



“The high incidence of Lyme disease is perhaps the greatest failure of contemporary public health in the United States and perhaps also in Europe, considering that we know the immunologic basis of control but have no licensed vaccine. A new vaccine would protect people of all ages from serious complications of this bacterial infection.”

— STANLEY A. PLOTKIN

Emeritus Professor of the Wistar Institute at the University of Pennsylvania and inventor of the Rubella vaccine



*Advancing vaccines
for better lives.*

- 1 Global Vaccine Demand. Geneva, World Health Organization; 2018. http://www.who.int/immunization/programmes_systems/procurement/market/global_demand/en
- 2 Smith, Brian G et al. "Lyme disease and the orthopaedic implications of Lyme arthritis" Journal of the American Academy of Orthopaedic Surgeons vol. 19,2 (2011): 91-100.
- 3 As estimated by the CDC: <https://www.cdc.gov/lyme/stats/humancases.html>
- 4 Estimated from available national data. Number largely underestimated according to WHO Europe Lyme Report, as case reporting is highly inconsistent in Europe and many Lyme disease infections go undiagnosed; ECDC Tick-Borne Diseases Meeting Report 2011: <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/Tick-borne-diseases-meeting-report.pdf>
- 5 www.cdc.gov/lyme/FAQ/index.html
- 6 Adrion ER, Aucott J, Lemke KW, Weiner JP (2015) Health Care Costs, Utilization and Patterns of Care following Lyme Disease. PLoS ONE 10(2): e0116767. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0116767>
- 7 www.cdc.gov/Lyme
- 8 Methods to Prevent Tick Bites and Lyme Disease. Ogden, Lindsay, Schofield. Clin Lab Med. 2015 Dec;35(4):883-99. doi: 10.1016/j.cll.2015.07.003. Epub 2015 Aug 28.
- 9 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.
- 10 <https://www.valneva.com/en/investors-media/news/2018#303>
- 11 <http://www.valneva.com/en/investors-media/news/2018#282>
- 12 No differences in the safety profile were observed for the adjuvanted groups compared to the non-adjuvanted treatment groups
- 13 IgG levels were substantially higher after three immunizations (Day 84) compared to after two (Day 56)

For further reference

Plotkin, Stanley A., Need for a New Lyme Disease Vaccine, The New England Journal of Medicine (375;10), September 8, 2016

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LYME DISEASE

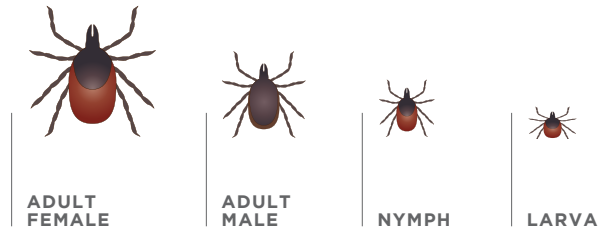
A severe tick-transmitted infection and rapidly growing public health threat

— [valneva.com](http://www.valneva.com)



WHAT IS LYME DISEASE?

Lyme disease is caused by *Borrelia* bacteria, which are transmitted to humans through the bite of infected blacklegged ticks¹.



Inadequately treated or not treated in the early stages of infection, Lyme disease can be disabling and lead to very serious complications, including chronic joint pain in the elbows and knees, paralysis of facial muscles, shortness of breath, and heart inflammation².

WHO IS AT RISK?

Each year, an estimated 300,000³ Americans and 200,000⁴ Europeans contract Lyme disease. In addition, the global footprint of Lyme disease is rapidly expanding putting more and more people at risk every year.

WHAT IS THE PUBLIC HEALTH IMPACT?

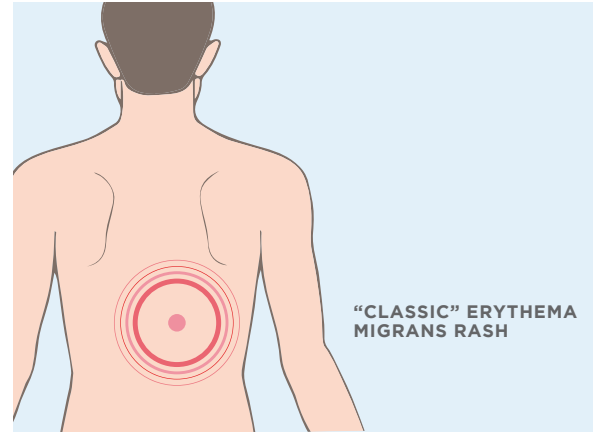
Lyme disease presents a significant unmet medical need:

- Lyme disease symptoms – apart from the classic “bullseye”-shaped Erythema migrans rash, which is not always present and can be overlooked – are nonspecific and can be misdiagnosed as other conditions.
- Early in the disease, the two-tiered testing system recommended by the CDC may not be capable of detecting all cases⁵.

It is also an extremely costly medical burden. The U.S. health care system spends between \$712 million and \$1.3 billion a year and \$3,000 per patient related to Lyme disease.⁶

DIAGNOSIS

Diagnosing the disease is difficult, since people do not associate the most common early symptoms (fever, headache, fatigue and a rash occurring in 70-80% of cases⁷) with Lyme disease.



TREATMENT

Immediate treatment with antibiotics is successful in most cases, but there are numerous undiagnosed cases which can lead to serious, permanent symptoms.

PREVENTION

Today, preventing Lyme disease means preventing tick bites⁷, but personal protective measures are underutilized⁸ and pest management efforts have only had limited success in controlling ticks and the associated diseases⁹.

Currently no Lyme disease vaccine is available for humans, although it has been shown that the disease can be prevented by immunization with an Outer surface protein A (OspA)-based vaccine.

VALNEVA'S MULTIVALENT LYME VACCINE CANDIDATE: VLA15

VLA15 is currently the most advanced active clinical vaccine program of its kind and has the potential to prevent people suffering from this debilitating illness. It is designed to offer protection against the six most common types of *Borrelia* spirochetes that cause Lyme disease in North America and Europe.

Valneva's goal with VLA15 is to prevent Lyme disease in adults and children aged two years and older, aiming for protection against the majority of human pathogenic *Borrelia* species.

VLA15 was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017.

PHASE 2 STUDY (VLA15-201) INITIATED DECEMBER 2018

Valneva recently announced¹⁰ the first of two planned, parallel Phase 2 studies of VLA15 to be conducted at trial sites in the U.S. and Europe.

The overall Phase 2 objective is to determine the optimal dosage level and schedule for use in Phase 3 pivotal field efficacy studies, based on immunogenicity and safety data.

Valneva previously released positive interim Phase 1 clinical trial results for VLA15 in March 2018¹¹:

- VLA15 met the primary study endpoint, showing a favorable safety profile: no safety concerns were associated with VLA15 in any treatment group¹²
- VLA15 was also immunogenic in all doses and formulations tested, with good OspA-specific IgG antibody responses against all OspA serotypes¹³

Valneva expects to announce interim Phase 2 data in 2020.