Fostemsavir in Treatment-Experienced Patients
AI438-011 Study
Fostemsavir in Treatment-Experienced Patients AI438-011: Results

Study Design

- Randomized, active controlled
- Phase 2b study
- Location: International
- Treatment Experienced
- HIV RNA ≥ 1,000 copies/ml
- CD4 ≥ 50 cells/mm³
- Susceptible to:
  - Raltegravir
  - Tenofovir
  - Temsavir

- Fostemsavir 400 mg BID + Raltegravir + Tenofovir DF (n = 50)
- Fostemsavir 800 mg BID + Raltegravir + Tenofovir DF (n = 49)
- Fostemsavir 600 mg QD + Raltegravir + Tenofovir DF (n = 51)
- Fostemsavir 1200 mg QD + Raltegravir + Tenofovir DF (n = 51)
- Atazanavir + RTV 300/100 mg qd + Raltegravir + Tenofovir DF (n = 51)

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Proportion with HIV RNA <50 copies/mL at 24 weeks (FDA snapshot analysis)

All regimens given in combination with a backbone of raltegravir + tenofovir DF

Interpretation: “In a comparison with ritonavir-boosted atazanavir, efficacy and safety of BMS-663068 up to the week 24 analysis support continued development of BMS-663068, which is being assessed in a phase 3 trial in heavily treatment-experienced individuals.”

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