Efficacy and Safety of Switching From Boosted Protease Inhibitor–Based Regimens to Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide for Treatment of HIV-1 Infection: Subgroups Analysis by Baseline Regimen

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INTRODUCTION

The primary endpoint in EMERALD was the proportion of patients with cumulative virologic rebound through Week 48, defined as confirmed infection on a bPI + FTC/TDF regimen (treatment-experienced, virologically suppressed adults with HIV-1 infection on a bPI + FTC/TDF regimen). Effort was made to ensure the uniform distribution of study drug across all subgroups.

METHODS

Study Design

- EMERALD is an ongoing phase 1, randomized, noninferiority trial of treatment-experienced, virologically suppressed adults with HIV-1 infection on a bPI + FTC/TDF regimen. Overall, baseline demographic characteristics were generally similar in the overall population and across subgroups based on antiretroviral (ARV) regimen used at baseline.

- The study population was stratified by bPI at screening.

- Patients must have had HIV-1 RNA <50 copies/mL for 12 to 28 months prior to study entry, and must have had virologic suppression with a bPI + FTC/TDF regimen used at baseline for at least 6 months prior to enrollment.

- Overall population: Mantel-Haenszel test adjusted for bPI at screening (ATV with rtv or COBI, DRV with rtv or COBI, LPV with rtv) and 2:1 randomization (D/C/F/TAF vs. control). A total of 378 and 763 patients were randomized to receive D/C/F/TAF or control, respectively.

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RESULTS

Patient Population

Overall, baseline demographic characteristics were generally similar in the overall population and across subgroups based on antiretroviral (ARV) regimen used at baseline.

- At baseline, patients were using bPI-containing regimens.
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Resistance

- Post baseline genotypic were available for 65% of the patients who had virologic suppression with a bPI + FTC/TDF regimen used at baseline.
- One patient was in the D/C/F/TAF arm (25% at baseline), and 1 were virologically suppressed (pooled across all arms).
- No new mutations were observed in either treatment arm across subgroups.

Table 1. Baseline Demographic and Clinical Characteristics (Overall Population)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall population</th>
<th>D/C/F/TAF</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range), years</td>
<td>56 (18-84)</td>
<td>56 (18-84)</td>
<td>55 (18-84)</td>
</tr>
<tr>
<td>Gender, % female</td>
<td>54</td>
<td>54</td>
<td>54</td>
</tr>
<tr>
<td>Race, % Black or African American</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>CD4+ cell count, median (range), cells/mm³</td>
<td>600 (19-1810)</td>
<td>590 (19-1810)</td>
<td>610 (19-1810)</td>
</tr>
<tr>
<td>HIV-1 RNA &lt;50 copies/mL</td>
<td>99</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>Previous experience (number of ARVs or non-DRV VF), and pre-switch experience (number of bPIs)</td>
<td>3 (1-6)</td>
<td>3 (1-6)</td>
<td>3 (1-6)</td>
</tr>
<tr>
<td>Patients with virologic rebound</td>
<td>19</td>
<td>11</td>
<td>8</td>
</tr>
</tbody>
</table>

Efficacy

- Overall, baseline demographic characteristics were generally similar in the overall population and across subgroups based on antiretroviral (ARV) regimen used at baseline.
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Table 2. Incidence (%) of AEs Through Week 48

<table>
<thead>
<tr>
<th>Event</th>
<th>Overall population</th>
<th>D/C/F/TAF</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinuation</td>
<td>8</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>AE-related</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

CONCLUSIONS

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REFERENCES

1. Hahn BH, et al. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI); March 4-7, 2018; Boston, MA. Poster 502.