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Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15

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- ***Pfizer will invest €90.5 million in Valneva***
- ***Planned Phase 3 study confirmed to initiate in Q3 2022***

SAINT-HERBLAIN, France & NEW YORK--(BUSINESS WIRE)-- Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE) today announced that they have entered into an Equity Subscription Agreement and have updated the terms of their Collaboration and License Agreement for Lyme disease vaccine candidate VLA15. As previously announced on April 26, 2022, Pfizer plans to initiate the Phase 3 study of VLA15 in the third quarter of 2022.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220619005037/en/

As part of the Equity Subscription Agreement, Pfizer will invest €90.5 ($95) million in Valneva, representing 8.1% of Valneva's share capital at a price of €9.49 per share, through a reserved capital increase to further support the strategic Lyme partnership between the two companies. The per share purchase price was determined based on the average closing price of the Company's Shares on Euronext Paris during the 10 trading days preceding the date of the Equity Subscription Agreement. The equity investment is due to close on June 22, 2022. Valneva is planning to use the proceeds from Pfizer's equity investment to support its Phase 3 development contribution to the Lyme disease program.

In addition, Valneva and Pfizer updated the terms of their collaboration and license agreement which they announced on April 30, 2020[1]. Valneva will now fund 40% of the remaining shared development costs compared to 30% in the initial agreement. Pfizer will pay Valneva tiered royalties ranging from 14% to 22%, compared to royalties starting at 19% in the initial agreement. In addition, the royalties will be complemented by up to $100 million in milestones payable to Valneva based on cumulative sales. Other development and early commercialization milestones are unchanged, of which $168 million remain, including a $25 million payment to Valneva upon Pfizer's initiation of the Phase 3 study.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented "Pfizer's investment in Valneva highlights the quality of the work that we've done together over the past two years and is a strong recognition of Valneva's vaccine expertise. This subscription agreement will contribute to our investment in the Phase 3 study while limiting the impact on our cash position. Lyme disease is spreading and represents a high unmet medical need which impacts the lives of millions of people in the Northern Hemisphere. We are looking forward to further investigating our VLA15 candidate in Phase 3, which will take us a step closer to potentially help protect

both adults and children from this devastating disease."

"Lyme disease continues to place a heavy burden on countries in North America and Europe, with an estimated 600,000 cases each year across both regions," said **Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer**. "As the geographic footprint of Lyme disease widens, the medical need for vaccination becomes even more imperative.We are excited to continue partnering with Valneva on the development of VLA15 and look forward to working together to progress the program with the goal of bringing forward a vaccine that could help prevent this debilitating disease."

Pending successful initiation and completion of the planned Phase 3 study for VLA15, Pfizer could potentially submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration as early as 2025.

Dilution

The 9,549,761 new ordinary shares to be issued to Pfizer pursuant to the Equity Subscription Agreement will represent a dilution of approximately 8.1% of the share capital of the Company. On an illustrative basis, a shareholder holding 1% of Valneva's capital before this capital increase will now hold a stake of 0.919%.

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 one of the most dominant surface proteins 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 *Borrelia burgdorferisensu lato* species that are prevalent in North America and Europe. VLA15 has demonstrated a strong immunogenicity and safety profile in pre-clinical and clinical studies so far. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[2]. Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15[1].

About Lyme Disease

Lyme disease is a systemic infection caused by *Borreliaburgdorferi* bacteria transmitted to humans by infected *Ixodes* (aka deer or blacklegged) ticks[3]. It is considered the most common vector-borne illness in the Northern Hemisphere and according to a study published on June 13, 2022 in BMJ Global Health, Lyme disease has likely infected 14.5% of the world's population[4]. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called *erythema migrans* or more unspecific 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. The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens[5].

About Valneva SE

Valneva is a specialty vaccine company focused on the development 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 successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

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.

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 estimates for future performance. 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.

Pfizer Disclosure Notice

The information contained in this release is as of June 20, 2022. 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 an Equity Subscription Agreement and a Collaboration and License Agreement between Pfizer and Valneva for VLA15, including their potential benefits and a planned Phase 3 clinical trial, 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 or enrollment targets 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 planned 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, 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.

1 Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15 – Valneva
2 https://valneva.com/press-release/valneva-receives-fda-fast-track-designation-for-its-lyme-disease-vaccine-candidate-vla15/
3 Stanek et al. 2012, The Lancet 379:461–473
4 https://gh.bmj.com/content/7/6/e007744?utm_source=STAT%20Newsletters&utm_campaign=c7e76c7c4eMR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-c7e76c7c4e-150175797
5 New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017. https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/

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