



# Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

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***Phase 2 vaccine candidate, VLA15, is being evaluated for adult and pediatric indications in North America and Europe.***

**Saint Herblain (France) and New York, NY, April 30, 2020** – Valneva SE (“Valneva”), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE) today announced a collaboration to develop and commercialize Valneva’s Lyme disease vaccine candidate VLA15, which is currently in Phase 2 clinical studies.

VLA15 is the only active Lyme disease vaccine program in clinical development today, and covers six serotypes that are prevalent in North America and Europe. The investigational multivalent protein subunit vaccine, VLA15, targets the outer surface protein A (OspA) of *Borrelia*, an established mechanism of action for a Lyme disease vaccine. OspA is one of the most dominant surface proteins expressed by the bacteria when present in a tick. VLA15 has demonstrated strong immunogenicity and safety data in pre-clinical and Phase 1 studies. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017. Valneva has completed patient enrolment and follow-up for two Phase 2 studies of its Lyme disease vaccine candidate, in more than 800 people. Valneva expects to report the first Phase 2 results in mid-2020.

Valneva and Pfizer will work closely together throughout the development of VLA15. Valneva is eligible to receive a total of \$308 million cash payments consisting of a \$130 million upfront payment, \$35 million in development milestones and \$143 million in early

commercialization milestones. Under the terms of the agreement, Valneva will fund 30% of all development costs through completion of the development program, and in return Pfizer will pay Valneva tiered royalties starting at 19%. Pfizer will lead late-stage development and have sole control over commercialization.

**Thomas Lingelbach, Chief Executive Officer, Valneva**, commented “This collaboration is extremely exciting as it provides the opportunity for the rapid development and launch of a vaccine that has the potential to address a major unmet medical need. It validates Valneva’s strong vaccine R&D capabilities. We believe that Pfizer is the best partner for our Lyme disease vaccine given their outstanding development and commercial capabilities. Our team is thrilled about the prospect of working with such a successful partner.”

“Lyme disease is the most commonly reported tick-borne illness in the United States and is growing in its prevalence and geographic reach. We look forward to working closely with Valneva to continue advancing the VLA15 program and potentially bring a new solution to patients for this significant unmet need,” said **Nanette Cocero, Global President, Pfizer Vaccines**. “As both a research company, and a manufacturer of pediatric and adult vaccines including a vaccine for tick-borne encephalitis in Europe, we believe that Pfizer’s vaccine heritage, scientific expertise, and global commercial capabilities will help allow the VLA15 program to reach its maximum potential in helping protect children and adults from Lyme disease.”

This transaction is subject to customary closing conditions and clearances under antitrust law, including the Hart-Scott Rodino Antitrust Improvements Act.

Lazard served as exclusive financial advisor to Valneva and Dechert LLP served as Valneva’s legal counsel for the collaboration.

## **About Lyme Disease**

Lyme disease is a systemic infection caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks<sup>2</sup>. It is considered the most common vector borne illness in the Northern Hemisphere. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 300,000 Americans<sup>3</sup> are diagnosed with Lyme disease each year with at least a further 200,000 cases in Europe<sup>4</sup>. 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 disease footprint widens<sup>5</sup>.

## **About Pfizer Inc.: 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](http://www.pfizer.com). In addition, to learn more, please visit us on [www.pfizer.com](http://www.pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer\_News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

## **About Valneva SE**

Valneva is a specialty vaccine company focused on prevention against diseases with major unmet needs. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. Valneva has various vaccines in development including unique vaccines against Lyme disease and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 500 employees. More information is available at [www.valneva.com](http://www.valneva.com)

## **Forward-Looking Statements**

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the

intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. 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 indicative of their 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. 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 April 30, 2020. 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 exclusive licensing agreement between Pfizer and Valneva for VLA15, including their potential benefits and the expected timing of Phase 2 results, 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, 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; the impact of COVID-19 on our business, operations and financial results; risks related to the satisfaction or waiver of the conditions to closing the transaction in the anticipated timeframe or at all; 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, 2019 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

*1 <https://valneva.com/press-release/valneva-receives-fda-fast-track-designation-for-its-lyme-disease-vaccine-candidate-vla15/> 2 Stanek et al. 2012, *The Lancet* 379:461-473 3 As estimated by the CDC, <https://www.cdc.gov/lyme/stats/humancases.html>. 4 Estimated from available national data. Number largely underestimated based on WHO Europe Lyme Report as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed; ECDC tick-borne-diseases-meeting-report 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/>*

**Valneva Investor and Media Contacts** Laetitia Bachelot-Fontaine Director of Investor Relations & Corporate Communications M +33 (0)6 4516 7099 [investors@valneva.com](mailto:investors@valneva.com)

Teresa Pinzolits Corporate Communications Specialist T +43 (0)1 20620 1116  
communications@valneva.com

**Pfizer Media and Investor Contacts** Europe Media Relations: Dervila Keane +353  
862110834 Dervila.M.Keane@pfizer.com

U.S. Media Relations: Steve Danehy +1 (978) 273-3946 Steven.Danehy@pfizer.com

Investor Relations: Chuck Triano +1 (212) 733-3901 Charles.E.Triano@Pfizer.com