4069-A-2209

Long-term Safety and Immunogenicity of an Adjuvanted Chikungunya Virus-Like Particle (CHIKV VLP) Vaccine: Results of a Phase 2, Parallel-Group, Randomized, Double-Blind Trial

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Background: An unadjuvanted CHIKV VLP candidate vaccine has previously demonstrated an acceptable safety profile and robust immunogenicity in phase 1 and 2 trials in CHIKV-naive and exposed adults. Here, we assessed long-term safety and immunogenicity of an adjuvanted CHIKV VLP vaccine.

Methods: Healthy US adults (18-45 years) were given 1- or 2-doses of CHIKV VLP at doses of 6-40 µg over a 2- or 4-week period, with or without adjuvant. Induction of serum neutralizing antibody was assessed by a luciferase-based anti-CHIKV neutralization assay (NT80) at multiple time points up to two years (731 days) after the last dose, and expressed as seroconversion or geometric mean titers (GMT). The primary endpoint was anti-CHIKV GMT 28 days after the last dose. Safety was monitored for the duration of the study.

Results: All regimens were well-tolerated, with mostly mild or moderate solicited adverse events. No vaccine-related serious adverse events were reported. Across 8 dosing regimens, seroconversion occurred in 72-98% of subjects within 7 days after dose 1, and in 100% of subjects by 28 days after the last dose, with GMTs ranging from 920-2057. The immune response was durable, with 100% seroconversion and a GMT of 280 two years after receiving a single adjuvanted 40 µg dose.

Conclusion: CHIKV VLP vaccine was well-tolerated and generated rapid SNA antibody responses that persisted for 2 years, with GMTs like those seen after natural infection.