Cabotegravir IM + Rilpivirine IM

LATTE-2
Cabotegravir IM + Rilpivirine IM versus Cabotegravir + ABC-3TC

LATTE-2: Design

**Study Design:**

- **Background:** Phase 2b, randomized, open-label trial assessing dual therapy with long-acting, injectable agents for maintenance

- **Inclusion Criteria**
  - Age > 18
  - Antiretroviral-naïve
  - HIV RNA >1,000 copies/mL
  - CD4 count >200 cells/mm³
  - CrCl >50 mL/min
  - No major drug resistance mutations, pregnancy, significant hepatic impairment, or AIDS defining condition

**Lead-In Phase**

- Week 16
- CAB 30 mg PO QD + ABC-3TC
- Rilpivirine PO Added

**Maintenance Phase**

- Week 20
- CAB 400 mg IM Q4w + RPV 600 mg IM Q4w (n = 115)
- CAB 600 mg IM Q8w + RPV 900 mg IM Q8w (n = 115)
- CAB 30 mg PO QD + ABC-3TC (n = 56)

Continued to Maintenance Phase if HIV RNA <50 copies/mL from week 16 to 20

Cabotegravir IM + Rilpivirine IM versus Cabotegravir + ABC-3TC LATTE-2: Results at Week 48

HIV RNA < 50 copies/mL

- CAB 400 mg IM Q4w + RPV 600 mg IM Q4w: 91/105/115
- CAB 600 mg IM Q8w + RPV 900 mg IM Q8w: 92/106/115
- CAB 30 mg PO + ABC-3TC PO: 89/50/56

Abbreviations: CAB = cabotegravir; RPV = rilpivirine; ABC-3TC = abacavir-lamivudine

IM Cabotegravir + Rilpivirine versus Oral Cabotegravir + 2 NRTI’s
LATTE-2 Study

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>Q4 Weeks CAB + RPV IM (n = 115)</th>
<th>Q8 Weeks CAB + RPV IM (n = 115)</th>
<th>Oral CAB + ABC-3TC (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyrexia</td>
<td>5 (4%)</td>
<td>3 (3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4 (3%)</td>
<td>2 (2%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Influenza-like illness</td>
<td>2 (2%)</td>
<td>3 (3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Headache</td>
<td>2 (2%)</td>
<td>2 (2%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Rash</td>
<td>3 (3%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Drug-related grade 3-4 AE’s, excluding ISR</td>
<td>4 (3%)</td>
<td>2 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>AE’s leading to withdrawal</td>
<td>7 (6%)</td>
<td>2 (2%)</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

Abbreviations: Q = every; IM = intramuscular; ISR = injection site reaction; ; CAB = Cabotegravir; RPV = rilpivirine; ABC-3TC = abacavir-lamivudine
IM Cabotegravir + Rilpivirine versus Oral Cabotegravir + 2 NRTI’s
LATTE-2 Study: Incidence of Injection Site Reactions

For patients with injection site reactions, 99% were mild (82%) or moderate (17%); 90% resolved ≤7 days

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*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.*