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TMC114 PROVIDES DURABLE VIRAL LOAD SUPPRESSION IN TREATMENT-EXPERIENCED PATIENTS: POWER 1 AND 2 COMBINED WEEK 48 ANALYSIS

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BACKGROUND: In the POWER 1 (TMC114-C213) and 2 (TMC114-C202) 24-week primary analysis, TMC114 (darunavir) with lowdose ritonavir (TMC114/r) demonstrated better antiviral activity than control PIs (CPIs) in treatment-experienced patients. The highest dose (600/100mg bid) provided the greatest virologic response. The combined 48-week analysis of these trials assesses long-term efficacy and safety of TMC114/r 600/100mg bid versus CPIs.

METHODS: In both trials, PI-, NRTI- and NNRTI-experienced patients with ≥ 1 baseline primary PI mutation were randomized to receive an optimized background regimen plus one of four TMC114/r doses or boosted CPI. Virologic response and adverse events (AEs) in patients initially randomized to TMC114/r 600/100mg bid and CPIs were compared at Week 48 (ITT-TLOVR). The primary efficacy parameter was the proportion of patients with ≥ 1 log₁₀ viral load reduction.

RESULTS: At the recommended dose for treatment-experienced patients, TMC114/r achieved significantly higher virologic response rates than CPIs at Week 48, similar to those observed at Week 24 (table).

Pooled POWER 1 and 2 virologic response rates

Efficacy parameter	Week 24			Week 48		
	TMC114/r	CPI	P-	TMC114/r	CPI	P-

	600/100mg bid (n=131)	(n=124)	value	600/100mg bid (n=110)	(n=120)	value
Patients with HIV RNA ≥1.0 log ₁₀ reduction (%)	70	21	<0.001	61	15	<0.001
Patients with HIV RNA <50 copies/ mL (%)	45	12	<0.001	46	10	≤0.003
Mean HIV RNA log ₁₀ reduction (copies/mL)	-1.89	-0.48	<0.001	-1.63	-0.35	<0.001
Mean CD4 increase (cells/ mm ³)	92	17	<0.001	102	19	≤0.005

The most commonly reported AEs during TMC114/r 600/100mg bid treatment were diarrhea (20%), nausea (18%), headache (15%), nasopharyngitis (14%) and fatigue (12%), reported in 28%, 13%, 20%, 11% and 17% of CPI patients, respectively. The majority of AEs were grade 1 – 2 in severity.

CONCLUSIONS: TMC114/r has demonstrated sustained efficacy in this treatment-experienced population. Its tolerability profile is similar to that of CPIs, with a lower incidence of diarrhea.

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