Weight and Body Mass Index Changes in Women Receiving Cabotegravir + Rilpivirine Long-Acting or Bictegravir in the SOLAR Study

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Key Takeaways

- SOLAR is the first randomized study to compare metabolic, weight, and anthropometric changes in a standardized manner among people living with HIV-1 switching to cabotegravir (CAB) + rilpivirine (RPV) long-acting (LA) every 2 months (Q2M) or continuing daily oral bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF).
- Median changes in weight and BMI were modest and comparable through Month (M) 12 for female (sex at birth) participants.
- In this study, switching to CAB + RPV LA Q2M vs. remaining on an established BIC/FTC/TAF regimen resulted in an overall neutral metabolic impact among female (sex at birth) participants through 12 months.

Background

- Weight gain and metabolic alterations have been reported with long-acting straddles (INSTIs), and tenofovir alafenamide-based regimens. ¹,2
- No studies with weight gain have been described, including being female (sex at birth) and being a person of colour. ³,4
- CAB, an INSTI plus RPV, a non-nucleoside reverse transcriptase inhibitor (NNRTI), administered once monthly by subcutaneous injection, is a LA regimen recommended by treatment guidelines for the maintenance of HIV-1 virologic suppression in patients who are virologically suppressed. ⁵,6
- SOLAR (NCT0452070) is a Phase 3b, randomized, controlled study that demonstrated the noninferiority of switching to CAB + RPV LA Q2M vs. continuing daily oral BIC/FTC/TAF over 12 months.⁷
- Here we report weight and metabolic changes for female (sex at birth) participants switching to CAB + RPV LA Q2M vs. continuing daily oral BIC/FTC/TAF.

Methods

**Figure 1. SOLAR Study Design**

- Phase 3b, randomized, open-label, active-controlled, multicenter, parallel-group, noninferiority study.
- **Primary endpoint**: Changes in metabolic syndrome or insulin resistance among female (sex at birth) participants living with HIV-1 switching to CAB + RPV LA Q2M vs. remaining on an established BIC/FTC/TAF regimen.
- **Secondary endpoints**: Changes in weight, BMI, and waist circumference from baseline through 12 months.

**Figure 2. Weight Through M12 in Female Participants (Sex at Birth)**

- Median weight and BMI through M12 in female participants switching to CAB + RPV LA Q2M vs. continuing daily oral BIC/FTC/TAF.
- **Primary endpoint**: Changes in metabolic syndrome or insulin resistance among female (sex at birth) participants living with HIV-1 switching to CAB + RPV LA Q2M vs. remaining on an established BIC/FTC/TAF regimen.
- **Secondary endpoints**: Changes in weight, BMI, and waist circumference from baseline through 12 months.

**Figure 3. BMI Through M12 in Female Participants (Sex at Birth)**

- Median BMI through M12 in female participants switching to CAB + RPV LA Q2M vs. continuing daily oral BIC/FTC/TAF.

**Figure 4. Waist and Hip Circumference Through M12 in Female Participants (Sex at Birth)**

- Median waist and hip circumference through M12 in female participants switching to CAB + RPV LA Q2M vs. continuing daily oral BIC/FTC/TAF.

**Figure 5. Metabolic Syndrome* and Insulin Resistance* Through M12 in Female Participants (Sex at Birth)**

- Change in the proportion of female participants with metabolic syndrome and insulin resistance was similar between arms at M12 (Figure 5).

**Table 1. Baseline Characteristics of Female Participants (Sex at Birth)**

<table>
<thead>
<tr>
<th>Case status</th>
<th>Baseline</th>
<th>M2</th>
<th>M6</th>
<th>M12</th>
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<tbody>
<tr>
<td>LA</td>
<td>70</td>
<td>64</td>
<td>63</td>
<td>64</td>
</tr>
<tr>
<td>BIC/FTC/TAF</td>
<td>70</td>
<td>64</td>
<td>63</td>
<td>64</td>
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</tbody>
</table>

**Table 2. Baseline Characteristics of Female Participants (Sex at Birth)**

<table>
<thead>
<tr>
<th>Age group</th>
<th>Baseline</th>
<th>M2</th>
<th>M6</th>
<th>M12</th>
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</thead>
<tbody>
<tr>
<td>≥18 years</td>
<td>70</td>
<td>64</td>
<td>63</td>
<td>64</td>
</tr>
<tr>
<td>20-29 years</td>
<td>70</td>
<td>64</td>
<td>63</td>
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</table>

**Conclusions**

- This is the first randomized controlled study to evaluate weight and anthropometrics using standardized measurements and metabolic changes among female (sex at birth) participants living with HIV-1 switching to CAB + RPV LA Q2M or continuing daily oral BIC/FTC/TAF.
- Median changes in weight and BMI from baseline were modest and comparable between treatment arms.
- The proportion of participants experiencing ≥10% weight increase from baseline was similar in both low and between treatment arms.
- A modest increase in the proportion of participants with metabolic syndrome and insulin resistance at M12 in both treatment arms was observed.
- In this study, switching to CAB + RPV LA Q2M vs. remaining on an established BIC/FTC/TAF regimen resulted in an overall neutral metabolic impact among female (sex at birth) participants through 12 months.

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