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

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

- **Background**: Open-label, randomized, 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:
    - EVG-COBI-TDF-FTC (n=459)
    - EFV-TDF-FTC (n=376)
    - ATV + RTV + TDF-FTC (n=385)
    - 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 study onset, 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 from Baseline

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

Week 48: Change in Plasma Lipids from Baseline

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.”
The National HIV Curriculum is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.