

## ACTG A5257 Participant Summary Sheet

### **Title of Study: Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers**

**Brief Description:** This study is for people who are HIV infected but have never taken HIV medications. Each person will go into one of three groups. Each group will be taking a different set of HIV medications.

**Purpose of this Study:** To learn whether the medication combinations work equally well in people who have never taken HIV medications before. It will also look at how easy the medications are to take and their side effects.

#### **Requirements to Enter Study:**

- HIV-1 infected people at least 18 years of age
- Have not taken HIV medication (there are a few exceptions that the study staff can discuss with you):
- No resistance to the type (class) of medications provided by the study on a test called a genotype.
- HIV viral load (HIV level) currently 1000 copies/mL or higher
- Other requirements which your study nurse will discuss with you

#### **Study Drugs**

During the study you will assigned (by chance) to one of the following treatments:

- Arm A: Atazanavir 300 mg once daily + ritonavir 100 mg once daily + emtricitabine/tenofovir disoproxil fumarate 200/300 once daily
- Arm B: Raltegravir 400 mg twice daily + emtricitabine/tenofovir disoproxil fumarate 200/300 once daily
- Arm C: Darunavir 800 mg once daily + ritonavir 100 mg once daily + emtricitabine/tenofovir disoproxil fumarate 200/300 once daily

All study medications are provided with the exception of ritonavir which must be obtained through a primary care physician.

All of the drugs used in this study are approved by the U.S. Food and Drug Administration (FDA) for treating HIV/AIDS; however, darunavir and raltegravir are not currently approved by the FDA for treating people who have never taken HIV medication before.

**Duration of Study:** About 2 years after the last person starts the study.

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