Pfizer and Valneva Issue Update on Phase 3 Clinical Trial Evaluating Lyme Disease Vaccine Candidate VLA15

New York & Saint-Herblain (France), February 17, 2023 – Pfizer Inc. (NYSE: PFE) and Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) today announce that Pfizer, as the study sponsor, has decided to discontinue a significant percentage of participants in the U.S. who had been enrolled in the Vaccine Against Lyme for Outdoor Recreationists (VALOR) (NCT05477524) Phase 3 clinical study. The study is investigating the efficacy, safety and immunogenicity of an investigational Lyme disease vaccine candidate, VLA15. These study participants, representing approximately half of the total recruited participants in the trial, are being discontinued following violations of Good Clinical Practice (GCP) at certain clinical trial sites run by a third-party clinical trial site operator. The discontinuation of these participants was not due to any safety concerns with the investigational vaccine and was not prompted by a participant-reported adverse event.

GCP is the international ethical and scientific quality standard for clinical trials that all clinical researchers need to follow. These standards are designed to put participants' interests first and ensure high scientific integrity. Once Pfizer learned of potential violations of GCP, it conducted a thorough review of the operations and data collection at the clinical trial sites run by the third party and followed standard operating safeguards to determine the correct course of action.

The clinical trial remains ongoing with other sites not operated by the third party, and Pfizer continues to enroll new participants at those sites. The companies intend to work with regulatory authorities, and as previously announced,[1,2] aim for Pfizer to 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, pending successful completion of the Phase 3 studies and subject to the agreement of these regulatory agencies to proposed modifications of the clinical trial plan.

Participants are being notified and Pfizer has also notified the FDA, other regulatory agencies and the independent Institutional Review Board for this study.

Integrity of data collected in clinical trials is critical to provide evidence and confidence in a potential vaccine or medicine's safety and efficacy. Pfizer and Valneva are committed to collecting robust data needed for potential regulatory submission of VLA15. While VLA15 is still under investigation, to date the companies have been encouraged by the data from the Phase 2 clinical studies, which demonstrated strong immunogenicity and acceptable safety and tolerability profiles.[2-4]

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 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 Lyme Disease
Lyme disease is a systemic infection caused by *Borrelia burgdorferi* bacteria transmitted to humans by 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 United States and 130,000 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 joints (arthritis), the heart (carditis) or the nervous system.[12] The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens.[10]

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 February 17, 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, VALOR, a Phase 3 clinical study investigating the efficacy, safety and immunogenicity of VLA15, 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 recruit and enroll participants, and 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, 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, manufacturing 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 commercialize three vaccines and to rapidly advance a broad range of vaccine candidates 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 and recruitment of clinical trials, discussions with regulatory agencies, modifications to clinical trial plans, results of clinical trials, and timing for filing for potential regulatory approval of 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 or delays, 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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