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

- *Strong immune response shown in both children and adolescents one month after booster dose (month 19) in VLA15-221 study*
- *Previously observed high anamnestic antibody response in adults confirmed*
- *VLA15 well-tolerated in all age groups following booster dose*

Saint-Herblain (France) & New York, September 7, 2023 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) and Pfizer Inc. (NYSE: PFE) announced today positive pediatric and adolescent immunogenicity and safety data for their Lyme disease vaccine candidate, VLA15, when given as a booster. These results from the VLA15-221 Phase 2 study showed a strong anamnestic antibody response for all serotypes in pediatric (5 to 11 years of age) and adolescent participants (12 to 17 years of age), as well as in adults (18 to 65 years of age), one month after administration of a booster dose (month 19).

Depending on the primary schedule they received (month 0-2-6 or month 0-6), participants seroconverted after the booster dose, yielding seroconversion[1] rates (SCRs) of 95.3% and 94.6% for all outer surface protein A (OspA) serotypes in all age groups, respectively. Additionally, OspA antibody titers were significantly higher one month after the booster dose compared to one month after the primary schedule with 3.3- to 3.7-fold increases (Geometric Mean Fold Rises) in adults, 2.0- to 2.7- fold increases in adolescents and 2.3- to 2.5-fold increases in children for all serotypes.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, "We are pleased with these data which validate the use of a booster dose in all age groups. Lyme disease continues to spread, representing an important unmet medical need that impacts the lives of many people in the Northern Hemisphere. With each new set of positive data, we come one step closer to potentially bringing this vaccine to both adults and children living in areas where Lyme disease is endemic."

The Phase 2 booster results emphasize the vaccine candidate's potential to provide immunity against Lyme disease in pediatric and adolescent populations. Geometric Mean Titers (GMTs) one month following the booster dose were similarly high for children and adolescents.

The safety and tolerability profile of VLA15 after a booster dose was consistent with previous studies as the vaccine candidate was well-tolerated in all age groups regardless of the primary vaccination schedule. No vaccine-related serious adverse events (SAEs) and no safety concerns were observed by an independent Data Safety Monitoring Board (DSMB).

"Protection against Lyme disease is important for anyone who lives or spends time outdoors in areas where Lyme disease is endemic. This data from the VLA15-221 study is vital to improve our understanding of how vaccination may help to protect both adults and children from this potentially devastating disease," said **Annaliesa Anderson, Ph.D., Senior Vice President and Head Vaccine Research and Development at Pfizer**. "We are encouraged by the positive Phase 2 results for VLA15, and, in partnership with Valneva, look forward to continuing to study the vaccine candidate in ongoing Phase 3 clinical trials."

These results follow six-month antibody persistence data in children and adults reported for the VLA15-221 study in December 2022[2] and positive immunogenicity and safety data reported in April 2022[3].

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[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 Authorisation Application (MAA) to the European Medicines Agency (EMA) in 2026, subject to positive Phase 3 data.

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 a Phase 3 study 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 covers the six most common OspA serotypes expressed by the *Borrelia burgdorferi sensu 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.[5,6] The program was granted Fast Track designation by the U.S. FDA in July 2017.[7]

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 in two 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. All eligible subjects received a booster dose of VLA15 or placebo at month 18 (booster phase) and will be followed for three additional years to monitor antibody persistence. In addition, all eligible subjects will be asked to receive an additional booster dose of VLA15 or placebo at month 30, in order to generate additional data and assess the need for 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 an infected *Ixodes* ticks.[8] It is considered the most common vector-borne illness in the Northern Hemisphere.[9] 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.[10,11] 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 skin, joints (arthritis), the heart (carditis) or the nervous system.[10] The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens.[12]

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 September 7, 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 a Lyme disease vaccine candidate, VLA15, and a collaboration between Pfizer and Valneva for VLA15, including their potential benefits, booster data, 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, 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 focused on the development, manufacturing and commercialization of prophylactic vaccines for infectious diseases. We take a highly specialized and targeted approach to vaccine development by focusing on vaccine solutions addressing unmet medical needs to ensure we can make a difference to peoples' lives. We apply our deep understanding of vaccine science, including our expertise across multiple vaccine modalities, and our established vaccine development capabilities, to develop vaccines against diseases which are not yet vaccine-preventable, or for which there are limited effective treatment options. Today, we are leveraging our expertise and capabilities to rapidly advance a broad range of vaccines into and through the clinic, including candidates against the chikungunya virus and Lyme disease.

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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