TOPIC: EFFICACY AND SAFETY OF ONCE-DAILY ORAL TERIFLUNOMIDE IN PATIENTS WITH EARLY STAGE MS

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BACKGROUND: Teriflunomide is a once-daily oral immunomodulator approved for relapsing–remitting multiple sclerosis (MS). Pivotal studies of teriflunomide in patients with relapsing MS (TEMSO:NCT00134563; TOWER:NCT00751881) showed consistent efficacy across key clinical and MRI (assessed in TEMSO only) measures, and a well-characterised safety profile.
OBJECTIVES: To report the efficacy and safety outcomes from the phase 3 TOPIC trial (NCT00622700).
METHODS: TOPIC was a double-blind, placebo-controlled, parallel-group study in patients with a first clinical episode consistent with MS. Patients were randomised to teriflunomide 14mg, teriflunomide 7mg or placebo. The primary endpoint was occurrence of a new clinical relapse confirming clinically definite MS, and the key secondary endpoint was occurrence of a new clinical relapse or MRI lesion. Safety and tolerability were assessed.
RESULTS: Baseline characteristics were generally well balanced across groups. Teriflunomide 14mg significantly reduced the risk of a new clinical relapse (42.6%; p=0.0087) and the risk of a new clinical relapse or MRI lesion (34.9%; p=0.0003) versus placebo. Teriflunomide 14mg significantly reduced total lesion volume increase from baseline and the number of gadolinium-enhancing T1 lesions versus placebo. Significant reductions were also observed with teriflunomide 7mg versus placebo. Safety outcomes were consistent with previous studies.
CONCLUSIONS: Teriflunomide demonstrated efficacy in patients with early stage MS. Consistent with TEMSO and TOWER, these findings demonstrate greater efficacy of teriflunomide 14mg versus teriflunomide 7mg, and support the beneficial effect of teriflunomide in patients with MS early and later in their disease course, and across a range of disease activity.

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