Results

**Background**

Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) is a single-tablet regimen recently approved by the US FDA for treatment of HIV-1 infection in treatment-naïve and virologically-suppressed adults without evidence of resistance.

**Methods**

- **Study Design:** Randomized, open label, triple class switch of treatment-naïve participants to B/F/TAF or PI + 2NRTI (ABC/DTG/3TC).

**Participants:** 405 participants enrolled from clinical trials.

**Eligibility Criteria:**
- HIV-1 RNA <50 c/mL
- DTG+ABC/3TC or ABC/DTG/3TC

**Outcomes:** Primary: virologic failure (HIV-1 RNA ≥ 200 c/mL at Week 48). Secondary: resistance.

**Rescue Regimen:**
- For virologic failure, participants were offered a new treatment regimen.

**Conclusions:**

- **Virologic Success:**
  - 92.1% virologic success at Week 48 in the B/F/TAF group.
  - 82.6% virologic success in the PI + 2NRTI group.

- **Resistance Analyses:**
  - Baseline INSTI resistance mutations were observed in 8% of participants.
  - Baseline PI resistance mutations were observed in 8% of participants.

**Table 1. Frequency of Baseline INSTI Resistance-Associated Substitutions**

<table>
<thead>
<tr>
<th>Substitution</th>
<th>Number of Participants, n (% of Activity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S148N</td>
<td>n=20 (16%)</td>
</tr>
<tr>
<td>L100I</td>
<td>n=16 (13%)</td>
</tr>
<tr>
<td>V179L</td>
<td>n=8 (6%)</td>
</tr>
</tbody>
</table>

**Table 2. Distribution of Baseline NNRTI Substitutions**

<table>
<thead>
<tr>
<th>Substitution</th>
<th>Number of Participants, n (% of Activity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>K103N</td>
<td>n=6 (5%)</td>
</tr>
<tr>
<td>V106A</td>
<td>n=4 (3%)</td>
</tr>
<tr>
<td>K103E</td>
<td>n=2 (2%)</td>
</tr>
</tbody>
</table>

**References**

1. SAX PE, et al., Journal of Acquired Immune Deficiency Syndromes, 2018

**Acknowledgements**

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**Poster 506**

**Resistance Analyses of Bictegravir/Emtricitabine/Tenofovir Alafenamide Switch Studies**

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