

Oral presentation

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## OA07-04 LB. Immunogenicity of ALVAC-HIV® (vCPI521) and AIDSVAX® B/E prime boost vaccination in RV144, the Thai Phase III HIV vaccine trial

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### Background

The Phase III trial of ALVAC-HIV® and AIDSVAX® B/E in Thailand began in October 2003 and concluded in June 2009. Both vaccine candidates express HIV-1 circulating recombinant form (CRF) 01\_AE and subtype B antigens. This study assessed whether the Phase III vaccine lots show immunogenicity comparable to the previous Phase I/II study of the identical immunization regimen.

### Methods

A list of blinded samples from persons completing all 4 injections with either placebo or vaccine and remained HIV negative at the end of the trial was provided. Peripheral blood mononuclear cells (PBMC) or plasma were tested to CRF 01\_AE and subtype B vaccine antigens in the following validated assays: (1) Interferon-gamma (IFN- $\gamma$ ) ELISpot; (2) IFN- $\gamma$ /interleukin-2 intracellular cytokine staining (ICS); (3) Binding antibody (BAb). ELISpot and ICS assays measured responses to Env (92TH023) and Gag (LAI) peptide pools prior to and 6 months following the completion of immunization. BAb was measured using reciprocal dilution EIA to A244 and MN gp120 and BH10 p24 prior to and at 2 weeks following the completion of immunization.

### Results

Data will be un-blinded to treatment assignment by October 2009. Analyses of post-injection responses to Env and Gag by ELISpot revealed an overall frequency of 14%, with Env responses (11%) predominating over Gag (5%). The overall frequency of ICS responses to HIV peptides in samples studied to date was 35% and was greater for CD4 (26%) than CD8 (9%) T cells, with responses to Env again predominating: 26% versus 1% Gag for CD4 and 6% Env versus 2% Gag for CD8 T cells. The frequency of BAb responses to p24 was 37% and was identical for CRF01\_AE and MN gp120 (70%).

### Conclusion

Cellular and humoral immune responses to the ALVAC-HIV® + AIDSVAX® B/E regimen were predominantly to HIV Env and appear similar to those seen in the earlier Phase I/II study.