Simplification to EVG-COBI-TAF-FTC plus Darunavir

Study 119
Simplification to EVG-COBI-TAF-FTC plus DRV
Study 119: Design

### Study Design: Study 119

**Background**: Open-label, randomized Phase 3 trial comparing simplification to EVG-COBI-TAF-FTC plus darunavir versus continuation of baseline salvage ART regimen containing darunavir

**Inclusion Criteria (n = 135)**
- HIV RNA <50 copies/mL on DRV-containing regimen for ≥ 4 months
- At least 2 prior regimen failures and ≥ 2-class DRMs
- No DRV RAMs, no INSTI resistance, ≤ 3 TAMs, no Q151M or T69ins

**Treatment Arms**
- EVG-COBI-TAF-FTC + DRV (Switch group)
- Remain on baseline ART (No switch group)

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*Abbreviations: RAM = resistance associated mutation, INSTI = integrase strand transfer inhibitor, TAM’s = thymidine analogue mutations*

### Simplification to EVG-COBI-TAF-FTC plus DRV

**Study 119: Design**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>EVG-COBI-TAF-FTC + DRV (N=89)</th>
<th>Baseline Regimen (N=46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, years</td>
<td>49</td>
<td>47</td>
</tr>
<tr>
<td>Male</td>
<td>82</td>
<td>61</td>
</tr>
<tr>
<td>Black (or African descent)</td>
<td>39</td>
<td>57</td>
</tr>
<tr>
<td>Median CD4 count, cells/mL</td>
<td>519</td>
<td>518</td>
</tr>
<tr>
<td>Median eGFR, mL/min (Cockroft-Gault)</td>
<td>99</td>
<td>100</td>
</tr>
<tr>
<td>Median # pills per day in ART regimen</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>≥6 pills per day in ART regimen, %</td>
<td>40</td>
<td>37</td>
</tr>
<tr>
<td>At least BID dosing, %</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Tenofovir, %</td>
<td>61</td>
<td>54</td>
</tr>
<tr>
<td>Raltegravir, %</td>
<td>56</td>
<td>50</td>
</tr>
<tr>
<td>2 class / 3 class resistance, %</td>
<td>70 / 26</td>
<td>74 / 20</td>
</tr>
<tr>
<td>M184V/I / K65R, %</td>
<td>85 / 20</td>
<td>78 / 30</td>
</tr>
<tr>
<td>NNRTI resistance / PI resistance</td>
<td>89 / 38</td>
<td>87 / 28</td>
</tr>
</tbody>
</table>

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Study 119: Results

Week 24 and 48: Virologic Response (Full analysis set)

Simplification to EVG-COBI-TAF-FTC plus DRV
Study 119: Results

Week 24 and 48: Medication Adherence

Simplification to EVG-COBI-TAF-FTC plus DRV
Study 119: Result

Week 48: Urine Protein-to-Creatinine Ratios

Tubular Proteinuria

- Proteinuria (UPCR): Median % Change from Baseline -27.0
- RBP:Cr: Median % Change from Baseline -17.0
- β2M:Cr: Median % Change from Baseline -29.0

RBP:Cr = retinol binding protein:creatinine ratio; β2M:Cr = beta-2 microalbumin:creatinine ratio

Conclusions: “This study demonstrated that regimen simplification from a 5-tablet regimen to the 2-tablet, once-daily combination of E/C/F/TAF plus DRV has durable maintenance of virologic suppression and improvements in specific markers of renal safety. Such a strategy may lead to greater adherence and improved quality of life.”

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*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*