Key Takeaways

- **ATLAS-2M** is a multicenter, Phase 3b, randomized, open-label study investigating cabotegravir + rilpivirine long-acting (CAB + RPV LA) dosed every 8 weeks (Q8W) and every 4 weeks (Q4W) as a maintenance regimen for people living with HIV-1.

- Participants were found to be satisfied with CAB + RPV LA Q8W and Q4W as a treatment for the maintenance of virologic suppression across a range of patient-reported outcomes (PROs).

- Several PRO instruments were included at pre-defined time points in ATLAS-2M to assess tolerability and acceptability of treatments, treatment satisfaction, and treatment preference (Table 1).

- PRs were included in the preference questionnaire o with patient consent. Further details on patient consent are shown in Figure 1 (Panels A and B).

- In patients without prior exposure, satisfaction improved from baseline to Week 152 across both arms of the 12 individual items, with Q4W and Q8W scoring similarly across the 12 individual items (Figure 5, consistent with the Week 48 analyses).

- The Week 152 analysis, the preference questionnaire was limited to those who had received oral therapy during oral daily treatment.

- Most participants across both arms preferred LA therapy over the daily oral ARTs.

- The FPRO data, along with safety and efficacy data, support the therapeutic potential of monthly or every 2 months CAB + RPV and highlight participants’ preference for LA therapy during daily oral dosing.

- These findings underscore the high retention and low discontinuation rates observed in ATLAS-3B.

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**Background**

- **CAB + RPV LA administered mouth** or every 2 months is the first complete LA regimen recommended by treatment guidelines for the maintenance of HIV-1 virologic suppression in people living with HIV-1.

- **CAB + RPV LA dosing** reduces dosing frequency compared with daily oral antiretroviral therapy (ART), reduces pill burden, and other concerns including fear of disclosure, anxiety around medication adherence, and daily reminders of HIV status.

- **Durable noninferior efficacy of CAB + RPV LA** was demonstrated between Q4W dosing and oral comparator ART at Week 48 in the ATLAS (NCT02951052) study, and at Week 48 and Week 96 in the FLAIR (NCT03298320) study.

- **Noninferior efficacy was also established between Q8W and Q4W dosing at Weeks 48, 96, and 152 in the ATLAS-2M study (NCT03299049).**

- **PRs in ATLAS-2M,** an important element to understand participants’ preferences and experiences with this novel LA treatment regimen, updated through Week 152 are presented.

**Methods**

- **ATLAS-2M** is a multicenter, Phase 3b, randomized, open-label study investigating CAB + RPV LA dosed Q8W or Q4W as a treatment for the maintenance of virologic suppression across a range of patient-reported outcomes (PROs).

- Participants with no previous experience with CAB + RPV LA reported increases in treatment satisfaction over their previous daily oral regimen through 3 years of therapy.

- Participants with prior exposure to CAB + RPV LA reported high satisfaction at baseline, which remained high through 3 years of therapy.

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**Table 1: PRO Measures**

<table>
<thead>
<tr>
<th>Description</th>
<th>Endpoint</th>
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<tbody>
<tr>
<td>Perceived change in HIV understanding</td>
<td>Satisfaction with HIV understanding?*</td>
</tr>
<tr>
<td>Perceived change in trust in one's provider</td>
<td>Trust in one's provider?*</td>
</tr>
<tr>
<td>Perceived change in trust in the medication</td>
<td>Worry as much about remembering to take medication (74% [n=52/70])</td>
</tr>
<tr>
<td>Perceived change in trust in regimen</td>
<td>Satisfaction with mode of administration.</td>
</tr>
<tr>
<td>Perceived change in trust in regimen</td>
<td>Satisfaction with HIV understanding?*</td>
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<td>Perceived change in trust in regimen</td>
<td>Satisfaction with mode of administration.</td>
</tr>
</tbody>
</table>

**Note:**

- **HIVTSQ** refers to the HIV Treatment Satisfaction Questionnaire (HIVTSQs), a validated measure of treatment satisfaction. **HIVTSQs** contains 12 individual items that produce the general satisfaction with mode of administration.

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**Results**

**Baseline Characteristics (Intention-to-Treat Exposed Population)**

- **Baseline characteristics were similar between the Q4W and Q8W arms.**

- Median age of 42 years (interquartile range [IQR] 34-50)

- 77% (n=331/430) were White

- 73% (n=309/424) were Male

- 60% (n=254/424) had prior exposure to CAB + RPV

- 62% (n=264/424) had prior exposure to ART

- Participants entered ATLAS phase 3b study after week 244.

**Figure 6: Treatment Preference (Subgroup of Participants Who Received Oral Therapy to Cover Missed Injections, n=70) at Week 152**

- In patients without prior exposure, satisfaction improved from baseline to Week 152 across both arms of the 12 individual items, with Q4W and Q8W scoring similarly across the 12 individual items (Figure 5, consistent with the Week 48 analysis).

- The Week 152 analysis, the preference questionnaire was limited to those who had received oral therapy during oral daily treatment.

- Most participants across both arms preferred LA therapy over the daily ART regimen they received to cover missed injections (Figure 6). The most common reasons supporting LA preference were convenience (81% [n=57/70]) and not having to worry about missing or remembering to take medication (74% [n=52/70])

**Conclusions**

- Participants entered ATLAS-3B with generally high levels of treatment satisfaction and continuing oral ART or either LA in the ATLAS study or daily oral ART.

- CAB + RPV LA was associated with high levels of treatment satisfaction and acceptance across both treatment arms, irrespective of prior CAB + RPV exposure at study entry.

- Of those without prior exposure of CAB + RPV, treatment satisfaction and acceptance for LA treatment over daily oral ART substantially increased for both LA dosing schedules.

- For those transitioning from LA in ATLAS, high levels of treatment satisfaction were maintained among 152 weeks on CAB + RPV LA therapy.

- The majority of participants who received oral ART to cover missed injections during oral ART and had no prior CAB + RPV LA exposure continued to strongly prefer LA therapy over daily oral dosing.

- These findings underscore the high retention and low discontinuation rates observed in ATLAS-3B.