

**Case Western Reserve University/University Hospitals Case Medical Center  
AIDS Clinical Trials Unit**

**A5336 Clinician Summary: A Randomized, Pilot Study of Ruxolitinib  
in Antiretroviral-Treated HIV-1 Infected Adults**

**Brief Summary:**

This is a randomized, open-label, two arm (phase IIa) study. Eligible participants on select antiretroviral therapy (ART) with virologic suppression will be randomized to receive ruxolitinib or no study treatment to measure safety, tolerability, PK and to determine whether there are changes in systemic immune activation and inflammation after 5 weeks of treatment with ruxolitinib.

**Objectives:**

- To evaluate the safety and tolerability of ruxolitinib in ART-treated HIV-1 infected virologically suppressed participants during 5 weeks of treatment.
- To compare changes in levels of interleukin-6 (IL-6) and other markers of inflammation and immune activation between baseline and week 5 in ART-treated HIV-1 virologically suppressed participants who are randomized to ruxolitinib and those randomized to receive no study treatment.

**Inclusion/Exclusion Criteria:**

- HIV-1 positive men and women,  $\geq 18$  and  $\leq 75$  years old;
- CD4+ T cell count  $> 350$  cells/mm<sup>3</sup>
- Continuous ART for  $> 2$  years with documented virologic suppression  $> 2$  years (one blip 200 or below allowed in 2<sup>nd</sup> year before study entry);
- Current regimen must include tenofovir/emtricitabine (TDF/FTC) or abacavir/lamivudine (ABC/3TC) + a NNRTI or INSTI, not containing cobicistat, for at least 60 days, inclusive, prior to study entry;
- ANC  $\geq 1000$ /mm<sup>3</sup>, Hgb  $\geq 12.0$  g/dL, Plts  $\geq 200,000$ /mm<sup>3</sup>, LFTs  $\leq 1.5 \times$ ULN
- CrCl  $\geq 80$  mL/min
- No changes in ART in 12 weeks prior to study entry;
- No history of progressive multifocal leukoencephalopathy;
- No history of untreated latent tuberculosis infection diagnosed by tuberculin skin test or interferon gamma release assay;
- Not currently prescribed any CYP3A4 inhibitors or inducers;
- No diagnosis of CDC Cat C AIDS-indicator conditions, varicella zoster or lymphoproliferative malignancy in the 2 years prior to study entry.

**Treatment:** Randomized at entry to either:

ARM A: Ruxolitinib 10 mg orally (PO) BID. Participants must remain on ART regimen (not provided by the study) for the duration of the study.

ARM B: No study treatment. Participants will be encouraged to remain on ART regimen (not provided by the study) for the duration of the study.

**Duration of Study:** 12 weeks on study. Compensation provided. Bus tickets/parking provided. 7 visits (including screening and pre-entry visit).

For more information about this trial, please contact  
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[www.clevelandhiv.org](http://www.clevelandhiv.org)  
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