Dolutegravir versus Raltegravir in Treatment Experienced
SAILING Study
Dolutegravir versus Raltegravir in Treatment Experienced SAILING: Study Design

**Study Design: SAILING**

- **Background**: Randomized, double-blind, active-control phase 3 trial evaluating efficacy, safety, and emergent resistance with dolutegravir versus raltegravir in antiretroviral-experienced, integrase inhibitor-naïve persons with HIV who have at least 2-class resistance.

- **Inclusion Criteria (n = 715)**
  - Age ≥18 years
  - Resistance to ≥2 ARV classes
  - Integrase inhibitor-naïve
  - 2 consecutive HIV RNA ≥400 copies/mL (unless >1,000 copies/mL at screening)

- **Treatment Arms**
  - Dolutegravir + up to 2 background ARTs
  - Raltegravir + up to 2 background ARTs

Dolutegravir versus Raltegravir in Treatment Experienced SAILING: Results

Week 48 Virologic Response, By Baseline HIV RNA Level

<table>
<thead>
<tr>
<th>Baseline HIV RNA Level</th>
<th>Dolutegravir + Background ART</th>
<th>Raltegravir + Background ART</th>
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<tbody>
<tr>
<td>≤50,000 copies/mL</td>
<td>71/251 (27%)</td>
<td>75/186 (41%)</td>
</tr>
<tr>
<td>&gt;50,000 copies/mL</td>
<td>64/230 (28%)</td>
<td>71/180 (40%)</td>
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Dolutegravir versus Raltegravir in Treatment-Experienced
SAILING: Results

Week 48 Virologic Failure

Per Protocol VF
- Dolutegravir + Background ART: 21/354
- Raltegravir + Background ART: 45/361

VF due to Non-Response
- Dolutegravir + Background ART: 2/21
- Raltegravir + Background ART: 19/45

VF with Treatment-Emergent Resistance
- Dolutegravir + Background ART: 4/354
- Raltegravir + Background ART: 17/361

VF = Virologic Failure

**Interpretation**: “Once-daily dolutegravir, in combination with up to two other antiretroviral drugs, is well tolerated with greater virological effect compared with twice-daily raltegravir in this treatment-experienced patient group.”

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