

Lyme Disease Vaccine Candidate: Development Timeline



About VLA15 candidate clinical trial program



VLA15 is the Lyme disease vaccine candidate which has **advanced the furthest** along the clinical development timeline.¹



VLA15 has demonstrated a **favorable safety profile** across all trials to date.^{2,3,4}

**DEC
2016**

Valneva receives FDA and European approvals to start clinical testing of **VLA15**⁵

**JUL
2017**

VLA15 is granted FDA Fast Track Designation⁶

**MAR
2018**

Positive Phase 1 results from **VLA15-101**^{7,8}

- 179 participants in Europe and the U.S. aged 18-<40
- Participants received one of three doses of VLA15 (12µg, 48µg or 90µg) during a day 0-28-56 vaccination schedule

Results

- VLA15 demonstrated a favorable safety profile across all treatment groups⁶
- VLA15 was also shown to be immunogenic in all doses and formulations tested, with OspA-specific antibody responses against all OspA serotypes
- Alum-adjuvanted formulations elicited higher immune-responses

**JUL
2019**

Phase 2 **VLA15-202** trial started^{11,12}

**DEC
2018**

Phase 2 **VLA15-201** trial started^{9,10}

**APR
2020**

Pfizer and Valneva announce collaboration to co-develop and commercialize **VLA15**¹³

**JUL
2020**

Phase 2 **VLA15-201** meets endpoints^{14,15}

- 572 participants from Europe and the U.S. aged 18-65
- Participants received three doses of VLA15 (135µg or 180µg), or placebo
- Month 0-1-2 vaccination schedule

Results

- Immunogenicity profiles confirmed in older adults (50-65 years)
- Immunogenicity increased and higher doses (180µg) elicited higher antibody responses across all serotypes, compared to Phase 1
- VLA15 had a favorable safety profile across all doses and age groups tested



OCT
2020

Phase 2 VLA15-202 meets endpoints^{16,17}

- 246 participants from the U.S. aged 18-65
- Participants received three doses of VLA15 (135µg or 180µg), or placebo
- Month 0-2-6 vaccination schedule, with booster dose at month 18

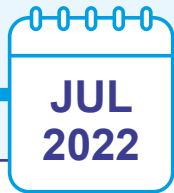
Results

- The extended vaccination schedule improved immunogenicity and demonstrated functionality of antibodies across all serotypes
- 180µg confirmed as the optimal dosage
- Administration of a booster dose at month 18 improved antibody titers substantially
- VLA15 demonstrated a favorable safety profile across all treatment groups



MAR
2021

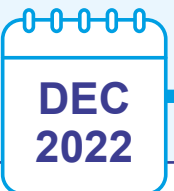
Phase 2
VLA15-221
trial initiation¹⁸



JUL
2022

Phase 3 VALOR trial started¹⁹

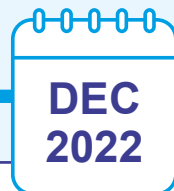
- First Phase 3 trial which will assess efficacy, safety, lot consistency and immunogenicity of VLA15
- 9,437 participants aged 5 years and older across Europe, Canada and the U.S.
- Participants receive four doses of VLA15 or placebo (1:1 ratio)
- Month 0-2-(5-9) vaccination schedule, with a booster dose 9-12 months following completion²⁰



DEC
2022

Phase 3 pediatrics safety trial (C4601012) started²²

- 3,550 pediatric participants to provide further evidence on the safety of VLA15 in the pediatric population



DEC
2022

Interim analysis of Phase 2 VLA15-221²¹

- 585 participants including first pediatric participants from the U.S. aged 5-65
- All participants received 180µg dose of VLA15 or placebo
- Two and three-dose dosing schedules evaluated, Month 0-2-6 and Month 0-6, with a booster dose at month 18

Results

- Antibodies were higher in pediatric and adult participants who received a 3-dose primary vaccination series
- Based on these results, it was confirmed that a 3-dose primary series vaccination schedule would be used in Phase 3 trial protocols
- VLA15 was found to be immunogenic and have a favorable safety profile in pediatric populations
- Strong immune response shown in both children and adolescents one month after booster dose (month 19)²²

Pending successful completion of the Phase 3 trials...

Pfizer could submit a **Biologics License Application (BLA)** to the U.S. FDA and **Marketing Authorization Application (MAA)** to the European Medicines Agency (EMA) in **2026²²**



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