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Poster presentation

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The safety and efficacy of tenofovir DF in combination with lamivudine and efavirenz in antiretroviral-naïve patients through 7 years

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Purpose of the study

Study 903 is a Phase III trial with a 3-year, double-blind phase comparing tenofovir DF (TDF) to stavudine in combination with lamivudine (3TC) and efavirenz (EFV). In the study, TDF was associated with durable efficacy, better lipid profiles and less lipodystrophy. Study 903E is the ongoing open-label (OL) extension evaluating up to 10-year safety and efficacy of a once-daily TDF+3TC+EFV regimen.

Methods

All patients in Argentina, Brazil, and the Dominican Republic who completed the double-blind (DB) phase were eligible to roll over to Study 903E and receive a once-daily regimen of open-label TDF+3TC+EFV.

Summary of results

86 patients (62% male, 70% white, mean age 33 yrs) originally randomized to TDF continued treatment in the OL extension. At DB baseline (BL), mean HIV-RNA = 4.9 $\log_{10}$ c/mL and mean CD4 count = 299 cells/mm^3. At year 7, 81% (M = F) had HIV-RNA <400 c/mL and 80% (M = F) had HIV-RNA<50 c/mL; mean CD4 cell increase from BL = 459 cells/mm^3. One patient discontinued study due to adverse event (elevated amylase/lipase) and four due to virologic failure. No patient developed K65R mutation. No patient discontinued due to renal adverse events. Mean change from BL in glomerular filtration rate (GFR) by Cockcroft-Gault was +1 mL/min. Decreases in spine and hip bone mineral density (BMD) by dual energy x-ray absorptiometry were seen in the first year and remained stable (mean % change from BL at year 7 in BMD was -1.5% in spine and -2.6% in hip). No patient sustained pathologic fractures. Median limb fat was 6.7 kg at year 2 and increased to 8.0 kg at year 7.

Conclusion

Through 7 years of therapy, the once-daily regimen of TDF+3TC+EFV demonstrated sustained antiretroviral activity with continued immunologic recovery in antiretroviral-naïve patients and was not associated with limb fat loss or progressive bone loss, nor was it associated with declines in estimated GFR.