Dolutegravir vs. Raltegravir

SPRING-2 Study
Study Design: SPRING-2

- **Background**: Randomized, double-blind study, phase 3 trial comparing dolutegravir versus raltegravir

- **Inclusion Criteria (n = 822)**
  - Antiretroviral-naïve patients
  - Age ≥ 18
  - HIV RNA ≥ 1,000 copies/ml
  - No active CDC AIDS condition

- **Treatment Arms**
  - Dolutegravir + 2NRTIs
  - Raltegravir + 2NRTIs
  - Fixed dose 2NRTIs = TDF-FTC or ABC-3TC

**Dolutegravir**: 50 mg QD
Fixed-dose NRTI backbone* (n = 411)

**Raltegravir**: 400 mg BID
Fixed-dose NRTI backbone* (n = 411)

Dolutegravir versus Raltegravir
SPRING-2: Results

Week 48: Virologic Response, by Baseline HIV RNA

<table>
<thead>
<tr>
<th>Baseline HIV RNA Level</th>
<th>Dolutegravir + 2NRTIs</th>
<th>Raltegravir + 2NRTIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>88/411</td>
<td>85/411</td>
</tr>
<tr>
<td>≤ 100,000 copies/ml</td>
<td>90/297</td>
<td>89/295</td>
</tr>
<tr>
<td>&gt; 100,000 copies/ml</td>
<td>82/114</td>
<td>75/116</td>
</tr>
</tbody>
</table>

Dolutegravir versus Raltegravir
SPRING-2: Results

Week 48: Virologic Response, by NRTI Component

Interpretation: “The non-inferior efficacy and similar safety profile of dolutegravir compared with raltegravir means that if approved, combination treatment with once-daily dolutegravir and fixed-dose nucleoside reverse transcriptase inhibitors would be an effective new option for treatment of HIV-1 in treatment-naive patients.”

Dolutegravir + 2NRTIs versus Raltegravir + 2NRTIs
SPRING-2 (Week 96): Results

Week 96 Virologic Response: Background Dual NRTI Therapy

Interpretation: “At week 96, once-daily dolutegravir was non-inferior to twice-daily raltegravir in treatment-naive, patients with HIV-1. Once-daily dosing without requirement for a pharmacokinetic booster makes dolutegravir-based therapy an attractive treatment option for HIV-1-infected treatment-naive patients.”
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.