

SAFETY AND IMMUNOGENICITY OF LIVE RECOMBINANT ALVAC-HIV (VCP1521) PRIMING WITH AIDSVAXÒ B/E GP120 BOOSTING IN THAI HIV-NEGATIVE ADULTS

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Background: The first safety and immunogenicity trial of ALVAC-HIV vCP1521 prime with an AIDSVAXÒ B/E gp120 boost was conducted in Thailand. vCP1521 is a recombinant canarypox vector vaccine that has been genetically engineered to express subtype E HIV-1 gp120 (92TH023) linked to transmembrane anchoring portion of gp41, and HIV-1 gag and protease (LAI strain). AIDSVAXÒ B/E is a recombinant bivalent HIV gp120 envelope glycoprotein vaccine. The ALVAC-HIV + AIDSVAXÒ B/E prime-boost combination is currently being evaluated for possible advancement to phase III efficacy testing in Thailand.

Methods: The study was a double-blind, randomized, placebo-controlled phase II trial. Volunteers were enrolled and divided into two groups based on the dose of AIDSVAXÒ B/E, and subjects were randomized to vaccine or placebo in a ratio of 3:1. 45 low-risk, HIV-seronegative Thai adults from each group were given ALVAC-HIV (vCP1521, 106.5 CCID50) at weeks 0, 4, 12 and 24. At weeks 12 and 24, 200 mg or 600 mg of bivalent AIDSVAXÒ B/E (100 mg or 300 mg of each antigen) was given. 15 other subjects from each group received placebo injections.

Results: Most reactogenicity was mild to moderate and comparable to previous studies of similar prime-boost combinations and adjuvant. Seven serious adverse events were reported, none attributable to vaccine. Among recipients of the 600 ug dose of AIDSVAXÒ B/E boost, 71% and 98% of vaccine recipients had neutralizing antibody to subtype E and B TCLA HIV

strains. HIV-specific CTL response is being analyzed. Among recipients of the 600 ug dose of AIDSVAXÒ B/E boost, 71% had lymphocyte proliferation to gp120 CM244, while 49% had proliferation to gp120 MN.

Conclusions: Prime-boost vaccination with ALVAC-HIV and AIDSVAXÒ B/E appears safe and well-tolerated. This prime-boost combination induces both humoral and cellular HIV-specific immune responses in Thai adults. It is an appropriate candidate for advancement to Phase III evaluation.

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