Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE Trial
Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Study Design

### Study Design: SECOND-LINE

**Background:** Randomized, parallel, open-label trial to compare dual therapy with lopinavir-ritonavir plus raltegravir with WHO 2nd line standard-of-care regimen of lopinavir-ritonavir plus NRTIs

**Inclusion Criteria (n=541)**
- Age ≥ 16
- Received first-line ART with 2 NRTIs + 1 NNRTI for ≥ 24 weeks (no change in past 12 weeks)
- No virologic failure
- Naïve to PIs and integrase inhibitors

**Treatment Arms**
- Lopinavir-ritonavir + Raltegravir
- Lopinavir-ritonavir + NRTIs

---

**Lopinavir-ritonavir 400-100 mg (QD or divided BID) + Raltegravir 400 mg BID**
(n = 271)

**Lopinavir-ritonavir 400-100 mg (QD or divided BID) + NRTIs**
(n = 270)

Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Result

Week 48: Virologic Response (Modified ITT)

Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Result

Week 48: Virologic Response (Modified ITT), by Baseline HIV RNA

Lopinavir-Ritonavir plus either Raltegravir or 2-3 NRTIs
SECOND-LINE: Result

<table>
<thead>
<tr>
<th>Emergent Resistance Associated Mutations (RAMs) with Virologic Failure</th>
<th>Raltegravir (n = 271)</th>
<th>Control (NRTIs) (n = 270)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virologic Failure with Resistance Data (Protease and reverse transcriptase)</td>
<td>42%</td>
<td>43%</td>
</tr>
<tr>
<td>Virologic Failure with Resistance Data (Integrase)</td>
<td>47%</td>
<td>46%</td>
</tr>
<tr>
<td>NtRTI-associated RAMs</td>
<td>0%</td>
<td>14%</td>
</tr>
<tr>
<td>Protease inhibitor-associated RAMs</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Integrase inhibitor-associated RAMs</td>
<td>14.9%</td>
<td>0%</td>
</tr>
<tr>
<td>No new RAMs in protease, reverse transcriptase, or integrase</td>
<td>83%</td>
<td>86%</td>
</tr>
</tbody>
</table>

**Interpretation:** “The raltegravir regimen was no less efficacious than the standard of care and was safe and well tolerated. This simple NtRTI-free treatment strategy might extend the successful public health approach to management of HIV by providing simple, easy to administer, effective, safe, and tolerable second-line combination antiretroviral therapy.”

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.*