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POWER 1 and 2: combined final 144-week efficacy and safety results for darunavir/ritonavir (DRV/r) 600/100 mg BID in treatment-experienced HIV patients

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Background

POWER 1 and 2 (TMC114-C213 and C202) are randomised, controlled, Phase IIb trials designed to evaluate the long-term efficacy and safety of darunavir co-administered with low-dose ritonavir (DRV/r) in comparison with control protease inhibitor (CPIs) in treatment-experienced HIV patients. This combined analysis evaluates the final 144-week efficacy, safety and tolerability results for DRV/r 600/100 mg BID.

Methods

Patients had documented HIV-1 infection, with ≥1 primary PI mutation and HIV-RNA >1,000 copies/mL at baseline. The analysis included patients in POWER 1 and 2 randomised to receive DRV/r 600/100 mg BID or CPI(s), plus an optimised background regimen (OBR; NRTIs ± enfuvirtide). The primary efficacy end-point was the proportion of patients with ≥1 $\log_{10}$ HIV-RNA reduction at week 144 from baseline (time-to-loss of virological response [TLOVR] algorithm) in the intent-to-treat (ITT) population.

Summary of results

There were 513 patients in the DRV/r group (of whom 131 received DRV/r 600/100 mg BID) and 124 patients in the CPI group. Baseline data for the DRV/r 600/100 mg BID group were: 89% male, 81% Caucasian, mean age 44 years, mean duration of infection 12 years, mean $\log_{10}$ HIV-RNA 4.6 copies/mL, median CD4 cell count 153 cells/mm^3, 36% CDC category C, median primary PI mutations 3. More than 90% of patients had previously used ≥4 NRTIs, ≥1 NNRTI or ≥2 PIs. All patients had reached week 144 or discontinued earlier (discontinuations: DRV/r 600/100 mg BID n = 49 [37%]; CPI n = 108 [87%]). At week 144, 48 (37%) patients in the DRV/r 600/100 mg BID group and 11 (9%) patients in the CPI group achieved HIV-RNA <50 copies/mL ($p < 0.001$; ITT-TLOVR). A ≥1 $\log_{10}$ HIV-RNA reduction was achieved by 67 (51%) patients in the DRV/r 600/100 mg BID group and 12 (10%) patients in the CPI group ($p < 0.001$; ITT-TLOVR). The median CD4 cell count increased from baseline by 97 cells/mm^3 in the DRV/r 600/100 mg BID group and 4 cells/mm^3 in the CPI group ($p < 0.001$; last observation carried forward analysis). The most common treatment-emergent adverse events from week 24 onwards in patients receiving DRV/r 600/100 mg BID over a median exposure of 120 weeks were diarrhoea (16%), nasopharyngitis (14%), sinusitis (13%) and bronchitis (13%). Most adverse events were grade 1 or 2.

Conclusion

Combined final efficacy and safety results for POWER 1 and 2 confirm that DRV/r 600/100 mg BID has long-term

efficacy and is a well-tolerated treatment option in treatment-experienced patients.

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