Elvitegravir-Cobicistat-TAF-FTC in Renal Impairment

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

Study Design: Study 112

- **Background**: Open-label, single arm phase 3 trial evaluating switching to once-daily elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine from baseline ART*

- **Inclusion Criteria (n = 242)**
  - HIV RNA < 50 copies/mL for ≥6 months
  - eGFR stable at 30-69 mL/min ≥3 months
  - CD4 ≥50 cells/mm³
  - No new AIDS conditions in past 30 days
  - No resistance to EVG, FTC, or TDF

- **Treatment Arms**
  - Switch to EVG-COBI-TAF-FTC

*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

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

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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