Atazanavir + [Cobicistat or Ritonavir] + TDF-FTC (Phase 3)

Study 114
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Study 114: Study Design

**Background:** Randomized, double-blind, double-dummy, active controlled phase 3 trial to compare the safety and efficacy of cobicistat and ritonavir as pharmacokinetic enhancers administered with atazanavir and fixed-dose tenofovir DF-emtricitabine in treatment-naïve adults with HIV infection

**Inclusion Criteria (n = 692)**
- Age ≥18 years
- Antiretroviral treatment-naïve
- Sensitive to atazanavir, tenofovir, and emtricitabine
- HIV RNA ≥5000 copies/mL

**Treatment Arms (all once daily)**
- Atazanavir-cobicistat (300/150 mg) + TDF-FTC
- Atazanavir 300 mg + Ritonavir 100 mg + TDF-FTC

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Study 114: Results

Week 48: Virologic Response (ITT, Missing=Failure)

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Adverse Events (AE) and Treatment Discontinuations

Conclusions: “COBI was noninferior to RTV in combination with ATV plus FTC/TDF at week 48. Both regimens achieved high rates of virologic success. Safety and tolerability profiles of the 2 regimens were comparable. Once-daily COBI is a safe and effective pharmacoenhancer of the protease inhibitor ATV.”

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