ACTG A5357
Clinician Summary Sheet

Study Title: A Study of Long-Acting Cabotegravir Plus VRC01LS to Maintain Viral Suppression in HIV-1-Infected Adults

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Brief Summary:
This study is for people who are infected with HIV-1 and have an undetectable viral load. We will evaluate the safety and effectiveness of a combination of two medications. The first drug is called cabotegravir. This will be given orally at first and then as an injection. The 2nd drug is called VRC-HIVMAB080-00-AB (VRC01LS). This drug will be given intravenous for about 15 to 30 minutes. We are studying these medications to see if they work well when taken together to keep your virus levels low. This study will also evaluate the safety of the drug combination.

Objectives:
- To see if the combination of long-acting cabotegravir and VRC01LS is safe and will prevent viral rebound in individuals who have achieved suppression with conventional antiretroviral therapy
- To evaluate the safety and tolerability of the combination of parenteral VRC01LS plus CAB LA in HIV-1 infected adults with well-controlled viral replication

Inclusion/Exclusion Criteria:
- HIV-1 infected individuals aged ≥18 years
- CD4+ T cell count ≥ 350 cells/mm^3
- Boosted protease inhibitor, a nonnucleoside reverse transcriptase inhibitor (NNRTI), or an integrase inhibitor, plus two NRTIs, with no history of a switch due to virologic failure
- HIV-1 RNA <40 copies/mL
- ANC ≥750/mm^3, Hgb ≥11.0 g/dL for men or ≥10.0 g/dL for women
- Platelet ≥100,000/mm^3, AST and ALT ≤2.0xULN, CrCl ≥50mL/min
- Susceptibility to VRC01LS based on IC50 ≤1.0 µg/mL using the Monogram Phenosense Assay
- Negative HBsAg
- Negative hepatitis C virus (HCV) antibody
- No acute or ongoing AIDS-defining illness within 60 days prior to study entry

Treatment: Randomized at entry to either:

Step 1: All participants will discontinue their current HIV regimen except for NRTIs and start oral CAB.
Step 2: You may receive CAB long acting drug by injection every 4 weeks plus VRC01LS by IV every 12 weeks.
Step 3: Participants will be switched back to a Standard of Care oral HIV regimen.

Duration of Study: Participants will be on study for about 101 weeks.

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