Two-year antibody persistence and safety of a single-dose live-attenuated chikungunya virus vaccine (VLA1553) in adults aged 18 years and above

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Valneva Summary and Core Strengths

Fully integrated specialty vaccine company focused on development, manufacturing and commercialization of **prophylactic vaccines for infectious diseases** with significant unmet medical need

- **Proven, integrated expertise:** Three in-house vaccine approvals (proprietary commercialized travel vaccines)
- **Focused R&D:** Advancing first-, only- or best-in-class vaccine candidates; Experience across multiple vaccine platforms
- **Leading in chikungunya virus:** World's first and only approved vaccine
- **Leading in Lyme disease:** Lead Phase 3 vaccine candidate partnered with Pfizer
- **Experienced leadership:** Substantial R&D, manufacturing and commercial expertise

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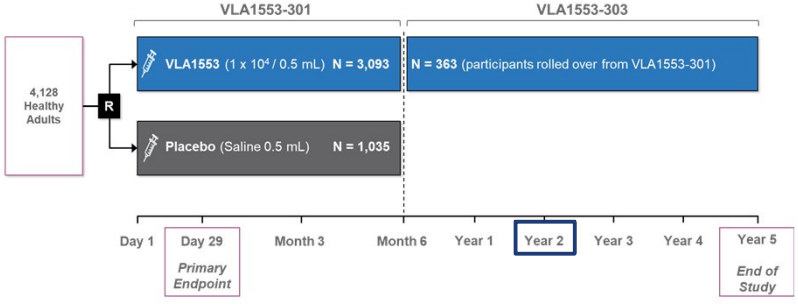
VLA1553-303: long-term follow-up clinical trial

Designed to evaluate antibody persistence and long-term safety of VLA1553

+ VLA1553-303 is an open-label phase 3b, single-arm trial
+ 363 participants rolled over from VLA1553-301, after completing the 6-month follow-up
+ **Primary objective**: Evaluate **persistence of antibodies** annually for up to 5 years after the single immunization with VLA1553
+ **Secondary objective**: Evaluate long-term **safety** through 2 years
  - › Includes new-onset Serious Adverse Events and any ongoing Adverse Events of Special Interest from VLA1553-301



N = number of participants in the intention-to-treat population

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VLA1553-303: Demographic Data

	18-64 Years N=310	>=65 Years N=53	All Participants N=363
Sex n (%)			
Female	177 (57.1)	30 (56.6)	207 (57.0)
Male	133 (42.9)	23 (43.4)	156 (43.0)
Race n (%)			
American Indian or Alaskan Native	2 (0.6)	0	2 (0.6)
Asian	6 (1.9)	0	6 (1.7)
Black or African American	44 (14.2)	8 (15.1)	52 (14.3)
Native Hawaiian or Other Pacific Islander	2 (0.6)	1 (1.9)	3 (0.8)
White	237 (76.5)	43 (81.1)	280 (77.1)
Other	19 (6.1)	1 (1.9)	20 (5.5)
Age (years)			
Mean	44.1 (12.02)	68.7 (3.37)	47.7 (14.15)
(Min/Max)	18, 64	65, 78	18, 78
Age Group n (%)			
18 years – 64 years	310 (100)	53 (100)	310 (85.4)
≥ 65 years			53 (14.6)

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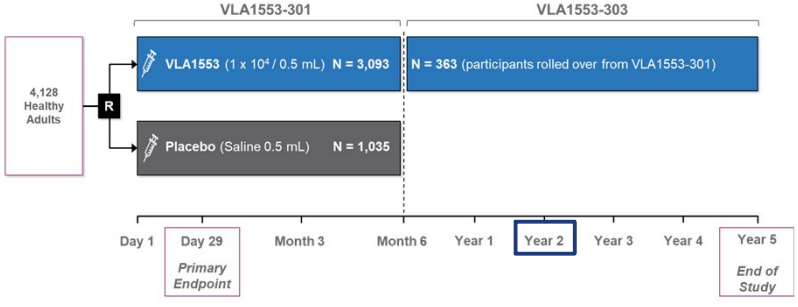

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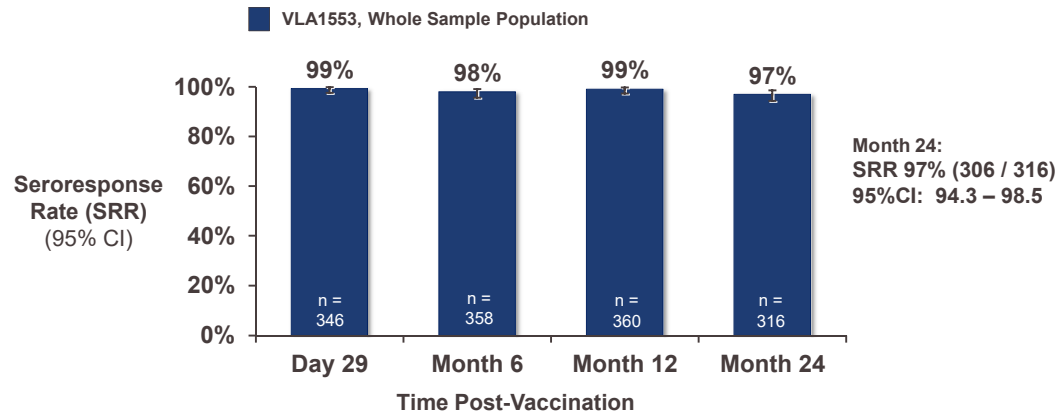
VLA1553-303: Seroresponse[1] in 97% of Participants Retained After 24 Months

Data support the anticipated long-term persistence of the immune response after a single dose



Seroresponse = CHIKV-specific neutralizing antibody titers ≥ 150
Sources: Buerger et at, presented at CISTM 2023; Valneva Press Release Dec 4, 2023 https://valneva.com/press-release/valneva-reports-positive-24-month-antibody-persistence-data-for-its-single-shot-chikungunya-vaccine-ixchiq/

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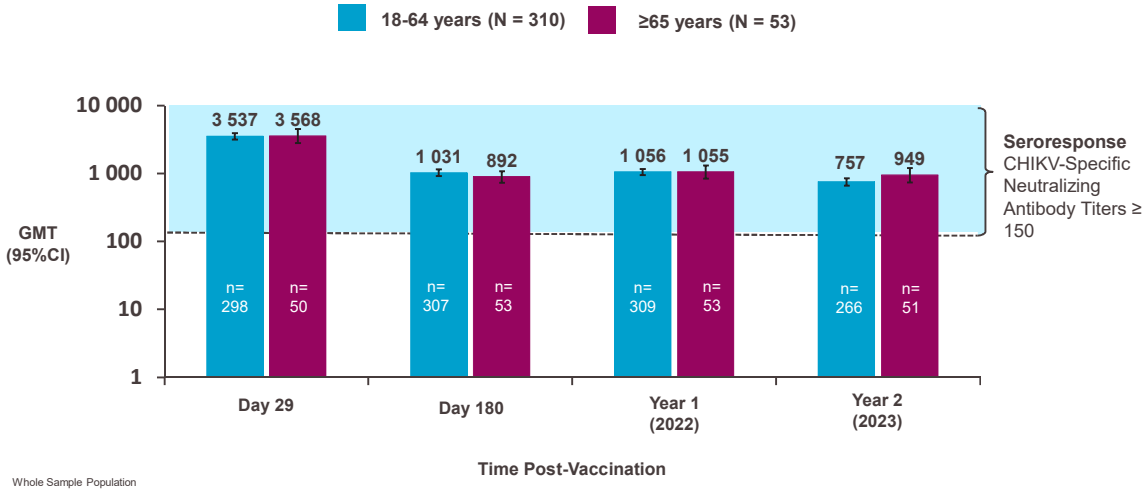
VLA1553-303: Comparable Titers Retained in Participants 18-64 or ≥65 Years

In older adults aged ≥ 65 years, antibody persistence was similar as in younger adults



Whole Sample Population

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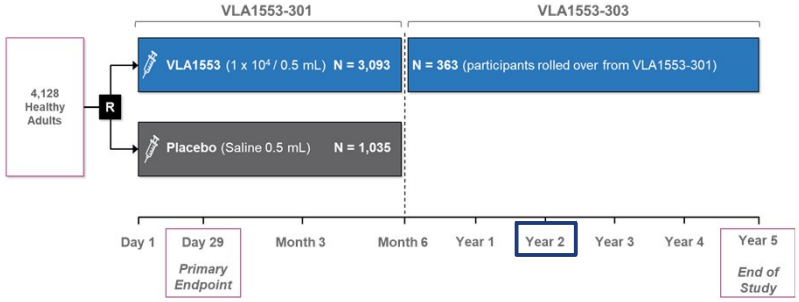

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VLA1553-303: Serious Adverse Events Month 6 until Year 2

No SAE deemed related to VLA1553 administration

	System Organ Class Preferred Term [n (%)]	18-64 Years N=310	>=65 Years N=53	All Subjects N=363
	Any SAE [n (%) m]	7 (**2.3**) 8	2 (**3.8**) 2	9 (2.5) 10
Months 6-12	**Pelvic Fracture**	1 (0.3)	0	1 (0.3)
	Intracranial Aneurysm	0	1 (1.9)	1 (0.3)
	Seizure	1 (0.3)	0	1 (0.3)
	Upper abdominal pain	1 (0.3)	0	1 (0.3)
Year 2	**Gun shot wound**	1 (0.3)	0	1 (0.3)
	Overdose	1 (0.3)	0	1 (0.3)
	Apallic syndrome	1 (0.3)	0	1 (0.3)
	Coronary artery disease	0	1 (1.9)	1 (0.3)
	Myocardial infarction	1 (0.3)	0	1 (0.3)
	Cholecystitis	1 (0.3)	0	1 (0.3)

Table 14.3.2.1, WS Population

Serious AEs (SAEs): results in death, life threatening, requires/prolongs hospitalization, results in significant disability, congenital defect, medical important condition.

n = number of subjects with an event
Any SAE displays n (%) m
m = number of events

VLA1553-303: Safety Summary

No safety concern identified during long-term follow-up

- Overall, 10 SAEs were reported:
  - Four SAEs were reported between Month 6 up to Year 1
  - Six SAEs were reported between Year 1 and Year 2
  - All cases were deemed not related by the investigator
- Additionally, trial VLA1553-303 intended to collect long-term safety by following-up any Adverse Event of Special Interest (AESI) from the preceding trial. However, when participants joined the follow-up trial, no AESI was ongoing.
- An independent Data Safety Monitoring Board regularly reviewed accruing safety information until Year 2. None of the data reviews raised any safety concerns.

VLA1553-303: Antibody Persistence Trial Conclusions

Data support the anticipated long-term persistence of the immune response

- The results are in line with our expectations for live-attenuated vaccines, which are known to induce long-lasting immunity after a single dose.
  - 24 months after the single-dose vaccination, 97% of participants retained neutralizing antibody titers above the seroresponse threshold of 150*.
  - At month 24, antibody levels remained high and were well above the defined seroresponse threshold.
  - Persistence of antibodies in older adults aged ≥ 65 years was as good as in younger adults, with both GMTs and SRRs slightly higher than those observed in younger individuals.
- No safety concerns were identified for the duration of the follow-up trial.

* A neutralizing antibody titer of ≥150 determined by µPRNT50, i.e. the antibody level agreed with regulators as endpoint under the accelerated approval pathway.

Acknowledgements

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Horizon 2020

Thank you

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