Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment

Study 112
Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment
Study 112: Design

<table>
<thead>
<tr>
<th>Study Design: Study 112</th>
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<tbody>
<tr>
<td><strong>Background:</strong> Open-label, single arm phase 3 trial evaluating switching to once-daily elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine from baseline ART*</td>
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<td><strong>Inclusion Criteria (n = 242)</strong></td>
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<td>HIV RNA &lt; 50 copies/mL for ≥ 6 months</td>
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<tr>
<td>eGFR stable at 30-69 mL/min ≥ 3 months</td>
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<tr>
<td>CD4 ≥ 50 cells/mm³</td>
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<tr>
<td>No new AIDS conditions in past 30 days</td>
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<tr>
<td>No resistance to EVG, FTC, or TDF</td>
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<td><strong>Treatment Arms</strong></td>
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<tr>
<td>Switch to EVG-COBI-TAF-FTC</td>
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*Baseline ART

**NRTIs:** Tenofovir DF 65%, Abacavir 22%, Other NRTI 7%, No NRTI 5%

**Third Agent:** PI 44%, NNRTI 42%, INSTI 24%, CCR5 Antagonist 3%
Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Result

Week 48 Virologic Response

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Subgroup Analysis Result

Change in Estimated GFR* from Baseline to Weeks 24 and 48

*GFR estimated by Cockcroft Gault

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Result

Week 48: Changes in General Proteinuria

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Result

Week 48: Changes in Tubular Proteinuria

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment
Study 112: Result

Week 48: Changes in Bone Mineral Density (BMD)

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Result

Week 48: Changes in Spine and Hip Bone Mineral Density (BMD)

**Spine**
- 37% ≥ 3% gain
- 59% Gain or loss <3%
- 4% Loss ≥3%

**Hip**
- 72% ≥ 3% gain
- 22% Gain or loss <3%
- 6% Loss ≥3%

Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment Study 112: Conclusions

**Interpretation:** “Switch to E/C/F/TAF was associated with minimal change in GFR. Proteinuria, albuminuria and bone mineral density significantly improved. These data support the efficacy and safety of once daily E/C/F/TAF in HIV+ patients with mild or moderate renal impairment without dose adjustment.”

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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.