

VLA15 vaccine candidate: What is it and how does it work?



Currently, there is no vaccine available for Lyme disease.

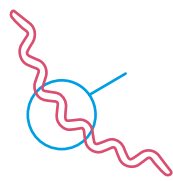


Personal preventive measures are currently the only recommended interventions to reduce Lyme disease.¹

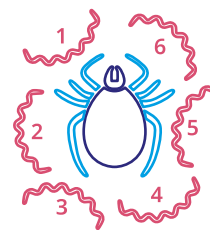


However, these have **varying levels of effectiveness** due to low utilization, poor adherence, or high cost.²

VLA15 is a vaccine candidate, that if approved, can help protect against several types of the *Borrelia* bacteria.³

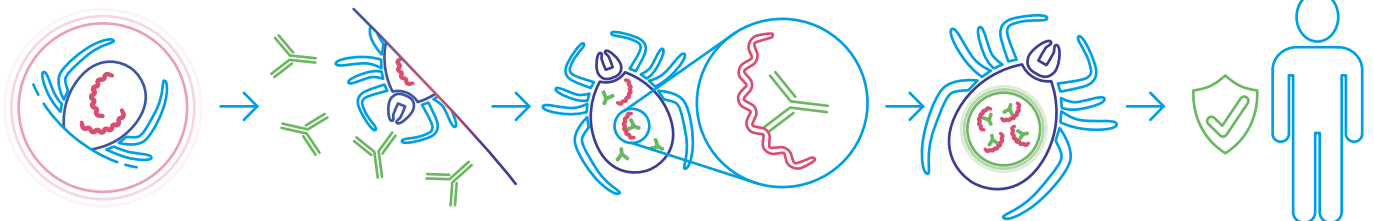


Outer surface protein A (OspA) is one of the most **dominant surface proteins** expressed by the bacterium when present in a tick.⁴



VLA15 covers the **six most common OspA serotypes** expressed by the *Borrelia* species that are prevalent in North America and Europe.³

VLA15 is based on a proven mechanism of action with an acceptable safety profile.³⁻⁵



When a tick attaches and bites an individual who is vaccinated with an OspA-based vaccine...

...the protective antibodies are ingested by the tick...

...binding to the OspA protein.

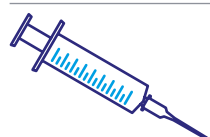
Binding to OspA inhibits the ability of the *Borrelia* bacterium to leave the tick...

...preventing it from being transmitted and causing Lyme disease infection.

VLA15 is the Lyme disease vaccine candidate which has **advanced the furthest** along the clinical development timeline.⁶

Three Phase 2 trials, involving a total of 1,403 participants, which assessed safety, immunogenicity, optimal dosage and vaccination schedule of VLA15 in adults and children⁷⁻⁹

Two ongoing Phase 3 trials, involving a total of 12,987 participants, which are assessing the efficacy, safety, lot consistency and immunogenicity of VLA15 in adults and children on a much larger scale^{10,11}



An approved vaccine could act as the first line of protection as part of a multi-layered prevention approach.

References

1. CDC. Preventing Tick Bites on People. 2019. Available at: https://www.cdc.gov/lyme/prev/on_people.html. Accessed: March 2024.
2. Schwartz A, Mackeprang J, et al. Effectiveness of personal protection measures against Lyme disease: A review of epidemiologic studies from the United States. *Zoonoses Public Health*. 2022 Nov;69(7):777-791. doi: 10.1111/zph.12984.
3. Pfizer. Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15. Available from: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-valneva-initiate-phase-3-study-lyme-disease>. Accessed: March 2024.
4. Fikrig E, et al. Long-term protection of mice from Lyme disease by vaccination with OspA. *Infect. Immun*. 60:773-777 (1992).
5. Poland G. Vaccines against Lyme disease: What happened and what lessons can we learn? *Clin Infect Dis*. 52 Suppl 3:s253-8. (2011).
6. Valneva. Lyme disease – VLA15. Available from: <https://valneva.com/research-development/lyme-disease/>. Accessed: March 2024.
7. ClinicalTrials.gov. Immunogenicity and Safety Study of a Vaccine Against Lyme Borreliosis, in Healthy Adults Aged 18 to 65 Years. December 2018. Randomized, Controlled, Observer-blind Phase 2 Study (VLA15-201). Available from: <https://clinicaltrials.gov/ct2/show/NCT03769194>. Accessed: March 2024.
8. ClinicalTrials.gov. Alternative Schedule Study For VLA15, a Vaccine Candidate Against Lyme Borreliosis (VLA15-202). May 2019. Available from: <https://clinicaltrials.gov/ct2/show/NCT03970733>. Accessed: March 2024.
9. ClinicalTrials.gov. Phase 2 Study Of VLA15, A Vaccine Candidate Against Lyme Borreliosis, In A Healthy Peadiatric And Adult Study Population. (VLA15-221). March 2021. Available from: <https://clinicaltrials.gov/ct2/show/NCT04801420>. Accessed: March 2024.
10. ClinicalTrials.gov. An Efficacy, Safety, Tolerability, Immunogenicity, and Lot-Consistency Clinical Trial of a 6-Valent OspA-Based Lyme Disease Vaccine (VLA15) (VALOR). July 2022. Available from: <https://www.clinicaltrials.gov/ct2/show/NCT05477524>. Accessed: March 2024.
11. Pfizer data on file.