**Title of Study:** A Phase I/II Study of Single Dose Romidepsin in HIV-Infected Adults with Suppressed Viremia on Antiretroviral Therapy to Assess Safety, Tolerability, and Activation of HIV-1 Expression

**Brief Description:** A5315 is a phase I/II, double-blinded, randomized, placebo-controlled, dose-escalation study to evaluate the safety and efficacy of a single dose administration of romidepsin (RMD). Three cohorts (1-3) of 15 subjects each will be sequentially enrolled into the study (depending on safety outcomes, which will determine whether to dose escalate or not). Toxicity related to the administration of RMD will be evaluated systematically.

**Inclusion/Exclusion Criteria:**

**Inclusion:**
- Taking antiretroviral therapy (ART) that includes a raltegravir, dolutegravir, or efavirenz-based regimen
- HIV-1 RNA (viral load) < 50 copies/ml for past 12 months
- CD4+ cell count ≥ 300 cells/mm³
- Men and non-pregnant women age ≥ 18 years
- Good veins to draw blood from in both arms
- Agree to follow a strict visit schedule
- Agree to follow birth control requirements, as needed

**Exclusion:**
- History of or current cytomegalovirus (CMV) end organ disease (eg, retinitis).
- History of seizure disorders.
- Poor vein circulation

**Treatment:** Subjects will be sequentially enrolled to each cohort and randomized 4:1 to receive RMD or placebo:

- **Cohort 1:** 12 subjects (0.5 mg/m² RMD in 0.9% saline) 3 subjects (placebo in 0.9% saline)
- **Cohort 2:** 12 subjects (2 mg/m² RMD in 0.9% saline) 3 subjects (placebo in 0.9% saline)
- **Cohort 3:** 12 subjects (5 mg/m² RMD in 0.9% saline) 3 subjects (placebo in 0.9% saline)

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