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POWER 3 analysis: 144-week efficacy and safety results for darunavir/ritonavir (DRV/r) 600/100 mg BID in treatment-experienced HIV patients

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Purpose of the Study

The POWER 3 analysis is based on a non-randomised, open-label study (TMC114-C215) investigating the long-term efficacy and safety of the protease inhibitor (PI) darunavir co-administered with low-dose ritonavir (DRV/r). This analysis evaluates the virological and immunological efficacy, safety and tolerability of DRV/r after 144 weeks of follow-up in TMC114-C215 patients who initiated treatment at 600/100 mg BID, the recommended dose for treatment-experienced HIV patients based on the POWER 1 and 2 (TMC114-C213 and C202) studies.

Methods

Treatment-experienced HIV-1-infected patients with HIV-1 RNA >1,000 copies/mL and ≥1 primary PI mutation were included. Patients received DRV/r 600/100 mg BID plus an optimised background regimen (OBR; NRTIs ± enfuvirtide) based on resistance testing at screening and treatment history. Intent-to-treat (ITT) efficacy and safety analyses were used. Virological response was assessed using the time-to-loss of virological response (TLOVR) algorithm.

Summary of Results

Of a total of 453 patients recruited in trial TMC114-C215, 336 were included in the POWER 3 analysis as they started treatment with DRV/r 600/100 mg BID using the DRV commercial 300 mg tablet formulation. Baseline data for these patients were: male = 87%, Caucasian = 75%, median age = 43 years, mean duration of HIV-1 infection = 13.0 years, mean baseline $\log_{10}$ HIV RNA = 4.58 copies/mL, median CD4 cell count = 120 cells/mm^3, CDC category C = 55%, median number of primary PI mutations = 4. These patients had a mean treatment duration of 110.6 weeks. Data for 325 patients were available for efficacy evaluation at week 144. 32% (105/325) and 39% (127/325) of patients achieved HIV-RNA <50 copies/mL and ≥1 $\log_{10}$ HIV-RNA reduction using the TLOVR algorithm, respectively. The mean CD4 increase from baseline at week 144 was 84 cells/mm^3 (non-completer status equals failure imputation algorithm). 34% (113/336) of patients experienced Grade 2–4 adverse events at least possibly related to study medication, with diarrhoea (4%), vomiting (3%) and hypertriglyceridaemia (3%) being the most common.

Conclusion

The POWER 3 144-week efficacy and safety results confirm and extend those observed at 24, 48 and 96 weeks. DRV/r 600/100 mg BID with an OBR was effective in HIV-1 infected patients with advanced disease and a high level of PI resistance, and was well-tolerated over time, indicating a sustained clinical benefit in this highly treatment-experienced population.