Title: Effect of Teriflunomide in Subgroups Defined by Prior Treatment: Pooled Analysis of the Phase 2 study and the Phase 3 TEMSO, TOWER, and TENERE Studies

Short title for Annual Meeting Mobile Application:

Effect of teriflunomide by prior treatment

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Background

Teriflunomide is a once-daily oral immunomodulator approved for treatment of relapsing forms of MS. The efficacy and safety of teriflunomide have been established in a Phase 2 (NCT01487096) study and the Phase 3 TEMSO (NCT00134563), TOWER (NCT00751881), and TENERE (NCT00883337) studies.

Objective

To investigate the efficacy/safety of teriflunomide in subgroups defined by prior treatment in a pooled post hoc analysis of the Phase 2 study and the Phase 3 TEMSO, TOWER, and TENERE studies.

Methods

In the Phase 2, TEMSO and TOWER studies, patients were randomized 1:1:1 to receive placebo, teriflunomide 7 mg, or teriflunomide 14 mg. In TENERE, patients were randomized 1:1:1 to receive subcutaneous interferon beta-1a, teriflunomide 7 mg, or teriflunomide 14 mg. Post hoc analysis of annualized relapse rate (ARR) was carried out for patients according to subgroups defined by prior MS treatment: Group 1, patients whose last DMT was discontinued within 6 months before randomization; Group 2, patients whose last DMT was discontinued 6 months to 2 years before randomization; and Group 3, patients who received no prior DMT. Data are reported for teriflunomide 14 mg and placebo groups.

Results

The pooled population included 2643 patients; 348, 412, and 1883 were in Groups 1, 2, and 3, respectively. ARR was statistically significantly lower in patients treated with teriflunomide 14 mg compared with placebo, regardless of prior treatment status: Group 1, 0.45 vs 0.81 (45% relative reduction; $P=0.0029$); Group 2, 0.53 vs 0.79 (34% relative reduction; $P=0.0117$), Group 3, 0.33 vs 0.53 (38% relative reduction; $P<0.0001$).

Conclusions

In this pooled analysis, the treatment effect of teriflunomide was consistent across subgroups of patients defined by prior MS treatment. Although patients with prior DMT use had a higher level of baseline disease activity than patients with no prior DMT use, teriflunomide demonstrated similar efficacy in subgroups.

Disclosures:

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