SAFETY AND REACTOGENICITY OF A MULTICLADE, MULTIPROTEIN ADENOVECTOR HIV VACCINE BOOST FOLLOWING A MATCHED DNA VACCINE PRIME: A MULTICENTER ROLLOVER TRIAL (HVTN 057)

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We present initial safety data from HVTN 057, a Phase I multicenter rollover clinical trial in which 70 of the 180 participants who received VRC-HIVDNA-009-00-VP (4 DNA plasmids encoding subtype B Gag-Pol-Nef and subtypes A,B, and C Env) or placebo in HVTN 052 received a single boost injection of VRC-HIVADV-014-00-VP (4 non-replicating Ad5 vectors expressing sequences matched to the HIV proteins and subtypes encoded in the priming DNA vaccine) versus formulation buffer placebo. The interval between first DNA vaccine in HVTN 052 and Ad5 boost in HVTN 057 was permitted to range between 5 and 10 months.

Preliminary, blinded reactogenicity data are available from 67 vaccinees who entered the rollover trial between November 22, 2004 and April 15, 2005. During the reactogenicity period local pain was reported as absent in 42 participants (63%), mild in 23 (34%) and moderate in 2 (3%). Local tenderness was absent in 17 (25%), mild in 48 (72%), and moderate in 2 (3%). Erythema and/or induration were absent in 59 (88%), <=10 cm2 in 5 (7%), and >10 to 25 cm2 in 3 (4%). Systemic symptoms (malaise, fatigue, myalgia, headache, nausea, vomiting, chills, arthralgia) were absent in 38 (57%), mild in 17 (25%), and moderate in 12 (18%). There were no fevers >38.6˚ C following injection, and no severe or life-threatening local or systemic reactogenicity findings. As of April 15, 2005 a total of 62 non-reactogenicity adverse events were reported in 32 participants. Of these AE's, 47 were mild, 13 moderate, 1 severe and 1 life threatening. The events classified as "severe" and "life threatening" were both elevations in serum CPK and were considered not related to study product. Conclusion: When administered as a boost following DNA priming, the VRC Ad5 HIV vaccine appears safe and well tolerated in an ongoing multicenter phase I trial.