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Phase 3 VALOR Lyme Disease Trial: Valneva and Pfizer Announce Primary Vaccination Series Completion

Wednesday, July 17, 2024 - 04:30pm

- *Participants completed primary vaccination series (3 doses) with VLA15*
- *Primary vaccination series to be followed by a booster approximately one year after completion*

New York, NY and Saint-Herblain (France), July 17, 2024 – Pfizer Inc. (NYSE: PFE) and Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) today announced that the participants of the Phase 3 trial "Vaccine Against Lyme for Outdoor Recreationists" (VALOR) have completed the primary vaccination series (three doses) of Lyme disease vaccine candidate VLA15. Participants will be monitored for the occurrence of Lyme disease cases until the end of the Lyme disease season in 2025.[1]

"The completion of the primary series of our VALOR trial is a critical step toward our goal of providing a safe and effective vaccine against Lyme disease," said **Annaliesa Anderson, Ph.D., Senior Vice President and Head of Vaccine Research and Development, Pfizer**. "VLA15, the Lyme disease vaccine candidate we are co-developing with Valneva, is the one which has advanced the furthest along the clinical development timeline, with two Phase 3 trials in progress."

Juan Carlos Jaramillo, M.D., Chief Medical Officer, Valneva, said, "We are pleased to see the progress of our Phase 3 VALOR trial. Lyme disease is the most prevalent vector-borne disease in the United States and Europe. It can result in debilitating complications and extensive healthcare treatments. Given the growing burden, high medical need, and lack of effectiveness with current interventions, there is an urgent need for novel approaches to help prevent Lyme disease."

The VALOR trial, for which Pfizer is the sponsor, is a multicenter, placebo-controlled, randomized, observer-blinded trial conducted at sites in areas where Lyme disease is highly endemic across the U.S., Canada, and Europe. The aim of the trial is to evaluate the efficacy, safety, tolerability, immunogenicity, and lot consistency of VLA15, a 6-valent OspA-based Lyme disease vaccine candidate.[1] Trial participants aged 5 years and older were randomized 1:1 into two trial groups and receive four doses of either VLA15 or a saline placebo – one dose each at months 0, 2, 5-9 and a booster one year after the third dose, shortly before the peak of the next Lyme disease season.[1]

Subject to positive data, Pfizer plans to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2026.

VLA15 has shown a favorable safety profile across all dose and age groups in all clinical trials to date.[2,3] No safety concerns have been observed to date by an independent Data Safety Monitoring Board (DSMB) in any treatment group.[2,3] A second Phase 3 trial (C4601012), aiming to provide further evidence on the safety profile of VLA15 in the pediatric population between 5 and 17 years of age is ongoing; this trial completed enrollment

in June 2023.

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.[4,5]

About VLA15
There are currently no approved human vaccines for Lyme disease, and VLA15 is the Lyme disease vaccine candidate which has advanced the furthest along the clinical development timeline, 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 prevalent OspA serotypes expressed by the *Borrelia burgdorferi sensu lato* species in North America and Europe.

About Lyme Disease
Lyme disease is a systemic infection caused by *Borrelia burgdorferi* bacteria transmitted to humans by the bite of 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, the Centers for Disease Control and Prevention (CDC) has estimated that approximately 476,000 people in the U.S. are diagnosed and treated each year and 129,000 cases are reported annually in Europe.[8,9] Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called erythema migrans or other nonspecific symptoms like fatigue, fever, headache, mild stiff neck, muscle and joint paints) 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]

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 175 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 X 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 July 17, 2024. 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 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, 2023 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 three 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 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 and the timing for submission of such product candidates for regulatory approval. In addition, even if the actual results or developments 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 financing environment, 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 in this press release will in fact be realized. Valneva is providing this information as of the date of this press release and disclaims 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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