ease the burden of acute, severe and sometimes persistent consequences in both adults and children. We look forward to progressing the trial with the goal of submitting a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2026, subject to positive data.”

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said: “The completion of enrollment is indeed an important milestone in the development of a potential vaccine for Lyme disease. VLA15 has the potential to address a high need in North America and Europe, as it has been designed to offer coverage for the most common circulating types of *Borrelia* bacteria that cause Lyme disease in these regions. We’re excited about the ongoing trials and the progress towards potentially offering a vaccine against this disease which can result in debilitating sequelae and excessive healthcare usage.”

The VALOR trial, which was initiated in August 2022, has enrolled 9,437* participants five years of age and older, at sites in areas where Lyme disease is highly endemic across the U.S., Europe and Canada. As part of the primary series, participants receive three doses of VLA15 or a saline placebo (1:1 ratio) within the first year, and one booster dose approximately one year after completion of the primary immunization.

The VLA15 candidate has demonstrated a strong immune response and had a favorable safety profile across all dose and age groups in pre-clinical and clinical trials so far.[1,2] No vaccine-related serious adverse events (SAEs)

and no safety concerns were observed by an independent Data Safety Monitoring Board (DSMB).[1,2] A second Phase 3 trial (C4601012), aiming to provide further evidence on the safety profile of VLA15 in the pediatric population, is also fully recruited.

The VALOR trial is expected to be concluded by the end of 2025. Pfizer and Valneva 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]

About VLA15
There are currently no approved human vaccines for Lyme disease, and VLA15 is the most advanced Lyme disease vaccine candidate currently in clinical development, with two Phase 3 trials in progress. 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 candidate covers the six most common OspA serotypes expressed by the *Borrelia burgdorferi sensu lato* species that are prevalent in North America and Europe. VLA15 is an alum-adjuvanted formulation, administered intramuscularly and has demonstrated a strong immune response as well as satisfactory safety profile in pre-clinical and clinical trials so far.

About the VALOR trial
VALOR is an ongoing randomized, observer-blind, placebo-controlled Phase 3 trial which has enrolled 9,437* participants 5 years of age and older to receive VLA15 or a saline placebo (1:1 ratio). As part of the primary series, participants receive three doses of VLA15 within the first year at months 0, 2 and 5-9, and one booster dose 9-12 months after completion of the primary immunization.[5] The final primary series vaccination for participants occurs just before the peak Lyme disease season for the region. Participants will be followed for the occurrence of Lyme disease. The trial is conducted at sites located in areas where Lyme disease is highly endemic across the U.S., Canada and Europe and has enrolled 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 *Borrelia burgdorferi* bacteria transmitted to humans by the bite of an infected Ixodes ticks.[6] It is considered the most common vector-borne illness in the Northern Hemisphere.[7,8] While the true incidence of Lyme disease is unknown, it is estimated to annually affect approximately 476,000 people in the U.S. and 129,000 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 chronic complications affecting the skin, joints (arthritis), the heart (carditis) or the nervous system.[9,10] The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens.[11]

* Number of evaluable participants

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 December 4, 2023. 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 an investigational Lyme disease vaccine candidate, VLA15, and a collaboration between Pfizer and Valneva for VLA15, including their potential benefits, Phase 3 clinical trials 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 and uncertainties relating to an agreement with regulatory authorities on any modifications to the clinical trial plan as needed, 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, 2022 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
We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions.

We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market two proprietary travel vaccines as well as certain third-party vaccines leveraging our established commercial infrastructure.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the world's first vaccine against the chikungunya virus, the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, as well as vaccine candidates against the Zika virus and other global public health threats.

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. 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.

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