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)

![Graph showing virologic response]

- **HIV RNA <50 copies/mL (%)**
- **Study Week**
  - 24 Weeks: 90%
  - 48 Weeks: 82%

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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.”

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