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## POWER 3 TRIAL: 24-WEEK EFFICACY AND SAFETY RESULTS OF TMC-114/R IN TREATMENT-EXPERIENCED HIV PATIENTS

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**OBJECTIVES:** In the POWER 1 and 2 (TMC-114–C213 and C202) studies, TMC-114 with low-dose ritonavir (TMC-114/r) provided a sustained efficacy compared to control. The efficacy and safety of the selected dose for treatment-experienced HIV patients, 600/100 mg bid, were further investigated in the nonrandomised, open-label TMC-114–C215 trial of POWER 3.

**METHODS:** Study inclusion/exclusion criteria were the same as for POWER 1 and 2. Patients received TMC-114/r 600/100 mg bid plus an optimised background regimen based on screening, resistance testing and treatment history. Analysis was intent-to-treat (TLOVR algorithm).

**RESULTS:** In total, 303 patients were enrolled; 235 reached week 24 and are included in this analysis. Median baseline characteristics were similar to those of POWER 1 and 2: viral load was 4.6 log<sub>10</sub> copies/ml and CD4 count was 116 cells/μl. HIV RNA <50 copies/ml and a reduction in HIV RNA of ≥1 log<sub>10</sub> copies/ml were achieved by 40% and 66% of patients, respectively. Baseline TMC-114 fold change was the strongest predictor of virological response. CD4 counts rose by a mean of 82 cells/μl. The most common AEs were diarrhoea (14%) and nausea (10%). Grade 3/4 triglyceride, cholesterol, ALT and AST elevations occurred in 5.5%, 4%, 2.4% and 1.8% of patients, respectively. Individual grade 3/4 AEs occurred in ≤4% of patients; 8 (2%) discontinued due to AEs. Serious AEs occurred in 13% of patients but no individual SAE occurred in (1% patients). The six deaths (2%) were not treatment-related.

**CONCLUSION:** POWER 3 efficacy and safety results confirm and extend those observed in POWER 1 and 2. TMC-114/r 600/100 mg bid provided patients with a substantial reduction in viral load and an increase in CD4 counts, and was generally safe and well-tolerated.

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