

## **SAFETY AND IMMUNOGENICITY OF LIVE RECOMBINANT ALVAC-HIV (VCP 1521) PRIMING WITH GP 120 BOOSTING IN THAI HIV SERONEGATIVE ADULTS**

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**Background:** Several phase I/II trials of ALVAC-HIV candidate vaccines alone or boosted with soluble protein antigens have demonstrated the safety and immunogenicity subtype B prime-boost vaccine candidates. The predominance of subtype E infections in Thailand suggests that prime-boost vaccine candidates appropriate for use in Thailand should contain subtype E antigens.

**Objective:** To evaluate the safety, tolerability and immunogenicity of subtype E based Aventis Pasteur live recombinant ALVAC-HIV (vCP1521) prime and Chiron gp120 CM235/SF2 E/B bivalent boost in HIV-seronegative Thai adults.

**Methods:** The study was double blind, randomized, placebo controlled. ALVAC or its placebo was given IM at weeks 0, 4, 12, and 24. gp120 or placebo was given at weeks 12 and 24. Reactogenicity and safety data were collected. Pre- and post-vaccination sera were tested for binding/neutralizing Ab, PBMCs for LPA and CTL responses.

**Results:** 62 volunteers were enrolled (46 vaccinees and 16 placebo recipients). Reactogenicity was mild-to-moderate in the overwhelming majority of cases. There were 6 SAEs, all unrelated to vaccination. The AE profile confirms the safety of ALVAC constructs seen in previous studies. No vaccinations were withheld due to reactions or intolerance. In one case, the 4th vaccination was withheld due to microscopic hematuria, unknown etiology. NAb against subtype E strains were detected in 98% and against SF2 strain in 60% of the vaccinees. LPA responses to CM 235 and to SF2 antigens developed in 69% and 64% of the vaccinees respectively. CTLs are currently being analyzed.

**Conclusions:** The prime boost vaccine combination of Aventis Pasteur ALVAC-HIV (vCP1521) and Chiron HIV Thai E (CM 235) gp120 + SF2 gp120 appeared safe and well tolerated in healthy Thai adults. Good immunogenicity was shown by neutralization assay and LPA. The safety profiles and the immunogenicity of this prime boost vaccine combination is appropriate for advancement to phase III testing.

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