Dolutegravir in Treatment-Experienced Adolescents

IMPAACT P1093
**Study Design: IMPAACT P1093**

- **Background:** Open-label, non-randomized phase I/II study treatment-experienced adolescents with HIV

- **Inclusion Criteria (n = 23)**
  - Age 12 to <18 years of age
  - Antiretroviral-experienced
  - Naïve to integrase inhibitors
  - HIV RNA >1,000 copies/mL
  - Genotype showing sensitivity to at least one other active antiretroviral agent

- **Treatment Arms**
  - Dolutegravir monotherapy, then dolutegravir with optimized background regimen

**Stage I**
- Intensive PK group n=10
- Functional monotherapy or monotherapy phase
- Optimize therapy continuation phase 48 week DTG + OBR
- Day 1
- Day 5-10 Intensive PK visit
- Week 48

**Stage II:** opens after dose/safety criteria met in stage I; n=13
- DTG and OBR from day 1

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IMPAACT P1093: Results

Week 48: Virologic Response

Virologic Suppression (%)

<table>
<thead>
<tr>
<th>Virologic Suppression Threshold</th>
<th>HIV &lt;400 copies/mL</th>
<th>HIV &lt;50 copies/mL</th>
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<td>74/23</td>
<td>14/23</td>
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Week 48: Patient-Reported Adherence

**Conclusions**: “Dolutegravir achieved target PK exposures in adolescents. Dolutegravir was safe and well tolerated, providing good virologic efficacy through week 48.”
Acknowledgment

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