Cobicistat-Boosted PIs in Patients with Renal Impairment

Study 118
Cobicistat-Boosted PIs in Patients with Renal Impairment
Study 118: Design

Study Design: 118

- **Background**: Phase 3, non-comparative, open label, 2 cohort study to compare the safety and efficacy of switching ritonavir to cobicistat in virologically suppressed adults with HIV infection and mild to moderate renal impairment.

- **Inclusion Criteria (n = 73)**
  - Antiretroviral treatment-experienced
  - HIV RNA undetectable x 6 months
  - On regimen of 2 NRTIs + ATV/r or DRV/r
  - Stable renal function with CrCl 50 to 89 mL/min

- **Treatment Arms**
  - Cobicistat 150 mg QD + [Atazanavir 300 mg QD or Darunavir 800 mg QD] + 2 NRTIs

*Note: only ritonavir-to-cobicistat switch cohort presented here*

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Study 118: Results

Week 24 and 48: Virologic Response (Snapshot Analysis)

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Study 118: Results

Week 48: Virologic Response, by Different Statistical Analyses

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Study 118: Results

Week 48: Changes in Creatinine Clearance, by Baseline CrCl

### Cobicistat-Boosted PIs in Patients with Renal Impairment

#### Study 118: Results

<table>
<thead>
<tr>
<th>Confirmed Renal Laboratory Abnormalities</th>
<th>Cobicistat + [ATV or DRV] + 2 NRTIs (n=73)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum creatinine increase ≥ 0.4mg/dL</td>
<td>4.1%</td>
</tr>
<tr>
<td>Hypophosphatemia (≥ grade 1 increase)</td>
<td>1.4%</td>
</tr>
<tr>
<td>Proteinuria (≥ grade 2 increase)</td>
<td>1.4%</td>
</tr>
<tr>
<td>Normoglycemic glycosuria (≥ grade 1 increase)</td>
<td>0</td>
</tr>
</tbody>
</table>

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Study 118: Results

Adverse Events and Treatment Discontinuations

Conclusions: “COBI was noninferior to RTV in combination with ATV plus FTC/TDF at week 48. Both regimens achieved high rates of virologic success. Safety and tolerability profiles of the 2 regimens were comparable. Once-daily COBI is a safe and effective pharmacoenhancer of the protease inhibitor ATV.”
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.

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