Long-Acting Cabotegravir and Rilpivirine with Oral Lead In versus Direct-to-Inject

FLAIR Study: Week 124 Extension Phase
Long-Acting IM CAB and IM RPV With or Without Oral Lead In FLAIR Study (124-Week Extension): Design

**Background:** Extension of phase 3, randomized, open-label trial assessing IM CAB + IM RPV compared to DTG-ABC-3TC for treatment-naïve adults

**Inclusion Criteria:** After 100-week maintenance phase, participants receiving IM CAB + IM RPV every 4 weeks could choose to continue (*Continuation Group*) or withdraw; those assigned to oral ART could choose to transition (*Switch Group*) to IM CAB + IM RPV after oral lead in or without oral lead in (“direct to inject”)

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**Oral lead in dosing:**
- Cabotegravir 30 mg daily and rilpivirine 25 mg daily x 4 weeks
- Loading injections: cabotegravir 600 mg IM and 900 mg rilpivirine IM x 1
- Maintenance injections: cabotegravir 400 mg IM and 600 mg rilpivirine IM monthly

Long-Acting IM CAB and RPV With or Without Oral Lead In FLAIR Study (124-Week Extension): Results in Extension Phase

Virologic Responses During 24-Week Extension Phase

<table>
<thead>
<tr>
<th>HIV RNA &lt;50 copies/mL (%)</th>
<th>93</th>
<th>93</th>
<th>99</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAB + RPV: Continuation</td>
<td>227/243</td>
<td>113/121</td>
<td>110/111</td>
</tr>
<tr>
<td>CAB + RPV: Oral Lead-In</td>
<td>227/243</td>
<td>113/121</td>
<td>110/111</td>
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<tr>
<td>CAB + RPV: Direct-to-Inject</td>
<td>227/243</td>
<td>113/121</td>
<td>110/111</td>
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Continuation group: randomized to IM CAB + IM RPV at baseline and at week 100 opted to continue IM CAB + IM RPV until week 124. Switch group: randomized to DTG-ABC-3TC and at week 100 switched to IM CAB + IM RPV with either oral lead in or direct-to-inject strategy.

Interpretation: “After 24 weeks of follow-up, switching to long-acting treatment with or without an oral lead-in phase had similar safety, tolerability, and efficacy, supporting future evaluation of the simpler direct-to-injection approach. The week 124 results for participants randomly assigned originally to the long-acting therapy show long-acting cabotegravir plus rilpivirine remains a durable maintenance therapy with a favourable safety profile.”

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