

12th Annual Conference of the British HIV Association



29 March–1 April 2006, Brighton, UK

RELATIVE ANTIVIRAL EFFICACY OF TMC-114/R AND TIPRANA VIR/R VERSUS CONTROL PI IN THE POWER AND RESIST TRIALS

HIV Med 2006; 7(Suppl. 1):11 (abstract no. P1)

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AIMS: To compare the relative antiviral efficacy of TMC-114 with low-dose ritonavir (TMC-114/r) and tipranavir (TPV/r) versus control PI (CPI) in treatment- experienced patients, using data from POWER 1/2 and RESIST 1/2 trials. The four trials all recruited antiretroviral (ARV)-experienced patients with HIV RNA >1000 copies/ml and at least one primary PI mutation, used optimised RTIs with or without enfuvirtide (ENF), plus investigator-selected CPI in the control arms, and had the same primary efficacy endpoint.

METHODS: Summary statistics were obtained from published presentations and drug labels. For the POWER trials, data from the 600/100 mg bid dose and CPI arms was included, while all data from the RESIST trials (TPV/r 500/200 mg bid and CPI) were included. The difference in week 24 efficacy for the new PI versus CPI was compared between the trials. All analyses used intent-to-treat TLOVR methods.

RESULTS: Overall baseline characteristics (age, gender, race, HIV RNA, IASUSA PI mutations) were well matched across the trials. At week 24, 72% of TMC-114/r patients achieved a ≥ 1 log₁₀ reduction in HIV RNA compared to 40% of TPV/r patients (CPI patients 21% and 18%, respectively). The treatment benefit of TMC-114/r over CPI in the POWER trials was greater (outside the 95% confidence intervals) than the benefit of TPV/r over CPI in the RESIST trials, for the 24-week HIV RNA endpoints of 1 log reduction, <400 copies and <50 copies/ml, plus for mean rise in CD4 count. This effect was also found for the subgroups of ENF-naïve patients and patients not using ENF.

CONCLUSION: Given the caveats of cross-study analysis, the efficacy benefits of TMC-114/r versus CPI in the POWER trials appear to be greater than the benefits of TPV/r versus CPI in the RESIST trials for HIV RNA suppression and CD4 rises.

2006-03-29
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