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Virological response with fully active etravirine (ETR; TMC125) after 48 weeks of treatment: pooled results from the DUET-1 and DUET-2 trials

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Background

The NNRTI etravirine (ETR; TMC125) has demonstrated durable antiviral activity and favourable tolerability in treatment-experienced patients in the Phase III DUET trials. We report week 48 virological response in the subgroup of patients who were fully sensitive to ETR, analysed according to enfuvirtide (ENF) use and number of active background agents.

Methods

HIV-1-infected, treatment-experienced patients with documented NNRTI-resistance, ≥3 primary PI mutations and viral load (VL) >5000 copies/mL were randomised 1:1 to receive ETR 200 mg BID or placebo following a meal plus a background regimen (BR) of darunavir/ritonavir, NRTI(s) and optional ENF. The current analysis included all patients who were fully sensitive to ETR. Phenotypic Sensitivity Score (PSS; Antivirogram®) was used to determine the number of active background agents; ETR was considered active if the fold change in EC50 (FC) was ≤3; darunavir if FC ≤10; NRTIs if FC was < cut-off defined on Antivirogram® and ENF if used de novo. The pooled analysis was pre-specified.

Summary of Results

In total, 599 and 604 patients received ETR + BR and placebo + BR, respectively. Baseline demographics and characteristics were similar between treatment groups, with a median VL of 4.8 $\log_{10}$ copies/mL in both treatment groups and CD4 cell counts of 99 vs. 109 cells/mm^3 in the ETR group and placebo groups, respectively. After 48 weeks of treatment, 61% of patients receiving ETR + BR in the overall population achieved a confirmed virological response (<50 copies/mL) vs. 40% in the placebo group ($p < 0.0001$). Virological response by PSS (0, 1 and ≥2 active antiretrovirals [ARVs]) in patients fully sensitive to ETR according to ENF use (de novo or not de novo) is presented in the table in Figure 1. In the overall and the ENF not de-novo subgroups, virological response increased with increasing number of active agents in the BR. The difference between the treatment groups was most apparent in patients who had no active background agents.

Conclusion

In patients with virus fully sensitive to ETR, the virological response was higher in the ETR + BR group than in the placebo + BR group, irrespective of ENF use or number of active background agents. These results complement current guidelines, which recommend a minimum of two active agents in any treatment regimen.

Number of fully active background ARVs*	VL <50 copies/mL at Week 48, % (n)		
	ETR + BR	Placebo + BR	p
Overall	**n=355**	**n=357**	
0	56 (31/55)§	8 (4/51)	<0.0001
1	71 (93/131)	37 (47/127)	<0.0001
≥2	82 (139/169)	68 (122/179)	0.0004
ENF *de novo*	**n=88**	**n=95**	
1	91 (21/23)	41 (9/22)	<0.0001
≥2	83 (54/65)	71 (52/73)	0.0867
Not de novo ENF†	**n=267**	**n=262**	
0	56 (31/55)	8 (4/51)	<0.0001
1	67 (72/108)	36 (38/105)	<0.0001
≥2	82 (85/104)	66 (70/106)	0.0011

*Excluding ETR; §values in parenthesis are number of patients with 0, 1 or ≥2 ARVs with an undetectable VL over the total number of patients in each ARV category. †Includes patients re-using or not using ENF.

Figure 1