

Oral presentation

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## Clinical Trials of DNA and Recombinant Adenovector (rAd) Vaccines for HIV

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### Background

Gene-based vaccine delivery is an important strategy for induction of T cell responses that may be critical for a successful AIDS vaccine. Despite promising results in animal models, evidence of immune responses to DNA and rAd vaccines in humans has been limited.

### Materials and methods

Three Phase I studies have evaluated a series of DNA and rAd vaccine candidates expressing constructs encoding clades A, B, and C Envelope and clade B Gag and Pol with or without Nef, as fusion proteins or individually.

### Results

T cell and antibody responses are detected by IFN- $\alpha$  ELISpot and FACS detection of intracellular IL-2 or IFN- $\alpha$  in the large majority of vaccinees. Env peptide pools elicit the strongest response, but the 6-plasmid and rAd product also induced robust responses to Gag, Pol, and Nef. Both T cell and humoral responses were dose dependent. The T cell responses induced by DNA are detectable for at least 52 weeks, and the pattern of cytokine expression evolves over time with fewer IFN- $\gamma$  and more IL-2 producing T cells at one year.

### Conclusion

DNA and rAd5 vaccine candidates are well tolerated and induce broad, durable immune responses. The combination will be tested in Phase II trials beginning 4Q2005.