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Poster presentation

Simplification of therapy (ART) with efavirenz/emtricitabine/tenofovir DF single tablet regimen vs. continued ART in suppressed, HIV-infected patients

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Purpose of the study

AI266073 is a 48-week, randomized, open-label, multicenter study with the primary objective of evaluating non-inferiority of simplification of ART to efavirenz/emtricitabine/tenofovir DF (EFV/FTC/TDF) vs. continuation of the same baseline regimen (SBR) unmodified.

Methods

Patients on stable ART with HIV-RNA (VL) <200 copies/mL for ≥3 months were stratified by NNRTI- or PI-based ART, and randomized (2:1) to switch to EFV/FTC/TDF or continue SBR. The primary end-point was maintenance of VL < 200 copies/mL at 48 weeks by time to loss of virologic response (TLOVR) algorithm (intent-to-treat, non-completers = failure [ITT, NC = F], Δ = 15%); efficacy was also assessed by VL <50 copies/mL (TLOVR; ITT, NC = F), pure virologic response (non-responders defined as two consecutive VL ≥50 copies/mL or one VL ≥50 copies/mL followed by study discontinuation; PVR – by Kaplan Meier); and by last observation carried forward (LOCF) analysis where early discontinuations for an adverse event (AE) were considered failures.

Summary of results

300 treated patients (EFV/FTC/TDF 203, SBR 97) were evaluated (prior PI/NNRTI 53%/47%). Treatment arms were well balanced: 88% males; 29% blacks; mean age 43 years; median baseline CD4 516 cells/mm^3; 96% had VL <50 copies/mL. (Table 1.)

At 48 weeks, EFV/FTC/TDF was found to be non-inferior to SBR. Similar virologic responses were also observed between arms when analyzed by PI and NNRTI strata and prior or no prior use of TDF. Overall discontinuation rates for EFV/FTC/TDF vs. SBR were 11% vs. 12% (AE 5% vs. 1%; withdrawal of consent 2% vs. 7%). In the EFV/FTC/TDF arm, one patient discontinued for virologic failure. Overall, more nervous system symptoms were reported for EFV/FTC/TDF vs. SBR (dizziness 11% vs. 1%, abnormal dreams 7% vs. 0%); these occurred early, were generally transient, mild, and more common with prior PI-based ART. At 48 weeks, estimated GFR (MDRD) was unchanged from baseline in both arms (median <1 mL/min/1.73 m^2; p = 0.870); a greater decline in fasting triglycerides was observed at 48 weeks with EFV/FTC/TDF vs. SBR (median -20 vs. -3 mg/dL; p = 0.035) which was more pronounced in prior PI patients.

Conclusion

High and comparable rates of virologic suppression were maintained with EFV/FTC/TDF vs. SBR, regardless of type of prior ART. The grade/frequency of AEs reported for patients switched to EFV/FTC/TDF was consistent with previous studies.

Table 1:

VL Endpoint (copies/mL)	EFV/FTC/TDF	SBR	Difference EFV/FTC/TDF – SBR (95% CI)
<200 by TLOVR	89%	88%	1.1% (-6.7%, 8.8%)
<50 by TLOVR	87%	85%	2.6% (-5.9%, 11.1%)
<50 by PVR	95%	86%	8.9% (-7.7%, 25.6%)
<50 by LOCF	94%	97%	-3.3% (-8.3%, 2.7%)