Executive Summary: The REPRIEVE (A5332) Trial

Title	Randomized Trial to Prevent Vascular Events in HIV – REPRIEVE (A5332)
Indication	To study the efficacy of statins to reduce the risk of cardiovascular disease in HIV-infected patients
Location	Multicenter trial conducted primarily at US trial sites, with select international sites
Brief Rationale	HIV-infected persons face an increased risk of CVD morbidity and mortality, yet no preventive strategies for CVD risk reduction have been proven for this population. Among HIV-infected individuals, immune activation may contribute in unique ways to atherosclerosis and ensuing cardiovascular events. Statins affect both traditional CVD risk factors (LDL cholesterol) and have pleiotropic effects to reduce inflammation and immune activation. Thus, statins may target the unique mechanisms of cardiovascular disease in HIV
Study Design and Duration	Prospective, double-blind, randomized, placebo-controlled, multicenter efficacy study in 6500 subjects, with individual subjects to be followed for up to 72 months.
Treatment	Pitavastatin 4 mg PO daily or matching placebo
Primary Objective	To determine the effects of pitavastatin as a primary prevention strategy for major adverse cardiovascular events (MACE) in HIV.
Secondary Objectives	1. The effects of pitavastatin on the components of MACE and all-cause mortality 2. The effects of pitavastatin on LDL and non-HDL in relationship to MACE 3. Whether baseline traditional risk factors and time updated HIV specific immunological risk factors are predictive of MACE and pitavastatin effects on MACE 4. The effects of pitavastatin on the incidence of serious non-CVD events 5. The safety of pitavastatin in the HIV population
Primary Endpoint	Major Adverse Cardiovascular Events
Secondary Endpoints -	Primary components of MACE, all cause mortality, LDL cholesterol, immune function, non-CVD events (malignancy, end stage liver and kidney disease, AIDS-defining events), and safety endpoints