Darunavir/r Once Daily or Twice Daily in Treatment Experienced

ODIN Trial
Once-daily versus Twice-daily Darunavir in Treatment-Experienced ODIN: Study Design

Study Design: ODIN

- **Background**: Randomized, open-label phase 3 trial to compare once daily versus twice-daily dosing of ritonavir-boosted darunavir in treatment-experienced patients with HIV infection

- **Inclusion Criteria** (n = 590)
  - Age ≥18
  - On stable antiretroviral regimen for >12 weeks
  - HIV RNA >1000 copies/mL
  - CD4 count >200 cells/mm³
  - No darunavir resistance-associated mutations

- **Treatment Arms**
  - Darunavir 800 mg QD + RTV 100 mg QD + OBR*
  - Darunavir 600 mg BID + RTV 100 mg BID + OBR*

*OBR = Optimized background regimen: ≥2 nucleoside reverse transcriptase inhibitors, investigator-selected

Once Daily versus Twice Daily Darunavir in ARV-Experienced ODIN: Result

Week 48: Virologic Response (ITT-TLOVR)

Once Daily versus Twice Daily Darunavir in ARV-Experienced ODIN: Result

Week 48: Changes in Lipids from Baseline

## Once Daily versus Twice Daily Darunavir in ARV-Experienced ODIN: Result

### Adverse Events Possibly Related to Darunavir + Ritonavir (≥ 2% incidence in either arm)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>DRV + RTV + OBR once daily (n = 294)</th>
<th>DRV + RTV + OBR twice daily (n = 296)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>10.9%</td>
<td>10.5%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>9.9%</td>
<td>15.2%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3.1%</td>
<td>5.4%</td>
</tr>
<tr>
<td>Rash</td>
<td>2.7%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Headache</td>
<td>1.4%</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

**Conclusion**: “Once-daily DRV/r 800/100 mg was non-inferior in virologic response to twice-daily DRV/r 600/100 mg at 48 weeks in treatment-experienced patients with no DRV RAMs, and with a more favorable lipid profile. These findings support use of once-daily DRV/r in this population.”

Acknowledgment

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.

*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*