



## **Randomized Trial to Prevent Vascular Events in HIV Participant Summary Sheet for ACTG A5332**

### **Brief Description:**

In this study, people between the ages of 40 and 75 with HIV will be randomized to take the pill pitavastatin OR a placebo to see if pitavastatin can help prevent heart disease and death in people who are taking HIV medication. The study lasts approximately 72 months and you will not know if you are taking pitavastatin or placebo. The REPRIEVE trial will enroll 6500 people from several countries.

### **Purpose of this Study:**

HIV causes inflammation (irritation) inside the body that cannot be felt but can be measured. Inflammation may contribute to diseases such as heart disease that have become some of the leading causes of death in people with HIV. HIV medications can lower inflammation somewhat, however sometimes the levels of inflammation can remain higher compared to people who are not infected with HIV.

Statins are used to lower the levels of cholesterol and triglycerides (fat in the blood) that people make, but clinical trials have shown that statins may have other benefits. For example, heart disease and the levels of inflammation can be lowered by statins.

Pitavastatin is a statin that, along with a diet, has been approved by the US Food and Drug Administration for the treatment of high cholesterol. It also lowers triglyceride levels in the blood.

**The main purpose of this clinical trial is to see if pitavastatin can prevent heart disease and heart disease related deaths in people with HIV infection who are taking HIV medications.**

**Requirements to Enter Study:** The study coordinator will review all of the criteria necessary to be eligible for the study with you. Listed below are a few key points.

- HIV infected and between the ages of 40 and 75.
- On antiretroviral therapy (ART) for at least 6 months prior to study entry.
- CD4+ cell count >100.
- Must not be pregnant and must agree not to participate in the conception process.
- No history of cardiovascular disease (history of heart attack or stroke, etc.).
- No history of cancer in the last 3 years.
- Not currently using a statin drug.

**Treatment:** Participants will be randomized (like flipping a coin) to take either:

- Pitavastatin 4 mg one pill daily with or without food **or**
- Placebo pitavastatin one pill daily with or without food

**Duration of Study:** You will be in this study for up to 6 years. You will need to be seen in clinic for a screening visit, an entry visit, one month later, and then every 4 months.

**For more information contact:**

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