

Valneva announces HSR clearance for Lyme vaccine collaboration with Pfizer

Saint-Herblain (France), June 8 2020 – [Valneva SE](#) (“Valneva” or “the Company”) announced today that the antitrust-related condition precedent for its Lyme vaccine collaboration agreement (the “Agreement”) with Pfizer (NYSE: PFE) has been met. As a result, the Agreement is now effective and Valneva will receive a \$130 million upfront payment.

Valneva and Pfizer announced their collaboration at the end of April 2020 to develop and commercialize Valneva’s Lyme disease vaccine candidate VLA15, which is currently in Phase 2 clinical studies.

Following execution of the Agreement, Pfizer and Valneva notified the US Federal Trade Commission and the Antitrust Division of the Department of Justice in accordance with applicable antitrust law including the Hart Scott Rodino Antitrust Improvements Act.

Under the terms of the Agreement, 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 the \$130 million upfront payment described above, \$35 million in development milestones and \$143 million in early commercialization milestones. 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.

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 program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017¹. Valneva has completed patient enrolment and follow-up for VLA15’s two Phase 2 studies in more than 800 people and expects to report first Phase 2 results in July 2020.

About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks². 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 Americans³ are diagnosed with Lyme disease each year with at least a further 200,000 cases in Europe⁴. 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 widens⁵.

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/mq23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/>

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

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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.