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Valneva and Pfizer Report Further Positive Phase 2 Booster Results for Lyme Disease Vaccine Candidate

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- *VLA15-221 Phase 2 study: strong immune response shown one month after a second booster dose (month 31) in pediatric and adult populations*
- *Significant anamnestic antibody response observed across all six serotypes, consistent with previous results*
- *Favorable safety profile of VLA15 observed in all age groups and for all vaccinations*

Saint-Herblain (France) and New York, NY, September 3, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) and Pfizer Inc. (NYSE: PFE) announced today positive immunogenicity and safety data from their VLA15-221 Phase 2 study following a second booster vaccination of their Lyme disease vaccine candidate, VLA15, given one year after receiving the first booster dose. The immune response and safety profile of VLA15 one month after receiving the second booster dose were similar to those reported after receiving the first booster dose, showing compatibility with the anticipated benefit of a booster vaccination prior to each Lyme season. 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. 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.[1,2]

These latest results from the VLA15-221 Phase 2 study again demonstrated a significant anamnestic antibody response across all six serotypes covered by the vaccine candidate in pediatric (5 to 11 years of age) and adolescent (12 to 17 years of age) participants, as well as in adults (18 to 65 years of age), measured one month after administration of this second booster dose (month 31). A high proportion of participants seroconverted after the second booster dose, yielding seroconversion rates* (SCRs) above 90% for all outer surface protein A (OspA) serotypes in all age groups, in-line with SCRs after the first booster. Geometric Mean Titers at one month post first and second booster (i.e. month 19 vs. month 31) were comparably high.

The participants of this Phase 2 study received VLA15 or placebo during the primary vaccination phase in two immunization schedules (month 0-2-6 or month 0-6), followed by a first booster dose at month 18 and a second booster dose at month 30.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, “We are encouraged by these data, which support the potential benefit of booster doses across all examined age groups. As Lyme disease continues to spread, it represents a significant unmet medical need, affecting numerous individuals throughout the Northern Hemisphere. Each new set of positive data brings us one step closer to potentially bringing this vaccine to both adults and children living in areas where Lyme disease is endemic.”

The safety and tolerability profile of VLA15 after a second booster dose was comparable to the profile observed after the first booster. To date, no safety concerns were observed by an independent Data Monitoring Committee

(DMC) in any treatment or age group.

“Personal preventive behaviors are currently the only recommended strategies to help protect yourself from Lyme disease. These data from the VLA15-221 study are an important step towards a potential vaccine that could help prevent the disease and ease the burden of acute, severe and sometimes persistent consequences,” said **Annaliesa Anderson, Ph.D., Senior Vice President and Head Vaccine Research and Development at Pfizer**. “Together with our partner Valneva, we look forward to progressing our vaccine candidate in the ongoing Phase 3 clinical trials.”

In August 2022, Pfizer and Valneva initiated the currently ongoing Phase 3 clinical study, Vaccine Against Lyme for Outdoor Recreationists (VALOR) (NCT05477524), to investigate the efficacy, safety and immunogenicity of VLA15 in participants five years of age and older in highly endemic regions in the United States (U.S.) and Europe.[3] The primary vaccination series for all participants was completed in July 2024.[4] A second Phase 3 study (VLA15-1012), aiming to provide further evidence on the safety profile of VLA15 in the pediatric population, is also ongoing.

Pfizer aims to submit 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 Phase 3 data.

About VLA15
VLA15 is an investigational multivalent protein subunit vaccine that 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 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). 560 healthy participants received either VLA15 in two immunization schedules (month 0-2-6 [N=190] or month 0-6 [N=181]) or placebo (month 0-2-6 [N=189]). Vaccine recipients received VLA15 at a dose of 180 µg, which was selected based on data generated in two previous Phase 2 studies. The main safety and immunogenicity readout (primary endpoint) was performed one month after completion of the primary series vaccination schedule. All eligible subjects received booster doses of VLA15 or placebo at month 18 and 30 (booster phase) and will be followed for an additional year to monitor antibody persistence. In addition, all eligible subjects will be asked to receive another booster dose of VLA15 or placebo at month 42, in order to assess the effect of periodic booster doses.

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 prior 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 infected Ixodes ticks.[5] It is considered the most common vector-borne illness in the Northern Hemisphere.[6,7] 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 pains) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious chronic complications affecting the skin, joints (arthritis), heart (carditis) or nervous system.[8,9] The medical need for

vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens.[10]

** Seroconversion was defined as the proportion of subjects that changed from seronegative at baseline to seropositive or showed a ?four-fold increase in IgG titers compared to baseline if tested OspA seropositive at baseline.*

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 September 3, 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, results from the VLA15-221 Phase 2 study, 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, including the world's first and only chikungunya vaccine, as well as certain third-party vaccines.

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, the most clinically advanced Shigella vaccine candidate, as well as vaccine candidates against the Zika virus and other global public health threats. More information is available at www.valneva.com.

Valneva Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to business partnerships, the progress, timing, results and completion of research, development and clinical trials for product candidates, to regulatory approval of product candidates and review of existing products. 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 and delays 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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