

Studies Open to Enrollment	Study Description	Treatment Arms	CD4, VL, other criteria
<p>ACTG A5240 PI: Skolnik MD Point Nurse: Betsy Adams RN 617-414-7082 beeper: 2731</p>	<p>A phase II study to evaluate the immunogenicity and safety of a quadrivalent human papillomavirus vaccine in HIV-1 infected females</p> <p>Duration: 72 wks</p>	<p>Open-label, single arm study</p> <p>Gardasil IM day 0, wk8 and wk24</p>	<p>CD4 > 200 to \leq 350 with any VL or</p> <p>CD4 \leq 200 with any VL or</p> <p>CD4 > 350 with VL > 10,000</p> <p>If on ARV, on for 12 wks</p>
<p>ACTG A5241 PI: Skolnik MD Point Nurse: Betsy Adams RN 617-414-7082 beeper: 2731</p>	<p>Optimized treatment that includes or omits NRTIs (OPTIONS) trial: a randomized strategy study for HIV-1 infected treatment experienced subject using the cPSS to select an effective regimen.</p> <p>Duration: 96 wks</p>	<p>Arm A: Study regimen + NRTIs</p> <p>Arm B: Study regimen + no NRTIs</p> <p>Study regimen picked from options sent by study team based on genotype, phenotype and tropism</p>	<p>Triple-class experienced or resistance.</p> <p>Currently on PI regimen</p> <p>HIV RNA > 1000</p>
<p>ACTG A5257 PI: Skolnik MD Point Nurse: Betsy Adams RN 617-414-7082 beeper: 2731</p>	<p>A phase III comparative study of three non-nucleoside reverse transcriptase inhibitor (NNRTI)-sparing antiretroviral regimens for treatment-naïve HIV-1 infected volunteers</p> <p>Duration: up to 96 wks</p>	<p>Arm A: ATV 300mg po qd + RTV 100mg po qd + Truvada one po qd</p> <p>Arm B: RAL 400mg po bid + Truvada one tab po qd</p> <p>Arm C: DRV 800mg po qd + RTV 100 po qd + Truvada one po qd</p>	<p>Treatment naïve except for PEP or when pregnant</p> <p>HIV RNA \geq 1000</p>
<p>ACTG A5262 PI: Skolnik MD Point Nurse: Betsy Adams RN 617-414-7082 beeper: 2731</p>	<p>A pilot efficacy and safety trial of raltegravir plus darunavir/ritonavir for treatment-naïve HIV-1-infected subjects</p> <p>Duration: 52 wks</p>	<p>Single-arm, open-label pilot study:</p> <p>RAL BID + DRV/RTV 100 mg QD</p>	<p>ARV drug-naïve (\leq 14 days)</p> <p>HIV RNA > 5000</p> <p>Relevant drug mutations</p>

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Merck 0518 055 PI: Skolnik MD Point Nurse: Betsy Adams RN 617-414-7082 beeper: 2731	A phase III open-label single arm study to evaluate the safety, tolerability, and efficacy of MK-0518/raltegravir in a diverse cohort of HIV-infected patients Duration: 48 wks	Open-label single arm study: Raltegravir 400mg bid in combination with other ARVs	Prior use of raltegravir or another HIV-integrase inhibitor
Pfizer A4001080 PI: Bica MD Point Nurse: Betsy Adams RN 617-414-7082 beeper: 2731	A multicenter, randomized, open, comparative trial of maraviroc versus etravirine each in combination with darunavir/ritonavir and raltegravir for the treatment of antiretroviral-experienced HIV-1 subjects co-infected with HepC and/or HepB. Duration: 48 wks	Arm A: DRV/r + RAL + ETR BID Arm B: DRV/r + RAL + MVC BID	HIV RNA \geq 1000 Detectable HepC VL or positive HepB surface antigen Previous treatment ARVs > 2mths CCR5 tropic
ACTG A5247 PI: Skolnik MD Point Nurse: Betsy Adams RN 617-414-7082 beeper: 2731	A phase II, randomized, double-blind, placebo-controlled clinical trial to evaluate the safety, tolerability, and immunogenicity of ZOSTAVAX (Zoster Vaccine Live) in human immunodeficiency virus (HIV)-1-infected adults on potent combination ART with conserved immune function Duration: 24 wks	Randomized 3:1 to the following groups: ZOSTAVAX at day 0 and wk 6 Placebo at day 0 and wk 6	Undetectable HIV RNA On stable ART CD4 \geq 200 Can't have add hx of CD4 < 100 Hx of varicella or herpes zoster > 1 year before vaccination or VZV seropositivity at any time prior to entry



Center for HIV/AIDS Care and Research

