Cabotegravir IM + Rilpivirine IM every one or two months versus oral CAB + ABC-3TC

LATTE-2
IM Cabotegravir + IM Rilpivirine versus Cabotegravir + ABC-3TC
LATTE-2 Study: Design

**Study Design:**

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

**Inclusion Criteria**
- Age ≥18 years
- Antiretroviral-naïve
- HIV RNA >1,000 copies/mL
- CD4 count >200 cells/mm³
- CrCl >50 mL/min

**Exclusions:**
- Major resistance mutations
- Pregnancy
- Significant hepatic impairment
- AIDS-defining condition

**Lead-In Phase**
- CAB 30 mg PO QD + ABC-3TC
- Week 16
- Rilpivirine PO Added
- Week 20

**Maintenance Phase**
- 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

IM Cabotegravir + IM Rilpivirine versus Cabotegravir + ABC-3TC
LATTE-2 Study: Results

Week 48 virologic results by FDA snapshot analysis

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

IM Cabotegravir + IM Rilpivirine versus Cabotegravir + ABC-3TC
LATTE-2 Study: Results

Week 96 virologic results by FDA snapshot analysis

HIV RNA <50 copies/mL

87

100/115

94

108/115

84

47/56

CAB 400 mg IM Q4w + RPV 600 mg IM Q4w

CAB 600 mg IM Q8w + RPV 900 mg IM Q8w

CAB 30 mg PO + ABC-3TC PO

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

### Treatment-related adverse events at 96 weeks (excluding injection site reactions)

<table>
<thead>
<tr>
<th></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>7 (6%)</td>
<td>5 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>12 (10%)</td>
<td>8 (7%)</td>
<td>5 (9%)</td>
</tr>
<tr>
<td>Headache</td>
<td>7 (6%)</td>
<td>6 (5%)</td>
<td>4 (7%)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>6 (5%)</td>
<td>1 (&lt;1%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Asthenia</td>
<td>3 (3%)</td>
<td>2 (2%)</td>
<td>3 (5%)</td>
</tr>
</tbody>
</table>

*All of the above treatment-related adverse reactions were grade 1-2.

Legend:
- Q = every
- IM = intramuscular
- CAB = Cabotegravir
- RPV = rilpivirine
- ABC-3TC = abacavir-lamivudine

Abbreviations: Q = every; IM = intramuscular; CAB = Cabotegravir; RPV = rilpivirine; ABC-3TC = abacavir-lamivudine

### Treatment-Related Injection Site Reactions

<table>
<thead>
<tr>
<th></th>
<th>Q4 Weeks CAB + RPV IM (n = 115)</th>
<th>Q8 Weeks CAB + RPV IM (n = 115)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any (Grade 3-4)</td>
<td>Any (Grade 3-4)</td>
</tr>
<tr>
<td>Pain</td>
<td>112 (97%) 6 (5%)</td>
<td>109 (95%) 8 (7%)</td>
</tr>
<tr>
<td>Nodule</td>
<td>35 (30%) 1 (&lt;1%)</td>
<td>29 (25%) 1 (&lt;1%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>34 (30%) 0</td>
<td>29 (25%) 1 (&lt;1%)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>33 (29%) 0</td>
<td>24 (21%) 0</td>
</tr>
<tr>
<td>Induration</td>
<td>25 (22%) 0</td>
<td>28 (24%) 1 (&lt;1%)</td>
</tr>
<tr>
<td>Warmth</td>
<td>21 (18%) 0</td>
<td>22 (19%) 1 (&lt;1%)</td>
</tr>
<tr>
<td>Bruising</td>
<td>14 (12%) 0</td>
<td>19 (17%) 0</td>
</tr>
<tr>
<td>Erythema</td>
<td>19 (17%) 0</td>
<td>12 (10%) 1 (&lt;1%)</td>
</tr>
<tr>
<td>Discoloration</td>
<td>6 (5%) 0</td>
<td>3 (3%) 0</td>
</tr>
</tbody>
</table>

**Abbreviations:** Q = every; IM = intramuscular; CAB = Cabotegravir; RPV = Rilpivirine

**Interpretation:** “The two-drug combination of all-injectable, long-acting cabotegravir plus rilpivirine every 4 weeks or every 8 weeks was as effective as daily three-drug oral therapy at maintaining HIV-1 viral suppression through 96 weeks and was well accepted and tolerated.”

Acknowledgment

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