

Progress of Clinical Development of a Live-Attenuated Single Shot Chikungunya Vaccine Candidate

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VLA1553 is a live-attenuated chikungunya virus (CHIKV) vaccine candidate designed for active immunization as a prophylactic measure. Due to the sporadic epidemic occurrence of chikungunya, an immunological surrogate to assess clinical efficacy was accepted by regulators.

A blinded, randomized phase 1 clinical trial evaluated the safety and immunogenicity of three dose levels of VLA1553, administered as a single intramuscular immunization in 120 participants (NCT03382964). This was followed by a pivotal phase 3 double-blinded, multicentre randomized trial that enrolled 4,115 adults to receive the selected final VLA1553 dose or placebo (NCT04546724). A further phase 3 trial evaluated bioequivalence between three lots of VLA1553 in 408 healthy adults randomized to each lot 1:1:1 (NCT04786444). Safety and immunogenicity data was collected for 29 days post vaccination in both trials.

In phase 1 clinical trial a single-shot of VLA1553 was well tolerated and highly immunogenic in an adult population. Participants were protected from vaccine-induced viremia upon re-vaccination. The first pivotal trial met its primary endpoint with 98.9% of subjects achieving seroprotection (263 of 266 participants in the per-protocol immunogenicity subgroup, 95% CI: 96.7-99.8). The bioequivalence study showed no significant differences between lots with regard antibody titres. VLA1553 was also highly immunogenic as seroprotection was achieved in 97.7% of participants. VLA1553 was also well tolerated with a favourable safety profile across phase 3 trials.

The generation of protective titers in nearly 100% of vaccinated participants analyzed indicates VLA1553 is an effective candidate for the prevention of disease caused by the CHIKV.