PATIENTS WITH HIGH DISEASE ACTIVITY IN TEMSO AND TOWER: POOLED ANALYSES OF TWO PHASE 3 PLACEBO-CONTROLLED TRIALS

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BACKGROUND: Teriflunomide is a once-daily oral immunomodulator approved for relapsing–remitting multiple sclerosis (MS).
OBJECTIVES: To present key efficacy outcomes from analyses of pooled data from two independent phase 3 studies of teriflunomide (TEMSO [NCT00134563] and TOWER [NCT00751881]) in a subgroup of patients with highly active relapsing MS.
METHODS: Patients were randomised to teriflunomide 14mg, 7mg or placebo. Primary and key secondary endpoints were annualised relapse rate (ARR) and 12-week confirmed disability progression. Subgroups of patients with high disease activity were analysed: subgroup A: ≥2 relapses in the year before study entry regardless of prior therapy; subgroup B: disease-modifying therapy (DMT) use in prior 2 years *and* either ≥1 relapse in the year before study entry or ≥1 gadolinium enhancing (Gd+) lesion on baseline MRI; OR no previous DMT and pre-existing neurological deficit (EDSS score ≥1.5) and either ≥2 relapses in the year before study entry or one relapse with ≥1 Gd+ lesion on baseline MRI.
RESULTS: Patient demographics and baseline disease characteristics were well balanced across treatment groups. In patients with high disease activity, teriflunomide 14mg significantly reduced ARR and disability progression confirmed for 12 weeks (both subgroups) and 24 weeks (subgroup B). Teriflunomide 7mg showed a similar effect on ARR but no significant reduction in disability progression.
CONCLUSIONS: This analysis demonstrates the strong efficacy of teriflunomide in patients with high disease activity and reaffirms the robust and consistent effect of teriflunomide 14mg on ARR and confirmed disability observed in individual studies.
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