Dolutegravir 10-Day, Dose-Ranging, Monotherapy Study
ING111521
**Dolutegravir Dose-Ranging Monotherapy ING111521 Study: Design**

**Study Design: ING111521**

- **Background**: Randomized, double-blind, dose-ranging, 10-day, phase 2a study to evaluate antiviral activity, safety, and pharmacokinetics/pharmacodynamics of dolutegravir

- **Inclusion Criteria (n = 35)**
  - Antiretroviral-naïve and antiretroviral-experienced
  - Integrase inhibitor-naïve
  - Age ≥18 and ≤65 years
  - CD4 ≥100 cells/mm³
  - HIV RNA ≥5,000 copies/mL
  - No AIDS conditions

- **Treatment Arms**
  - Dolutegravir 2, 10, or 50 mg daily, or placebo

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Baseline to Day 11: Change in Baseline HIV RNA Level

Change in HIV RNA from Baseline (Log10 copies/mL)

- Dolutegravir: 2 mg
- Dolutegravir: 10 mg
- Dolutegravir: 50 mg
- Placebo

Regimen (once daily dosing)

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Baseline to Day 11: Patients with Suppressed Viral Load at Nadir

**Conclusion**: “Dolutegravir demonstrated potent antiviral activity, good short-term tolerability, low pharmacokinetic variability, and a predictable pharmacokinetics/pharmacodynamics relationship, which support once daily dosing without a pharmacokinetic booster in integrase-naive patients in future studies.”
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