ACTG A5357
Participant Summary Sheet

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

Principal Investigator: Jorge L. Santana Bagur, MD, FIDSA

Brief Description: This study is for people who live 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 (CAB). This will be given orally at first and then as an injection. The 2nd drug is called VRC-HIVMAB080-00-AB (VRC01LS). This is a monoclonal antibody. A monoclonal antibody targets human proteins rather than attacking the virus directly. This drug will be given intravenous (directly into a vein) 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.

Key Requirements to Enter Study:

- HIV-1 positive persons aged 18 years and older
- On stable HIV treatment for a minimum of 8 weeks
- Screening CD4+ cell count ≥350 cells/mm^3
- Undetectable HIV viral load
- No current Hepatitis B or C infection
- No history of seizures or treatment for seizures within the past 2 years prior to study entry
- Not pregnant or breastfeeding

Treatment:

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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