

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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Background

VLA1553 is a live-attenuated chikungunya virus vaccine designed for active immunization as a prophylactic measure for individuals travelling to or living in endemic areas. Due to the sporadic epidemic occurrence of chikungunya, an immunological surrogate to assess clinical efficacy was accepted by regulators (FDA and EMA).

Methods

This phase 3 open-label, single arm long term antibody persistence and safety trial follows a subset (N=363) of VLA1553 vaccinees from a pivotal phase 3 trial (Schneider et al, 2023) where 4,115 adult participants received VLA1553 or placebo. The main study objective is to assess the proportion of participants with seroresponse (defined as $\mu\text{PRNT}_{50} \geq 150$) annually, from 1 until 5 years after single immunization. Additionally, serious adverse events (SAE) were monitored from month 6 until Year 2 post-vaccination. This presentation outlines immunogenicity and safety data collected until Year 2.

Results

The seroresponse rate was 97% (306/316, 95% CI 94.3% to 98.5%) at Year 2. The Day 29 GMT for the long-term follow-up cohort was 3,542, and GMT remained high with 785 at Year 2, considerably exceeding the seroresponse threshold of 150. In adults aged ≥ 65 years, antibody persistence was similar to younger adults throughout the follow-up. Ten SAEs were reported, all assessed as unrelated to VLA1553 by the investigators. Furthermore, no persistent adverse event of special interest was identified, indicating that no safety concern was identified in VLA1553-303 until Year 2.

Conclusions

These results suggest that our live-attenuated vaccine induces a robust and long-lasting immunity after a single dose.