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Poster presentation

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A Phase IIIb pilot study substituting darunavir/ritonavir (DRV/r) and etravirine (ETR) for enfuvirtide (ENF) and current PI in a suppressive regimen

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Purpose of the study

Early clinical experience with DRV/r plus ETR in several small pharmacokinetic and efficacy studies, as well as the ongoing DUET trials, demonstrated antiretroviral (ARV) activity and tolerability in treatment-experienced patients (pts). ENF has shown activity in treatment-experienced pts but requires twice daily subcutaneous injections, commonly leading to dosing fatigue and injection site reactions. This ongoing 48-week pilot study evaluates the efficacy and tolerability of the combination of DRV/r and ETR when substituted for ENF and current PI (and NNRTI, if applicable) in a virologically suppressive regimen. We report efficacy, safety and tolerability of the DRV/r and ETR-containing regimen at week 24.

Methods

Eligible HIV-infected adults were on a PI-based regimen including ENF, had viral load (VL) ≤400 copies/mL for at least 6 months, and had a history of 3-class drug resistance or ARV failure. Pts declined to continue ENF or had physicians' recommendation to discontinue. At study entry, all pts discontinued ENF, PI(s) and NNRTI(s), if applicable (NRTIs were continued) and substituted DRV/r 600/100 mg BID plus ETR 200 mg BID. Primary end-point: proportion of pts maintaining VL ≤400 copies/mL at 24 and 48 weeks. Virologic response, CD4 count, and lab values are reported as missing equals failure, last observation carried forward, and observed, respectively.

Summary of results

Target enrollment (40 pts) was not reached due to shortage of eligible pts. Ten male pts enrolled: median age 48 yrs; six Caucasian and four Hispanic; all baseline (BL) VL <50 copies/mL; median BL CD4 301 cells/mm^3. One pt discontinued due to dizziness (doubtfully-related) at week 8. All nine pts completing week 24 maintained VL <50 copies/mL. Median increase in CD4 count was 17 cells/mm^3. Most common treatment-related AEs were fatigue (n = 4), rash (n = 3), headache (n = 3) and diarrhea (n = 3). One serious AE (cholecystitis; doubtfully-related) and two grade 3/4 AEs (nausea and weight loss; not related) were reported. Median changes (min;max) in mg/dL from baseline to week 24 for triglycerides, total cholesterol (TC), HDL, LDL and TC/HDL ratio were -13(-228;118), -15(-31;60), -2(-15;17), -7(-27;6) and 0(-1.16;1.20), respectively.

Conclusion

In this study, following substitution of DRV/r and ETR for ENF, PI(s) and NNRTI(s), 9/9 previously suppressed pts who completed week 24 maintained VL <50 copies/mL. DRV/r and ETR were generally safe and well tolerated.