

# LYME DISEASE



## WHAT IS LYME DISEASE?

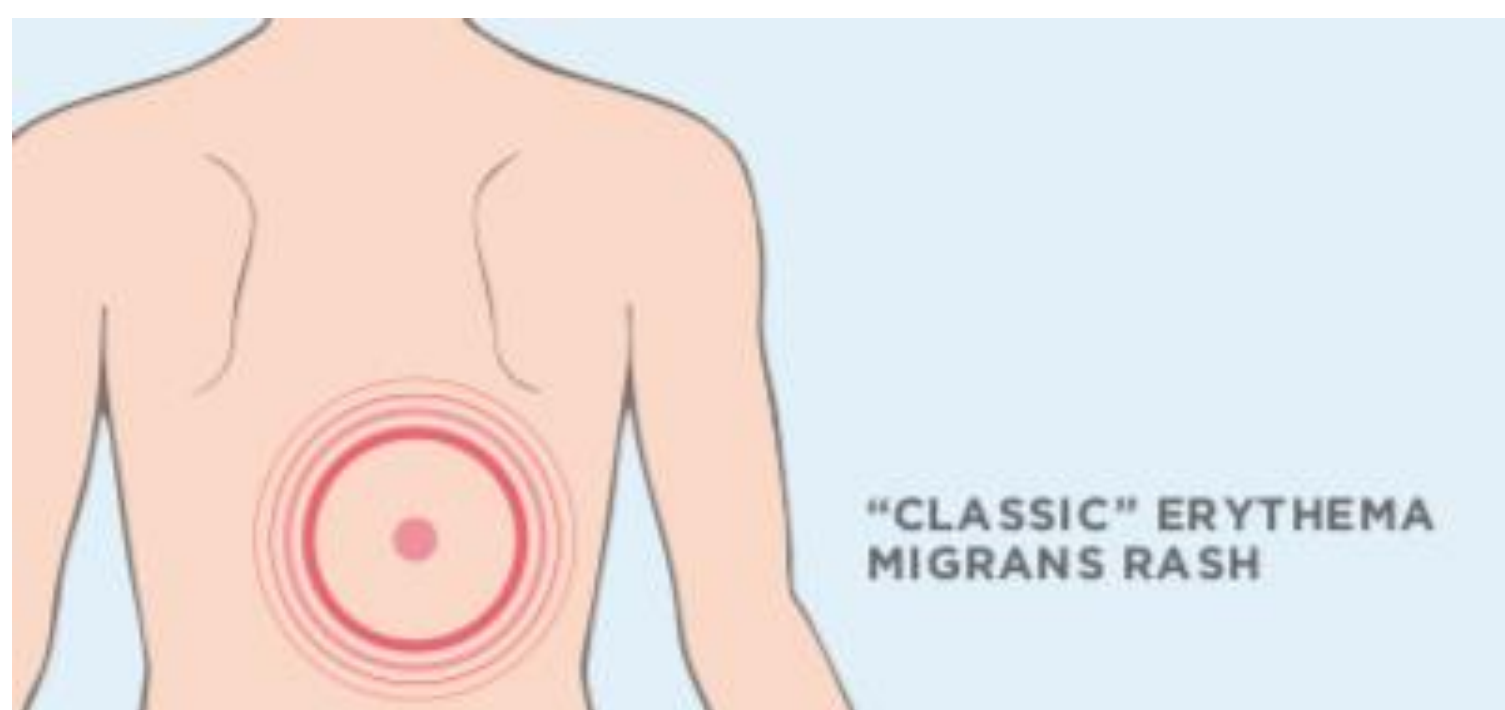
Lyme disease is the fastest growing and most common tick-borne illness in the Northern Hemisphere [1]. It is caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks [2]. In most cases, the tick must be attached to the human body for 36 to 48 hours before the bacteria can be transmitted [3].



## SYMPTOMS, DIAGNOSIS & TREATMENT

Early symptoms of Lyme disease (such as a gradually expanding red circular rash called *Erythema migrans* or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia [4,3]) are often overlooked or misinterpreted [5]. Approximately 80% of cases are characterized by the development of an acute *Erythema migrans* rash at the tick bite site, however, in approximately 20% of cases, the *Erythema migrans* is absent [3].

If diagnosed early, Lyme disease can be successfully treated with antibiotics [3]. However, 5-10% of all patients do not respond well to antibiotics and experience ongoing debilitating symptoms [2]. Left untreated, the disease can spread and cause more serious complications affecting the joints (arthritis), the heart or the nervous system [2].



## PREVENTION

Today, preventing Lyme disease means preventing tick bites [6], but personal protective measures are underutilized [7] and pest management efforts have only had limited success in controlling ticks and the associated diseases [8]. Currently, there is no Lyme disease vaccine available to protect humans from this devastating illness and the medical need for vaccination against Lyme is steadily increasing as the disease footprint widens [9].

## FACTS & FIGURES

**476,000** Americans are diagnosed and treated with Lyme disease each year [10] with at least a further 200,000 cases in Europe [11,12].

**\$712M - \$1.3B** Each year, the U.S. healthcare system spends \$712M - \$1.3B on Lyme disease [13].

**2x** The incidence of Lyme disease in the United States has nearly doubled since 1991 [14].

## LYME VACCINE CANDIDATE - VLA15

VLA15 is currently the only active Lyme disease vaccine candidate in clinical development. It is an investigational multivalent vaccine targeting the six most common species of the *Borreliosis spirochete* that cause Lyme disease in North America and Europe. The VLA15 vaccine candidate is a new construct based on the well-established principle of fighting Lyme transmission by targeting OspA proteins, one of the outer surface proteins expressed by the bacteria that causes Lyme disease.

## PARTNERED WITH PFIZER

### Further Positive Phase 2 Results

Valneva and Pfizer announced a collaboration for the development and commercialization of the vaccine candidate VLA15 at the end of April 2020 [15]. Following positive topline results for two Phase 2 clinical trials [16,17], the two companies have reported further positive Phase 2 results [18] in September 2021. An additional Phase 2 trial, VLA15-221, has also been initiated to accelerate the vaccine candidate's pediatric development.

Valneva and Pfizer are working closely together on the next development steps and are planning for a Phase 3 trial.

The VLA15 program was granted Fast Track designation by the FDA in July 2017 [19].

1. Lyme borreliosis in Europe: influences of climate and climate change, epidemiology, ecology and adaptation measures (2006), Retrieved from [https://www.euro.who.int/\\_data/assets/pdf\\_file/0006/96819/E89522.pdf](https://www.euro.who.int/_data/assets/pdf_file/0006/96819/E89522.pdf)
2. Stanek, G., Wormser, G. P., Gray, J., & Strle, F. (2012). Lyme borreliosis. *The Lancet*, 379(9814), 461-473. doi: 10.1016/s0140-6736(11)60103-7
3. Lyme Disease. (2019, December 16). Retrieved from <https://www.cdc.gov/lyme/index.html>
4. Shapiro, E. D. (2014). *Borrelia burgdorferi* (Lyme Disease). *Pediatrics in Review*, 35(12), 500-509. doi: 10.1542/pir.35-12-500
5. Aucott, J., Morrison, C., Munoz, B., Rowe, P. C., Schwarzwaldner, A., & West, S. K. (2009). Diagnostic challenges of early Lyme disease: Lessons from a community case series. *BMC Infectious Diseases*, 9(1). doi: 10.1186/1471-2334-9-79
6. LYME DISEASE: What you need to know. (2008). Retrieved from <https://www.cdc.gov/lyme/resources/brochure/lymediseasebrochure-P.pdf>
7. Methods to Prevent Tick Bites and Lyme Disease. Ogden, Lindsay, Schofield. *CI in Lab Med*. 2015 Dec;35(4) :883-99. doi: 10.1016/j.cll.2015.07.003. Epub 2015 Aug 28.
8. Integrated Pest Management in Controlling Ticks and Tick-Associated Diseases. Stafford, Williams, Molaei. *Journal of Integrated Pest Management*, (2017) 8(1) : 28; 1-7 doi : 10.1093/jipm/pmx018.
9. 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-lymedisease-is-set-to-explode-and-you-cant-protect-yourself>
10. CDC, Retrieved from: <https://www.cdc.gov/lyme/stats/humancases.html>, accessed on October 12,2021
11. Sykes RA, Makiello P. (2017) An estimate of Lyme borreliosis incidence in Western Europe. *J Public Health (Oxf)*. doi: 10.1093/pubmed/fdw017
12. 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
13. Adrion, E. R., Aucott, J., Lemke, K. W., & Weiner, J. P. (2015). Health Care Costs, Utilization and Patterns of Care following Lyme Disease. *Plos One*, 10(2). doi: 10.1371/journal.pone.0116767
14. <https://www.epa.gov/climate-indicators/climate-change-indicators-lyme-disease>, accessed on October 12,2021
15. Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15
16. Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate
17. Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate.
18. Valneva a Pfizer Report Further Positive Phase 2 Results, incl Booster Response, for Lyme Disease Vaccine Candidate
19. Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15