Pfizer Logo

Pfizer and Valneva's Lyme Disease Vaccine Candidate Marketing Authorization Application Validated by European Medicines Agency

Friday, August 14, 2026 - 12:00am

- *Submission based on favorable efficacy and safety results from Phase 3 VALOR trial*

NEW YORK & LYON, France--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) today announced that the European Medicines Agency (EMA) has validated the Marketing Authorization Application (MAA) for PF-07307405, the companies' 6-valent outer surface protein A (OspA)-based Lyme disease vaccine candidate and will begin its assessment of the application.

The application is based on encouraging efficacy of more than 70% observed in the Phase 3 VALOR "Vaccine Against Lyme for Outdoor Recreationists" clinical trial (NCT05477524), which investigated whether the vaccine candidate, PF-07307405, prevented Lyme disease cases in individuals aged five years and older. The vaccine was well tolerated in the trial, with no safety concerns identified.[1]

"I'm proud of the progress we have made with our Lyme disease vaccine candidate and excited about the opportunity to potentially bring the first vaccine of its kind to Europe. I look forward to collaborating with the EMA as this vaccine candidate advances through the review cycle," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Vaccines Officer, Pfizer. "Lyme disease remains the most common vector-borne illness in Europe, affecting more than 100,000 people each year. When left untreated, it can lead to serious and potentially long-lasting complications involving the skin, joints, nervous system, and heart. We believe vaccination has the potential to provide an important new layer of protection against this debilitating disease and help people continue to enjoy the outdoors with greater confidence."

"We would like to thank and congratulate our partner Pfizer for the significant progress achieved towards delivering a potential vaccine solution in the fight against Lyme disease. MAA acceptance represents a major milestone, especially considering that more than 200 million people live in Lyme disease risk areas in Europe," said Thomas Lingelbach, CEO and Board member of Valneva.

Developed in collaboration between Pfizer and Valneva,[2,3] the investigational 6-valent OspA-based Lyme disease vaccine has been evaluated for its efficacy, safety, tolerability, immunogenicity, and manufacturing lot consistency.[4] The companies entered into a collaboration and license agreement in April 2020 for the co-development of PF-07307405 and for Pfizer to exclusively manufacture and commercialize PF-07307405, assuming regulatory success.[2,3]

About Lyme disease vaccine candidate, PF-07307405
There are currently no approved human vaccines for Lyme disease. PF-07307405 is the current Lyme disease

vaccine candidate which has advanced the furthest along the clinical development timeline, with two pivotal Phase 3 trials completed. 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. When a person is immunized with PF-07307405, their body creates antibodies against six *Borrelia* OspA serotypes. As the tick feeds on the vaccinated person, these antibodies are ingested by the tick as part of its blood meal. Binding of vaccine-induced antibodies to OspA on *Borrelia* inside the tick inhibits the bacterium's ability to leave the tick, preventing it from being transmitted to the human host. The vaccine candidate covers the six most prevalent OspA serotypes expressed by the *Borrelia burgdorferi* sensu lato species in North America and Europe.

About VALOR

The VALOR trial was a multicenter, placebo-controlled, randomized, observer-blinded trial conducted at sites in areas of high incidence of Lyme disease across the U.S., Canada, and Europe.[4] 9,437 trial participants aged 5 years and older were randomized 1:1 into two trial groups and received four doses of either PF-07307405 or a saline placebo – one dose administered at months 0, 2 and 5-9 followed by a fourth dose one year later, shortly before the start of the following Lyme disease season (season 2).[4]

About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia burgdorferi* sensu lato bacteria that are transmitted to humans by the bite of infected *Ixodes* ticks.[5] It is considered the most common vector-borne illness in the Northern Hemisphere.[6,7] The Centers for Disease Control and Prevention (CDC) has estimated that approximately 476,000 people in the U.S. are diagnosed and treated each year and 132,000 cases are reported annually in Europe from countries with surveillance systems.[8] Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called erythema migrans or other nonspecific symptoms like fatigue, fever, headache, mild stiff neck, muscle and joint pains) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious chronic complications affecting the skin, joints (arthritis), the heart (carditis) or the nervous system.[7,9] 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 over 175 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 X at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

About Valneva SE

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions. We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market three proprietary travel vaccines. Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the only Lyme disease

vaccine candidate in advanced clinical development, which is partnered with Pfizer, the world's most clinically advanced Shigella vaccine candidate, as well as vaccine candidates against other global public health threats. More information is available at www.valneva.com.

Pfizer Disclosure Notice

The information contained in this release is as of August 14, 2026. 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, PF-07307405, and a collaboration between Pfizer and Valneva for PF-07307405, including their potential benefits, the results of the Phase 3 VALOR clinical trial and a Marketing Authorization Application (MAA) for PF-07307405 pending with the European Medicines Agency , 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, as well as uncertainties regarding the future of the Lyme disease vaccine program; 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 applications may be filed in any other jurisdictions for PF-07307405; whether and when the MAA or any such other applications that may be filed 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 PF-07307405 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 PF-07307405; uncertainties regarding the ability to obtain or maintain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; risks and uncertainties related to changes to vaccine or other healthcare policy in the U.S. or elsewhere; challenges related to public vaccine confidence or awareness; whether our collaboration with Valneva will be successful; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; 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, 2025 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.

Valneva Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the initiation, progress, results, and timing of regulatory review of vaccine 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 and delays 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 in this press release will in fact be realized. Valneva is providing this information as of the date of this press release and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

[1] Pfizer and Valneva Announce Lyme Disease Vaccine Candidate Demonstrates Strong Efficacy in Phase 3 VALOR Trial. Pfizer. March 23, 2026. Accessed July 2026. Available from: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-valneva-announce-lyme-disease-vaccine-candidate.

[2] Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15. April 2020. Accessed July 2026. Available from: https://www.pfizer.com/news/press-release/press-release-detail/valneva_and_pfizer_announce_collaboration_to_co_develop_and_commercialize_lyme_disease_vaccine_vla15.

[3] Valneva and Pfizer Enter into Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15. June 20, 2022. Accessed July 2026. Available at: https://www.pfizer.com/news/press-release/press-release-detail/valneva-and-pfizer-enter-equity-subscription-agreement-and.

[4] ClinicalTrials.gov. An Efficacy, Safety, Tolerability, Immunogenicity, and Lot-Consistency Clinical Trial of a 6-Valent OspA-Based Lyme Disease Vaccine (VLA15) (VALOR). Last Updated June 2026. Accessed August 2026. Available from: https://www.clinicaltrials.gov/ct2/show/NCT05477524.

[5] Stanek G, Wormser GP, Gray J, Strle F. Lyme borreliosis. Lancet. 2012;379(9814):461-473. doi:10.1016/S0140-6736(11)60103-7.

[6] Burn L, Tran TMP, Pilz A, et al. Incidence of Lyme borreliosis in Europe from national surveillance systems (2005–2020). Vector Borne Zoonotic Dis. 2023;23(4):156?171. doi:10.1089/vbz.2022.0071.

[7] Kugeler KJ, Schwartz AM, Delorey MJ, et al. Estimating the frequency of Lyme disease diagnoses, United States, 2010-2018. Emerg Infect Dis. 2021;27(2):616-619. doi:10.3201/eid2702.202731.

[8] Centers for Disease Control and Prevention. Signs and Symptoms of Untreated Lyme Disease. Updated May 15, 2024. Accessed July 2026. Available from: https://www.cdc.gov/lyme/signs-symptoms/index.html.

[9] Steere AC, Strle F, Wormser GP, et al. Lyme borreliosis. Nat Rev Dis Primers. 2016;2:16090. doi:10.1038/nrdp.2016.90.

[10] Centers for Disease Control and Prevention. Press Kit: Understanding Lyme and Other Tickborne Diseases. Updated June 26, 2024. Accessed July 2026. Available from https://www.cdc.gov/ticks/communication-resources/press-kit.html.

Pfizer Media Contacts:
PfizerMediaRelations@Pfizer.com

Pfizer Investor Relations:
IR@pfizer.com

Valneva Media Contacts:
+33 (0)6 4516 7099
Communications@valneva.com

Valneva Investor Relations:
+1 917 815 4520
investors@valneva.com

Source: Pfizer Inc.