ACTG A5324 Participant Summary Sheet

Title of Study:

A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV

Brief Description:
A5324 is a study for HIV-infected individuals with undetectable HIV viral load who have mild neurocognitive impairment. Subjects will be randomized to one of three study arms to add either placebo for maraviroc (MVC) and placebo for dolutegravir (DTG) (Arm A), DTG active drug and placebo for MVC (Arm B), or MVC and DTG active drugs (Arm C) to their existing antiretroviral therapy (ART).

Subjects will be assessed with neurocognitive tests and questionnaires about their daily functioning. There is an option to undergo lumbar punctures.

Purpose of this Study:
The main purpose of the study is to see if adding FDA approved HIV medications MVC and DTG will improve neurocognitive performance and functioning, (for example: ability to concentrate, remember, solve problems and make decisions) in subjects who have an undetectable viral load. Safety and tolerability of MVC and DTG when added to a stable ART regimen and the effect of the study drugs on selective areas in the blood and spinal fluid will also be studied.

Requirements to Enter Study:
- HIV-1 infected men and women at least 18 years of age
- On current ART for at least 12 months
- Undetectable HIV viral load (<50 copies/mL)
- No more than one viral load between 50 and 200 copies/mL (only one “blip”) in the past 6 months
- At least mild HIV-associated neurocognitive impairment on neurocognitive tests done at screening
- Able to complete the neuropsychological tests in English
- No medical condition not related to HIV that may cause cognitive impairment
- No current hepatitis C
- No prior or current use of any integrase inhibitor or MVC
- No active syphilis or treatment for syphilis

Study Drugs

Subjects will be randomized (1:1:1) to add one of the following regimens to their existing ART:

Arm A: placebo for MVC and placebo for DTG
Arm B: DTG and placebo for MVC

Arm C: MVC and DTG

Neuropsychological testing will be done at entry and every 24 weeks.
A subset of subjects will have optional lumbar punctures at entry and week 48.

Duration of Study: 96 weeks

For more information contact:

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