Darunavir/r versus Other PIs in Treatment Experienced

POWER 1 and 2
Study Design: POWER 1 and 2

- **Background**: Two randomized, phase 2b trials to compare the efficacy and safety of ritonavir-boosted darunavir with other protease inhibitors in treatment-experienced HIV-infected patients with PI resistance.

- **Inclusion Criteria (n = 155)**
  - Age ≥18
  - HIV RNA >1000 copies/mL
  - On PI-containing regimen
  - History of taking >1 NRTI, and ≥1 NNRTI as part of failing regimen
  - At least 1 primary PI mutation at screening

- **Treatment Arms**
  - Darunavir 600 mg BID + Ritonavir 100 mg bid + OBR*
  - Investigator-selected control PI + OBR*

*OBR = Optimized background regimen: ≥2 NRTIs +/- enfuvirtide

**Source:** Clotet B, et al. Lancet. 2007;369:1169-78.
Darunavir/r versus other PIs in Treatment-Experienced POWER 1 and 2: Result

Week 48: Virologic Response

![Graph showing virologic response at Week 48.](image)

- **Darunavir + RTV + OBR**
  - ≥1 log10 Decrease in HIV RNA: 61% (67/110)
  - HIV RNA <50 copies/mL: 45% (50/110)

- **Control PI + RTV + OBR**
  - ≥1 log10 Decrease in HIV RNA: 15% (18/120)
  - HIV RNA <50 copies/mL: 10% (12/120)

Darunavir/r versus other PIs in Treatment-Experienced
POWER 1 and 2: Result

Week 48: Virologic Response (ITT-TLOVR)

Darunavir/r versus other PIs in Treatment-Experienced POWER 1 and 2: Result

Week 48: Virologic Response, by Primary PI Mutations at Baseline

Darunavir/r versus other PIs in Treatment-Experienced POWER 1 and 2: Result

Week 48: Virologic Response, by DRV-Associated Mutations at Baseline

# Darunavir/r versus other PIs in Treatment-Experienced
## POWER 1 and 2: Result

## ACTG Grade 3 or 4 Adverse Events (≥ 1% incidence regardless of causality)

<table>
<thead>
<tr>
<th>Data given for Number of Patients</th>
<th>DRV + RTV + OBR (n = 131)</th>
<th>Control PI + RTV + OBR (n = 124)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Injection site reaction (2° enfuvirtide)</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Hip arthroplasty</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Peripheral neuropathy</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Anemia</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Hyperbilirubinemia</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Herpes zoster</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

Interpretation: “Efficacy responses with darunavir-ritonavir 600/100 mg twice daily plus optimised background regimen were greater than those with control PI and were sustained to at least week 48, with favourable safety and tolerability in treatment-experienced patients. This regimen could expand the treatment options available for such patients.”
Darunavir/r versus other PIs in Treatment-Experienced POWER 1 and 2: Result

Week 24: Virologic Response, by Viral Susceptibility at Baseline

Acknowledgment

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