Simplification of Antiretroviral Therapy with Efavirenz/Etravirine/Tenofovir DF Single Tablet Regimen vs. Continued Unmodified Antiretroviral Therapy in Virologically-Suppressed, HIV-1-Infected Patients

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Background / Objective

• An optimized ENF/TDF/EFV is the most dosely single-tablet antiretroviral (ARV) regimen approved in the United States, Canada, and Europe.

• This study evaluated the efficacy and tolerability of the ENF/TDF/EFV regimen in virologically-suppressed, HIV-1 infected patients whose prior antiretroviral therapy (ART) had been simplified with EFV-based ART.

Methods

• Key Inclusion / Exclusion Criteria:
  - HIV RNA < 200 copies/mL for 2 months on current ARV regimen
  - Receiving a PI-based regimen, or documented suppression on a previous PI regimen at time of prior change in therapy
  - Age and gender
  - No evidence of known resistance
  - No concurrent medications

• Statistical Methods:
  - Non-inferiority margin of 15% at 80% power
  - Per-protocol analysis

Results

• The primary endpoint of non-inferiority of ENF/TDF/EFV to SBR was demonstrated.

• ENF/TDF/EFV was well tolerated with low discontinuation rates observed in both treatment arms.

• The median (IQR) change from baseline in HDL-cholesterol at Week 48 for patients in the prior PI stratum was 5.0 (3, 7) mg/dL for ENF/TDF/EFV vs. 0 (-1, 5) mg/dL for SBR (p = 0.044); for this stratum there was also a trend toward improvement in total cholesterol/HDL ratio (p = 0.092).

Conclusions

• ENF/TDF/EFV was well tolerated with low discontinuation rates observed in both treatment arms.

• The median (IQR) change from baseline in HDL-cholesterol at Week 48 for patients in the prior PI stratum was 5.0 (3, 7) mg/dL for ENF/TDF/EFV vs. 0 (-1, 5) mg/dL for SBR (p = 0.044); for this stratum there was also a trend toward improvement in total cholesterol/HDL ratio (p = 0.092).

• The results of this study support the use of ENF/TDF/EFV as a simplified, single-tablet regimen for the management of virologically-suppressed HIV-1 infected patients.