TERIFLUNOMIDE EFFICACY AND SAFETY ANALYSES: RESULTS FROM TEMSO AND TOWER

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Introduction: Teriflunomide is a novel, once-daily, oral immunomodulator recently approved in the USA and Australia for treatment of relapsing multiple sclerosis (RMS). We report efficacy and safety results from the Phase III trials TEMSO and TOWER.
Methods: In TEMSO/TOWER,1088/1169 patients with RMS (18–55 years; EDSS score ≤5.5 at screening; ≥1 or ≥2 relapses in the 12 or 24 months before randomisation, respectively) were randomised to placebo, teriflunomide 7mg or teriflunomide 14mg. Treatment duration was 108 (TEMSO) or 48–152 weeks (TOWER). Primary and key secondary endpoints were annualised relapse rate (ARR) and sustained disability progression (confirmed for 12 weeks). Additional endpoints included MRI measures (TEMSO only), safety and tolerability.
Results: Teriflunomide 14mg reduced ARR by 31.5%/36.3% (TEMSO/TOWER; $p<0.001$) and disability progression by 29.8%/31.5% ($p=0.028$/$p=0.044$) versus placebo. Teriflunomide 7mg reduced ARR by 31.2%/22.3% ($p<0.001$/$p=0.02$) versus placebo, but did not significantly reduce disability progression. In TEMSO, both teriflunomide doses demonstrated superiority to placebo for MRI endpoints, with evidence favouring 14mg. Cumulative drug exposure to teriflunomide 14mg was 614.2/576.2 patient-years (TEMSO/TOWER). Teriflunomide was generally well tolerated in both studies. The most frequently reported treatment-emergent adverse events more common with teriflunomide than placebo were alanine aminotransferase increase, hair thinning and diarrhoea. There were no deaths during TEMSO and four in TOWER; none deemed related to study treatment.
Conclusion: Findings suggest a superior benefit:risk for teriflunomide 14mg over 7mg, with significant reductions in ARR and disability progression in both studies and similar safety/tolerability profiles for both doses.
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