Cobicistat-Boosted Darunavir + 2 NRTIs
Study 130
Cobicistat-Boosted Darunavir + 2 NRTIs
Study 130: Design

**Study Design: 130**

- **Background**: Phase 3b, open label, single arm study to evaluate the safety and efficacy of cobicistat-boosted darunavir plus two NRTIs in antiretroviral treatment-naïve and treatment-experienced adults with HIV infection

- **Inclusion Criteria (n = 313)**
  - Antiretroviral treatment-naïve or -experienced
  - On stable ART for ≥12 weeks
  - HIV RNA ≥1000 copies/mL
  - GFR ≥80 mL/min
  - No darunavir-associated resistance mutations
  - Genotypic sensitivity to the two NRTIs
  - No past or current use of darunavir

- **Treatment Arms**
  - Cobicistat 150 mg QD + Darunavir 800 mg QD + 2 investigator-selected NRTIs

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Study 130: Results

Week 48: Virologic Response (Intent-to-Treat FDA Snapshot Analysis)

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Study 130: Results

Week 48: Virologic Response, by Different Statistical Analyses

HIV RNA <50 copies/mL (%)

Snapshot  
TLOVR analysis  
Missing=failure

Statistical Analysis

TLOVR = Time to loss of virologic response

Cobicistat-Boosted Darunavir + 2 N(t)RTIs
Study 130: Results

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>All patients (n=313)</th>
<th>Treatment-naïve (n=295)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>27%</td>
<td>27%</td>
</tr>
<tr>
<td>Nausea</td>
<td>23%</td>
<td>23%</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>14%</td>
<td>15%</td>
</tr>
<tr>
<td>Headache</td>
<td>12%</td>
<td>12%</td>
</tr>
</tbody>
</table>

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Study 130: Results

Adverse Events and Treatment Discontinuations

Conclusion: “Darunavir/cobicistat 800/150 mg once daily was generally well tolerated through Week 48, with no new safety concerns. Pharmacokinetics, virologic and immunologic responses for darunavir/cobicistat were similar to previous data for darunavir/ritonavir 800/100 mg once daily.”
The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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