A Phase 3b Open-Label Pilot Study to Evaluate Switching to Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/TAF) in M184V/I only: enrollment closed at 37 participants

To determine the safety and tolerability of E/C/F/TAF in participants switching from 2 NRTI + 3rd agent

Methods

Part 1: participants with M184V/I only: enrollment closed at 37 participants

Part 2: participants with M184V/I + up to 2 TAMs (M41L, D67N, K70R, L210W, T215Y/F, and N88S, T87A, or A71V)

Primary objective

To determine the safety and tolerability of E/C/F/TAF in participants who develop virologic failure after switching to E/C/F/TAF

Secondary objects

To determine the durability of suppression at Weeks 24 and 48 using PVR

Baseline Characteristics

<table>
<thead>
<tr>
<th>Part 1 (n=37)</th>
<th>Part 2 (n=27)</th>
<th>Overall (n=64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, years (range)</td>
<td>51 (22-76)</td>
<td>52 (25-79)</td>
</tr>
<tr>
<td>Female</td>
<td>6 (29%)</td>
<td>3 (11%)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>11 (30%)</td>
<td>8 (30%)</td>
</tr>
<tr>
<td>Black or African descent</td>
<td>3 (8%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Hispanic/Latino ethnicity</td>
<td>3 (8%)</td>
<td>6 (22%)</td>
</tr>
<tr>
<td>Median CD4 count, cell/mm&lt;sup&gt;3&lt;/sup&gt; (range)</td>
<td>724 (398-1493)</td>
<td>724 (280-1470)</td>
</tr>
<tr>
<td>Median estimated GFR ml/min (range)</td>
<td>60 (26-121)</td>
<td>60 (26-121)</td>
</tr>
</tbody>
</table>

Baseline Resistance

<table>
<thead>
<tr>
<th>M184V/I only</th>
<th>M184V/I + 1 TAM</th>
<th>M184V/I + 2 TAMs</th>
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<tr>
<td>37 (100%)</td>
<td>19 (100%)</td>
<td>4 (100%)</td>
</tr>
</tbody>
</table>

Baseline Analysis

No virological failures or emergence of new resistance

Week 24 PVR Analysis:

All 37 participants with M184V/I using pure virologic response (PVR)

Results

No virological failures or emergence of new resistance

No risk of partial non-adherence

Any Grade 2, 3 or 4 AE 28 (44) 6 (9) 34 (53)

Related to Study Drug

Death 1 No

Serious Adverse Events (SAEs)

Serious Adverse Events (SAEs)

E/C/F/TAF discontinuation prior to Week 24 for reasons other than viral rebound (i.e. no data before Week 24)

Week 24 Primary Analysis:

Viral Suppression: viral blips > 50 c/mL

No virological failures or emergence of new resistance

Results

No virological failures or emergence of new resistance

No virological failures or emergence of new resistance

No virological failures or emergence of new resistance

Week 24 Primary Analysis:

• No virological failures or emergence of new resistance

Week 12 Primary Analysis:

• No virological failures or emergence of new resistance

• No virological failures or emergence of new resistance

• No virological failures or emergence of new resistance

Conclusions

In this open-label study of participants with HIV RNA < 50 copies/mL harboring the M184V and/or M184I mutation +/- 1 TAMs, switching to E/C/TAF:

• Maintained virologic suppression (100%) using the Week 24 PVR analysis

• Was well tolerated with no study drug related SAE or Grade 3 AE

• No virologic failure due to adherence

• Switching to E/C/TAF may be an effective option for PLWH with pre-existing M184V and/or M184I mutations.