Darunavir-Cobicistat + 2 NRTIs

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

- **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

- **Inclusions 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

Darunavir-Cobicistat + 2 NRTIs
Study 130: Results

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

HIV RNA <50 copies/mL (%)

<table>
<thead>
<tr>
<th>Baseline HIV RNA</th>
<th>All patients</th>
<th>Treatment-naïve</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>81</td>
<td>83</td>
</tr>
<tr>
<td>≤100,000 copies/mL</td>
<td>81</td>
<td>84</td>
</tr>
<tr>
<td>&gt;100,000 copies/mL</td>
<td>80</td>
<td>81</td>
</tr>
</tbody>
</table>

Darunavir-Cobicistat + 2 NRTIs
Study 130: Results

Week 48: Virologic Response, by Different Statistical Analyses

TLOVR = Time to loss of virologic response

## Darunavir-Cobicistat + 2 NRTIs
### Study 130: Results

**Week 48: Adverse events (any grade), occurring in ≥ 10% of patients**

<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>

Darunavir-Cobicistat + 2 N(t)RTIs
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 supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,332,044 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.