Switching from enfuvirtide to etravirine – efficacy results from the etravirine early access programme

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Abstract

The next-generation NNRTI etravirine (ETR; TMC125) and the fusion inhibitor enfuvirtide (ENF) have shown strong efficacy in the DUET and TORO trials, respectively. Switching from ENF to ETR could improve convenience and tolerability, and reduce treatment costs. In the TMC125-C214 trial (global ETR expanded access programme), treatment-experienced patients with undetectable HIV RNA levels were permitted to switch from ENF to ETR.

Patients who switched from ENF to ETR, with screening HIV RNA <50 copies/mL, were followed up for 24 weeks. Data were analysed for patients in Europe and Canada. Patients could optimise other parts of the background regimen (BR) at the time of switch from ENF to ETR.

Overall, there were 37 patients switching from ENF to ETR in Europe (n=22) and Canada (n=15). Of these, 11% were female, 95% were Caucasian, with a mean age of 48 years. The baseline median CD4 cell count was 380 cells/μL (95% confidence interval [CI]: 312–449). Within this study, 36 of the 37 patients (97%) used darunavir with low-dose ritonavir (DRV/r) in the BR, with raltegravir used in 62%, maraviroc in 16%, and NRTIs for 89%. The percentage of patients with HIV RNA suppressed below 50 copies/mL was 83% at Week 4, 86% at Week 12 and 95% at Week 24. Of those with HIV RNA <50 copies/mL at Week 12, there were five HIV RNA levels just over the detection limit (50, 52, 56, 58 and 217 copies/mL). One additional patient had HIV RNA >50 copies/mL at screening, but <50 copies/mL at baseline. This patient had HIV RNA of 0.071 at Week 12 and 4.730 at Week 24, before changing treatment. This patient is not included in the analysis, because the screening HIV RNA was above 50 copies/mL.

Methods

• Patients who switched from ENF to ETR, with HIV RNA <50 copies/mL at screening, were followed up for 24 weeks
• Patients could optimise other parts of the BR at the time of switch from ENF to ETR

This analysis includes 37 patients with HIV RNA <50 copies/mL at screening, and HIV RNA data is at least Week 12, in Europe and Canada.

There were no treatment discontinuations for AEs

HIV RNA results

• All Week 12, 32/37 (86%) patients had HIV RNA <50 copies/mL, the five patients with HIV RNA >50 copies/mL had values of 52, 52, 56, 58 and 217 copies/mL
• All Week 24, 35/37 (95%) patients had HIV RNA <50 copies/mL, one patient had missing data, and one patient had HIV RNA 50 copies/mL

Other ARVs used with ETR

Other ARVs used with ETR

Conclusions

• In the early access programme in Europe and Canada, 37 patients with HIV RNA <50 copies/mL at screening switched from ENF to ETR. These patients also used DRV/r (n=36), raltegravir (n=23), maraviroc (n=6) and NRTIs (n=33)
• In the observed data analysis, HIV RNA was <50 copies/mL for 32/37 (86%) patients at Week 12, 35/37 (95%) patients at Week 24. CD4 cell counts remained stable during follow-up
• ETR may be an effective substitute for injectable ENF, for reasons of intolerance or patient preference. Further investigation of this approach is warranted

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