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Poster presentation

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Reduction in AIDS defining events/deaths with etravirine (ETR; TMC125) compared to placebo: pooled DUET 48-week results

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Purpose of the study

The benefit of newer antiretroviral regimens on clinical end-points for treatment-experienced, HIV-1-infected patients remains to be determined. Etravirine (ETR) demonstrated durable efficacy and safety in HIV-1 infected, treatment-experienced patients in the phase III DUET trials. We report adjudicated clinical end-points from a pre-specified pooled analysis of DUET-1 and DUET-2 after 48 weeks of treatment.

Methods

Patients were randomised 1:1 to receive either ETR 200 mg BID or placebo, both in combination with a background regimen of darunavir/r, investigator-selected nucleoside reverse transcriptase inhibitors and optional enfuvirtide (ENF). AIDS-defining events/deaths (ADE/D) were adjudicated by a 4-member independent panel masked to treatment assignment. All events were adjudicated, and only those confirmed or probable ADE/D were included in the analysis. Pre-specified analyses were stratified by *de novo* or not *de novo* (including recycled ENF or ENF not used) ENF use.

Summary of results

599 and 604 patients received ETR and placebo, with median treatment duration of 52.3 vs 51.0 weeks, respectively. At baseline, median CD4 cell count was 105 cells/mm^3, $\log_{10}$ HIV-RNA was 4.8 and 59% had clinical CDC C classification. Overall, 35 ETR patients (5.8%) and 59 placebo patients (9.8%) had an ADE/D (p = 0.041). In total, 22 ADE/D occurred in the first 30 days (six in the ETR group, 16 in the placebo group). Time to ADE/D was significantly shorter for patients in the placebo group compared with ETR (Figure 1). The most common ADEs were *Candida* esophagitis (one ETR, 10 placebo), *Pneumocystis* pneumonia (three ETR, six placebo), *Mycobacterium avium* complex (two ETR, seven placebo), herpes simplex virus (four ETR, four placebo), cytomegalovirus retinitis (one ETR, six placebo) and Kaposi's sarcoma (two ETR, four placebo). In the *de novo* ENF sub-group (ETR n = 153; placebo n = 159), events were similar, with an ADE/D reported for 11 patients in the ETR group (7.2%) and 14 patients in the placebo group (8.8%). However, in those not receiving *de novo* ENF (ETR n = 446; placebo n = 445), more events among patients in the placebo group were reported than among those in the ETR group (45 patients [10.1%] vs. 24 patients [5.4%]; p = 0.0086).

Conclusion

In addition to virological and immunological benefits, use of ETR was associated with a reduction in ADE/D and a significantly longer time to ADE/D than placebo in treatment-experienced, HIV-1-infected patients.

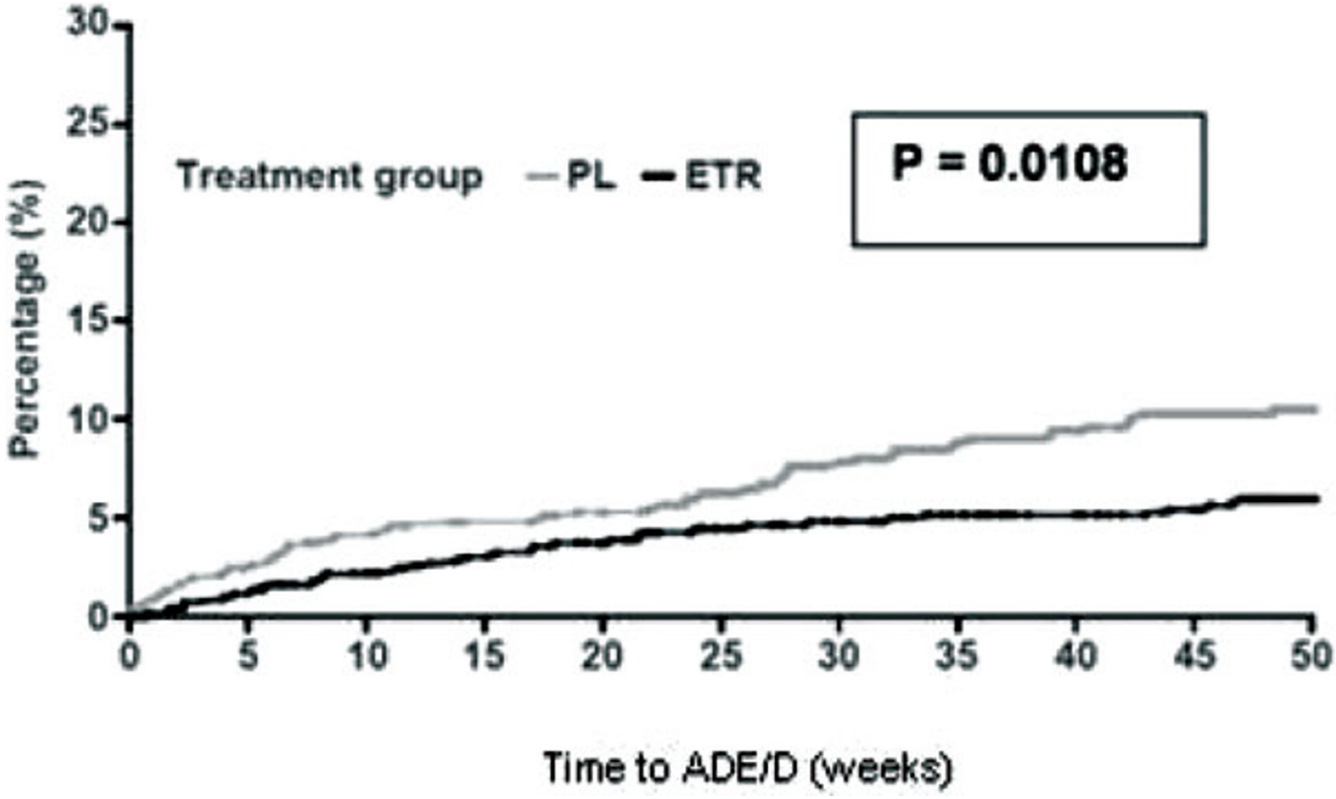

Figure 1