Switch to BIC-TAF-FTC in Women with Virologic Suppression

GS-380-1961
Switch to BIC-TAF-FTC in Women with Virologic Suppression GS-380-1961: Design

### GS-380-1844: Study Design

- **Background:** Randomized, phase 3, multicenter, open label, active-controlled study evaluating the efficacy and safety of switching women with HIV and viral suppression to BIC-TAF-FTC versus continuing their baseline regimen.

- **Inclusion Criteria**
  - Women aged ≥18
  - HIV RNA <50 copies/mL for at least 12 weeks
  - *Taking EVG/c/TAF/FTC, EVG/c/TDF/FTC, or ATV/r + TDF/FTC*
  - eGFR >50 mL/min
  - No suspected resistance to study drugs
  - Using contraception if child-bearing potential
  - Chronic hepatitis B or C allowed

*Regimens: 53% EVG/c/TAF/FTC and 42% EVG/c/TDF/FTC

### Study Design Diagram

- **Switch Regimen**
  - Bictegravir-TAF-FTC (n = 234)

- **Maintain Regimen**
  - INSTI or PI-Based Regimen (n = 236)

Switch to BIC-TAF-FTC in Women with Virologic Suppression GS-380-1961: Results

Interpretation: “Fixed-dose combination bictegravir-emtricitabine-tenofovir alafenamide provides a safe and efficacious option for ongoing treatment of HIV in women. This study contributes important data on safety, tolerability, and outcomes of antiretroviral therapy among women living with HIV.”

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