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Update on the clinical development of a live attenuated (1 dose) chikungunya vaccine candidate

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VLA1553 is a monovalent live attenuated chikungunya virus (CHIKV) vaccine candidate. It was designed by deleting part of the chikungunya virus genome.

A randomised, blinded Phase 1 clinical trial evaluated the safety and immunogenicity of three doses of VLA1553, administered intramuscularly in 120 participants (NCT03382964). This was followed by a pivotal phase 3, randomised, double-blind, placebo-controlled study (NCT04546724). The VLA1553-301 trial enrolled 4115 adults aged 18 years and older at 44 sites in the US. Another phase 3 trial evaluated the bioequivalence between three batches of VLA1553 in 408 healthy adults randomised to each batch 1:1:1 (NCT04786444). Safety and immunogenicity data were collected for 29 days after vaccination in both trials.

In the Phase 1 clinical trial, a single dose of VLA1553 was well tolerated and highly immunogenic in the adult population. The development of neutralising antibodies to chikungunya virus was observed with a 100% seroconversion rate in 120 healthy participants.) This rate was maintained for up to 12 months. Based on these results, VLA1553 entered Phase 3 clinical development.

The first pivotal trial met its primary endpoint with 98.9% seroprotection (263 of 266 participants, 95% CI: 96.7-99.8) one month after vaccination with a single dose of VLA1553. Seroprotection was maintained at 96.3% six months after a single dose. The safety and tolerability are therefore validated.

The bioequivalence study showed no significant differences in antibody titers between the batches. VLA1553 was also highly immunogenic as seroprotection was achieved in 97.7% of participants. VLA1553 was also well tolerated with a favourable safety profile in the Phase 3 trials.

The generation of protective titers in nearly 100% of the vaccinated participants tested indicates that VLA1553 is an effective candidate for the prevention of CHIKV-induced disease.