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The 10 year safety and efficacy of tenofovir disoproxil fumarate (TDF)-containing once-daily highly active antiretroviral therapy (HAART)

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Background

Study 903 was a Phase III randomized double-blind (DB) 3 year study comparing TDF to stavudine (d4T) each in combination with lamivudine (3TC) and efavirenz (EFV) in HIV-1 infected antiretroviral naïve patients. TDF was associated with durable efficacy and safety (better lipid profile, and less lipodystrophy and peripheral neuropathy). A subset of these patients now provides 10 years of longitudinal efficacy and safety data of TDF-containing once-daily HAART.

Methods

Subjects in Argentina, Brazil, and the Dominican Republic who completed the 3 year DB period of study were eligible to roll-over into an open-label (OL) study (Study 903E) of the once-daily HAART regimen, TDF+3TC +EFV. At DB baseline 86 subjects were randomized to TDF (62% male, 70% white, mean age 33 yrs, mean HIV RNA=4.9 $\log_{10}$ c/mL, and mean CD4 count=299 cells/mm^3). At OL baseline, 85 subjects (60% male, 64% white, mean age 37 yrs, median CD4=621 cells/mm^3)

Table 1

	TDF/TDF$^{\alpha}$ (n=86)	D4T/TDF$^{\alpha}$ (n=85)
Weeks on HAART/TDF	480/480	480/336
HIV RNA < 50 (copies/mL) at Week 480 (ITT, M=F)	63%	64%
HIV RNA < 50 (copies/mL) at Week 480 (ITT, M=E)	92%	96%
Change in Mean (SD) CD4, cells/mm^3	545 (287)	180 (290)
Drug-related Adverse Events (Grades 1-4)	66%	46%
Change in Mean (SD) Creatinine Clearance, mL/min$^{\beta}$	+2.5 (23.4)	-10.7 (22.6)
Median Limb Fat at Year 10, kg	10.4	7.5
Percent Change in Mean (SD) Spine BMD$^{\chi}$	-2.44 (5.08)$^{\delta}$	0.04 (4.72)
Percent Change in Mean (SD) Hip BMD	-2.94 (4.95)$^{\delta}$	-1.86 (4.67)$^{\delta}$
Discontinuations during open-label extension	25 (29.1%)	19 (22.4%)
Adverse event	2 (2.3%)	2 (2.4%)
Suboptimal virologic response	5 (5.8%)	1 (1.2%)
LTFU$^{\varepsilon}$, Nonadherent, Pregnancy, Consent Withdrawn, Death	13 (15.1%)	9 (10.6%)
Other	5 (5.8%)	7 (8.2%)

$^{\alpha}$TDF/TDF results measured from DB BL; d4T/TDF from OL baseline; $^{\beta}$Estimated by Cockcroft-Gault equation; $^{\chi}$Bone mineral density; $^{\delta}$p<0.01 by Wilcoxon Signed Rank Test; $^{\varepsilon}$Lost to follow-up

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switched from d4T to TDF. The results reflect only the period of TDF exposure.

Results

See Table 1

Conclusions

Antiretroviral-naïve subjects who received TDF-containing once-daily HAART for up to 10 years demonstrated sustained virologic and immunologic benefit, improved limb fat, stable renal function, and their BMD remained stable after a clinically insignificant decrease that occurred during the first year of TDF therapy.

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