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Poster presentation

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Antiretroviral treatment use and HIV-RNA suppression rates for 877 European patients in the etravirine expanded access programme

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Background

The next generation NNRTI etravirine (ETR, TMC125) has shown strong and durable efficacy in the DUET trials in combination with a background regimen of darunavir/r, NRTIs and optional enfuvirtide. The expanded access programme included a wider range of background regimens (BR).

Methods

The TMC125-C214 trial (etravirine expanded access programme) included patients with triple class experience (NRTI, PI, NNRTI) and who were unable to use currently approved NNRTIs owing to either intolerance or drug resistance. Patients were recruited from ten countries in Europe and received etravirine 200 mg BID with a range of background antiretrovirals.

Summary of results

By 31st May 2008, there were 877 European patients with data available: 21% were female, 87% were Caucasian, with a mean age of 46 years. The baseline mean CD4 count was 278 cells/uL (range 0–1647) with baseline mean HIV-RNA 5248 copies/mL (range 40 – 3,263,277). 667/882 (76%) patients used at least one PI, of which 606 (91%) used DRV/r. 251/882 (28.5%) patients did not use NRTIs in the background regimen. Of the 631 patients using NRTIs, the most common were tenofovir (69%), 3TC or FTC (91%), ZDV (20%) and ABC (18%). Other antiretrovirals used included raltegravir (54%) and maraviroc (14%). The percentage of patients with HIV-RNA <50 copies/mL was 13% at week 4, 48% at week 12 and 67% at week 24 (observed data analysis). CD4 counts rose by mean 75 cells/uL at week 12 and by 89 cells/uL at week 24. There were 131 serious adverse events (SAE's) recorded, of which 117 (89%) were judged to be not related to etravirine or doubtful causality. There were 14 SAE's judged to be at least possibly related to etravirine. Of these, there were five (0.6%) cases of rash (ETR permanently stopped in 4/5 cases), one elevation of ALT levels (0.1%) (ETR dose not changed) and one case of cholestatic acute hepatitis (0.1%) (ETR dose not changed).

Conclusion

The use of etravirine in the expanded access programme included a wide range of antiretrovirals in the background regimen, with a high percentage of patients showing HIV-RNA suppression below 50 copies/mL by weeks 12–24. Serious adverse events were mainly unrelated to ETR.