Switch from TDF-based to Elvitegravir-Cobicistat-TAF-FTC

Study 109
Switch to Elvitegravir-Cobicistat-TAF-FTC
Study 109: Design

Study Design: Study 109

- **Background**: Open-label, randomized study, Phase 3 trial comparing switch to EVG-COBI-TAF-FTC versus continuation of baseline regimen of TDF-based ART

- **Inclusion Criteria (n = 1443)**
  - HIV RNA < 50 copies/mL on ART for ≥ 96 weeks
  - CrCl > 50 mL/min
  - 1 of 4 baseline TDF-containing ART regimens:
    (a) EVG-COBI-TDF-FTC (n=459)
    (b) EFV-TDF-FTC (n=376)
    (c) ATV + RTV + TDF-FTC (n=385)
    (d) ATV-COBI + TDF-FTC (n=216)

- **Treatment Arms**
  - EVG-COBI-TAF-FTC (Switch group)
  - Remain on TDF-based ART (No switch group)

*NOTE*: Between randomization and start of study, 4 participants withdrew consent, 2 withdrew by investigator discretion, and 1 was lost to follow-up.

Switch to Elvitegravir-Cobicistat-TAF-FTC
Study 109: Subgroup Analysis Result

Week 48 Virologic Response, by Baseline Regimen

Switch to Elvitegravir-Cobicistat-TAF-FTC
Study 109: Result

Week 48: Changes in Bone Mineral Density (BMD)

Switch to Elvitegravir-Cobicistat-TAF-FTC
Study 109: Result

Week 48: Changes in Quantitative Proteinuria

Switch to Elvitegravir-Cobicistat-TAF-FTC
Study 109: Result

Week 48: Change in Plasma Lipids from Baseline

Switch to Elvitegravir-Cobicistat-TAF-FTC
Study 109: Conclusions

**Interpretation**: “Switching to a tenofovir alafenamide-containing regimen from one containing tenofovir disoproxil fumarate was non-inferior for maintenance of viral suppression and led to improved bone mineral density and renal function. Longer term follow-up is needed to better understand the clinical impact of these changes.”

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