Antiretroviral treatment use and HIV RNA suppression rates for 941 European patients in the etravirine early 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 (BR) of darunavir with low-dose ritonavir (DRV/r), NNRTIs and optional enfuvirtide (ENF). The early access programme included patients with triple-class experience (NNRTI, protease inhibitor [PI], NNRTI) and who were unable to use currently approved NNRTIs owing to either intolerance or drug resistance. Patients were recruited from 10 countries in Europe. Patients received ETR 200mg bid with a range of background antiretrovirals (ARVs).

Methods

- The TMC125-C214 trial (ETR early access programme) included patients with triple-class experience (NNRTI, protease inhibitor [PI], NNRTI) and who were unable to use currently approved NNRTIs owing to either intolerance or drug resistance.
- Within this global性 across programmes, patients were randomized to 10 countries in Europe. Patients received ETR 200mg bid with a range of background ARVs.

Results

- ETR has been used with a wide range of ARVs in the early access programme in Europe.
- In the overall cohort (N=941), the per cent of patients with HIV RNA <50 copies/mL increased from 15% at baseline to 74% at Week 24 (observed data).
- In a pre-planned substudy, the cohort of 176 patients who took ETR, DRV/r and enfuvirtide showed strong efficacy – 93% had HIV RNA levels below 400 copies/mL by Week 24, with 70% showing HIV RNA <50 copies/mL at this time.

Conclusions

- ETR has been used with a wide range of ARVs in the early access programme in Europe.
- In the overall cohort (N=941), the per cent of patients with HIV RNA <50 copies/mL increased from 15% at baseline to 74% at Week 24 (observed data).
- In a pre-planned substudy, the cohort of 176 patients who took ETR, DRV/r and enfuvirtide showed strong efficacy – 93% had HIV RNA levels below 400 copies/mL by Week 24, with 70% showing HIV RNA <50 copies/mL at this time.

- It is difficult to reliably evaluate efficacy by use of different ARVs in the early access cohort, since baseline drug resistance data is not available and there is minimal data collection in this very diverse patient population.

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Abstract

The next-generation NNRTI etravirine (ETR; TMC125) has shown strong and durable efficacy in the DUET trials in combination with a background regimen (BR) of darunavir with low-dose ritonavir (DRV/r), NNRTIs and optional enfuvirtide (ENF). The early access programme included patients with triple-class experience (NNRTI, protease inhibitor [PI], NNRTI) and who were unable to use currently approved NNRTIs owing to either intolerance or drug resistance. Patients were recruited from 10 countries in Europe. Patients received ETR 200mg bid with a range of background antiretrovirals (ARVs).

By 2 May 2008, there were 941 European patients with data available: 21% were female, 87% were Caucasian, with a mean age of 46 years. The baseline mean CD4 cell count was 299 cells/μL (range 0–1,647) with baseline mean HIV RNA 4,677 copies/mL (range 40–3,263,277). Overall, 69.8% used DRV/r. 70.6% patients used NNRTIs in the BR. Of the 664 patients using NNRTIs, the most common were tenofovir (70%), lamivudine or emtricitabine (91%), zidovudine (20%) and abacavir (18%). Other ARVs used included raltegravir (54%) and maraviroc (15%). The percentage of patients using NRTIs, the most common were tenofovir (70%), lamivudine or emtricitabine (91%), zidovudine (20%) and abacavir (18%). Other ARVs used included raltegravir (54%) and maraviroc (15%). The percentage of patients with HIV RNA <50 copies/mL was 51% at Week 4, 70% at Week 24 (observed data). CD4 cell counts rose by mean 79 cells/μL at Week 12 and by 101 cells/μL at Week 24. There were 131 serious adverse events (SAEs) recorded, of which 118 (89%) were judged to be at least possibly related to ETR. Of these, there were five (0.6%) cases of rash (ETR permanently stopped for four of the cases), one judgment to be not related to ETR or doubtful causality. There were 13 SAEs judged to be not related to ETR.

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