Cohen C, TMC114 (darunavir) is a novel PI, which is highly active against both wild-type HIV-1 strains.

Study inclusion/exclusion criteria were the same as for POWER 1 and 2. This analysis included patients who initiated treatment with TMC114/r 600/100mg bid plus 1000 mg/r 200/50mg bid for 28 days. Baseline (BL) characteristics were similar to those of POWER 1 and 2; 711 patients were evaluated. The mean HIV RNA was 4.6 log copies/mL, and median CD4 count was 115 cells/mm$^3$. For all patients who initiated treatment with TMC114/r 600/100mg bid, there was a pronounced decrease in triglycerides at Week 24 for patients with a substantial 15% reduction and CD4 cell increase, and was generally safe and well tolerated.

Conclusions: POWER 3 efficacy and safety results confirm and extend those observed in POWER 1 and 2 in a large population of treatment-experienced patients (OBR; 90% of whom were not naive), on an integrated 24-week analysis (POWER 3) was performed from two non-randomized, open-label trials (TMC114-C210, TMC114-C211). The overall incidence of 54% was 13%, no individual 54% occurred in >7 patients. All 54% reported during POWER 3 occurred in naive patients, with the majority of patients who had not received 54% treatment (50%); no serious AEs (SAEs) occurred in any patient.

References

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Table 1. BL characteristics for patients initiating TMC114/400/100mg bid treatment in POWER 1, 2 and 3.

Table 2. HIV RNA response rates (defined as HIV RNA <50 copies/mL) by BL characteristics at Week 24 of POWER 3.

Table 3. ACTG grade 3 or 4 laboratory abnormalities reported with an incidence of ≥2% in TMC114 patients (n=207) regardless of causality in POWER 3.

Table 4. Mean response (squares), geometric mean (g), and 95% confidence intervals (CI).

Table 5. Grade 3 or 4 laboratory parameters.

Table 6. Grade 3 or 4 AEs or laboratory abnormalities reported with an incidence ≥1% in 207 patients initiating TMC114/400/100mg bid treatment in POWER 3 (n=207) regardless of causality.

Table 7. No serious AEs (SAEs) occurred in any patient.

Table 8. Mean changes in lipid laboratory parameters between BL and Week 24 were small, with no significant differences in any lipid parameter observed between these two subgroups of patients.