STOP-TB
Pre-CROI Meeting

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Why are Rifamycin levels lower in HIV?

Perlman CID 2005, Gurumurthy AAC 2004

<table>
<thead>
<tr>
<th>Group</th>
<th>C&lt;sub&gt;max&lt;/sub&gt; (µg/ml)</th>
<th>T&lt;sub&gt;max&lt;/sub&gt; (h)</th>
<th>AUC&lt;sub&gt;0-&lt;infty&gt;&lt;/sub&gt; (µg/ml·h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary TB (n = 13)</td>
<td>7.2 (5.5–8.9)</td>
<td>2.4 (1.7–3.1)</td>
<td>33.0 (26.7–39.4)</td>
</tr>
<tr>
<td>HIV (n = 13)</td>
<td>3.4 (2.5–4.3)</td>
<td>3.9 (2.7–5.0)</td>
<td>14.1 (9.9–18.2)</td>
</tr>
<tr>
<td>HIV-TB (n = 15)</td>
<td>3.4 (2.7–4.2)</td>
<td>3.6 (2.7–4.5)</td>
<td>16.5 (12.4–20.6)</td>
</tr>
</tbody>
</table>
Relapses

4 mos: 13 (7%)
6 mos: 3 (1.6%)
Dose ranging
14 d single drug EBA
14 d combination EBA
Combination 8 wk SSCC
Combination Phase III

Mouse data

Adapted from Ginsberg 2010
Mouse data

14 d single drug EBA

14 d combination EBA

Combination 8 wk SSCC

Combination Phase III

Adapted from Ginsberg 2010
Dose ranging

14 d single drug EBA
14 d combination EBA
Combination 8 wk SSCC
Combination Phase III

Mouse data

Phase I Human Data

14 d single drug EBA
14 d combination EBA
Combination 8 wk SSCC

HIV

Phase IIa
Phase IIa
Phase IIb

• ART-TB PK studies

Adapted from Ginsberg 2010
Mouse data

14 d single drug EBA

14 d combination EBA

Combination 8 wk SSCC

Combination Phase III

Mouse data

• ART-TB PK studies

• Consider deferring ART if CD4 >200

Adapted from Ginsberg 2010