Next generation combination therapies with AGS-004
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AGS-004-003 phase 2b study

- AGS-004 fully autologous DC based immunotherapy electroporated with autologous HIV RNA. Tested in double blinded randomized 2:1 placebo controlled study
  - Primary and secondary endpoint were not met:
    - no significant impact on VL (immunized vs. placebo) after ART interruption
    - no significant impact on VL setpoints (pre vs. post treatment)
  - Immune responses were induced only in the AGS-004 group and not placebo during ART
Combination with Vorinostat Stage 1

Stage 1:
• Evaluating the kinetics of AGS-004 immune responses to understand best method of combining with Vorinostat

- Vorinostat at high concentrations blocks proliferation of established Ag-specific CTL upon DC stimulation

Stage 2:
• Optimal sequencing of AGS-004 with Vorinostat rather than concomitant administration
• Protocol approved by FDA and will initiate at UNC (Dr. David Margolis) shortly
Combination of AGS-004 with PD-1/PD-L1 blockade

- To understand why memory T cell responses induced in AGS-004-003 did not have significant impact on VL after ART interruption, we measured CTL PD1 positivity

- Although newly created anti-HIV memory T cells are PD-1-; a large number of PD-1+ T cells are found in patients

- Suggests that combining AGS-004 with a PD-1/PD-L1 blockade may result in incremental benefit

- We have initiated preclinical work to explore this possibility