Dolutegravir in Treatment-Experienced Adolescents

IMPAACT P1093
Dolutegravir in Treatment-Experienced Adolescents

IMPAACT P1093: Study Design

**Study Design: IMPAACT P1093**

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

**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

<table>
<thead>
<tr>
<th>Functional monotherapy or monotherapy phase</th>
<th>Optimize therapy continuation phase</th>
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<tbody>
<tr>
<td>DTG and OBR from day 1</td>
<td>48 week DTG + OBR</td>
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- 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

Dolutegravir in Treatment-Experienced Adolescents 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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<tr>
<td></td>
<td>17/23</td>
<td>61/23</td>
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Dolutegravir in Treatment-Experienced Adolescents
IMPAACT P1093: Results

Week 48: Patient-Reported Adherence

Dolutegravir in Treatment-Experienced Adolescents
IMPAACT P1093: Conclusions

**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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