

SUPPLEMENTAL DIGITAL CONTENT

Table S1. Baseline Patient Characteristics

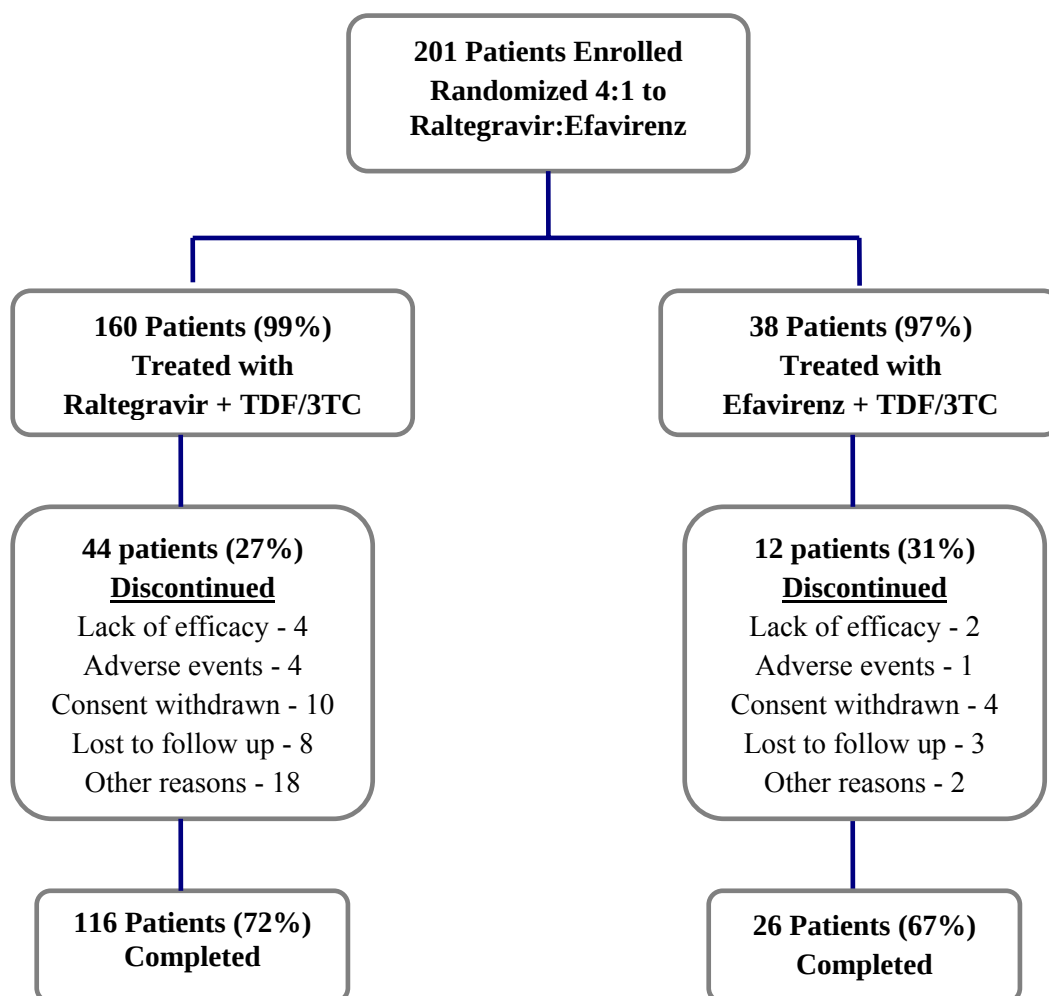
	Raltegravir (N = 160)	Efavirenz (N = 38)	Total (N = 198)
Gender, n (%)			
Male	128 (80.0)	29 (76.3)	157 (79.3)
Female	32 (20.0)	9 (23.7)	41 (20.7)
Race, n (%)			
White	49 (30.6)	12 (31.6)	61 (30.8)
Black	5 (3.1)	0 (0.0)	5 (2.5)
Asian	24 (15.0)	9 (23.7)	33 (16.7)
Hispanic American	47 (29.4)	11 (28.9)	58 (29.3)
Others	35 (21.9)	6 (15.8)	41 (20.7)
Region, n (%)			
North America	55 (34.4)	9 (23.7)	64 (32.3)
Central/South America	66 (41.3)	16 (42.1)	82 (41.4)
Asia Pacific	39 (24.4)	13 (34.2)	52 (26.3)
Age (years)			
Mean (SD)	35.9 (8.9)	35.5 (8.1)	35.8 (8.7)
Median (range)	35.0 (19 to 68)	35.0 (22 to 54)	35.0 (19 to 68)
CD4 Cell Count (cells/mm³)			
Mean (SD)	305 (168)	280 (154)	300 (165)
Median (range)	268 (70 to 1,017)	225 (77 to 744)	266 (70 to 1,017)
Plasma HIV RNA (log₁₀ copies/mL)			
Mean (SD)	4.7 (0.6)	4.8 (0.5)	4.8 (0.5)
Median (range)	4.8 (3.4 to 5.9)	4.9 (3.5 to 5.8)	4.8 (3.4 to 5.9)
History of AIDS, n (%)			
Yes	55 (34.4)	14 (36.8)	69 (34.8)
Viral Subtype[†], n (%)			
Clade B	137 (85.6)	29 (76.3)	166 (83.8)
non-Clade B	23 (14.4)	8 (21.1)	31 (15.7)
Plasma HIV RNA, n (%)			
≤ 50,000 copies/mL	73 (45.6)	13 (34.2)	86 (43.4)
> 50,000 copies/mL	87 (54.4)	25 (65.8)	112 (56.6)
≤ 100,000 copies/mL	107 (66.9)	24 (63.2)	131 (66.2)
> 100,000 copies/mL	53 (33.1)	14 (36.8)	67 (33.8)
CD4 Cell Counts, n (%)			
≤ 200 cells/mm ³	43 (26.9)	14 (36.8)	57 (28.8)
> 200 cells/mm ³	117 (73.1)	24 (63.2)	141 (71.2)

[†] Viral subtype missing for 1 patient in the efavirenz group.

SUPPLEMENTAL DIGITAL CONTENT

Figure S1. Patient Accounting

CONSORT diagram showing patient disposition through Study Week 240. A total of 3 randomized patients (2 in the raltegravir arm and 1 in the efavirenz arm) never received study drugs.



SUPPLEMENTAL DIGITAL CONTENT

Table S2. Efficacy Outcomes at Week 240, by Baseline Viral Load and Overall

Treatment	Baseline HIV RNA				Total	
	≤100,000 copies/mL		>100,000 copies/mL			
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)
Percent of patients with HIV RNA<400 copies/mL						
Raltegravir	107	72.9 (63.4, 81.0)	53	69.8 (55.7, 81.7)	160	71.9 (64.2, 78.7)
Efavirenz	24	70.8 (48.9, 87.4)	14	57.1 (28.9, 82.3)	38	65.8 (48.6, 80.4)
Difference between groups						5.6 (-10.0, 23.0)
Percent of patients with HIV RNA <50 copies/mL						
Raltegravir	107	70.1 (60.5, 78.6)	53	66.0 (51.7, 78.5)	160	68.8 (61.0, 75.8)
Efavirenz	24	70.8 (48.9, 87.4)	14	50.0 (23.0, 77.0)	38	63.2 (46.0, 78.2)
Difference between groups						6.1 (-9.1, 23.4)
Change from baseline in CD4 cell count (cells/mm³)						
Raltegravir	82	296 (253, 338)	41	314 (257, 371)	123	302 (268, 336)
Efavirenz	20	293 (206, 380)	11	244 (131, 357)	31	276 (210, 341)
Difference between groups						26 (-47, 99)

† Approach to handling missing values: For percentage of virologic responses, patients who discontinued assigned therapy, regardless of reasons, were considered as failures (NC=F);

For change from baseline in HIV RNA and CD4 cell counts, baseline value was carried forward for patients who discontinued assigned therapy due to lack of efficacy.

SUPPLEMENTAL DIGITAL CONTENT

Table S3. Treatment Emergent Mutations in Patients with Virologic Failure[†]

Treatment Group	Treatment Emergent Mutations			
	Raltegravir	Lamivudine	Tenofovir	Efavirenz
Raltegravir	N155H, V151I, L74M, L74M/L	K65K/R , M184M/I/V	K65K/R	None
	N155H	M184M/I/V	None	None
	S230R , Y143C	M184M/I/V	None	None
	None	M184V	None	None
	None	None	None	None
	None	None	None	None
	None	None	None	None
	None	None	None	None
	Not Tested [‡]	None	None	None
	Not Tested [‡]	None	None	None
Efavirenz	None	K65R	K65R	None
	None	K219Q , M184V	K219Q	K103K/N, Y188Y/H, Y188L
	None	None	None	Y188Y/H
	Not Tested [‡]	None	None	None
	Not Tested [‡]	None	None	None

[†] virologic failure (confirmed plasma HIV-1 RNA >50 copies/mL) or virologic relapse, defined as two consecutive measurements (at least one week apart) of (1) plasma HIV-1 RNA >50 copies/mL after initial response with plasma HIV-1 RNA <50 copies/mL, or (2) >1.0 log₁₀ increase in plasma HIV-1 RNA above the nadir level. Note: the threshold for inadequate suppression in the above definition was HIV-1 RNA >400 copies/mL prior to Week 144.

[‡] Patient did not have sufficient virus for amplification.

SUPPLEMENTAL DIGITAL CONTENT

Figure S2. Mean Change from Baseline in Serum Lipid Concentrations (mg/dL) Over Time

