INTRODUCTION

- Teriflunomide is a once-daily oral immunomodulator approved for the treatment of relapsing-remitting multiple sclerosis (RRMS).
- The effect of teriflunomide has been assessed in 2 phase 3 clinical studies in patients with relapsing MS: TEMSO (NCT00714543) and TOWER (NCT00751881).

OBJECTIVES

- To report primary efficacy outcomes and results of prespecified subgroup analyses of teriflunomide treatment effects in TOPIQ.

RESULTS

- Patient characteristics were well balanced across treatment groups (Table 1).

Main Outcomes

New Clinical Relapses

- Both doses of teriflunomide reduced the risk of a new clinical relapse confirming CDMS compared with placebo (Figure 1).
- Teriflunomide 14 mg significantly reduced the risk of a new clinical relapse by 43% (P=0.0087).
- Teriflunomide 7 mg significantly reduced the risk of a new clinical relapse by 37% (P=0.0271).

New Clinical Relapse or MRI Lesion

- Both doses of teriflunomide reduced the risk of a new clinical relapse or MRI lesion by 35% (P=0.0003).

Subgroup Analyses

- Both doses of teriflunomide had a consistently positive effect on time to new relapse and time to new relapse or occurrence of a new MRI lesion across patient subgroups defined by gender, age, baseline MRI variables, and monofocal/multifocal status.
- These results were obtained despite premature termination of the study, and therefore, the results may underestimate the true outcome.

CONCLUSIONS

- Both doses of teriflunomide had a consistently positive effect on time to new relapse and time to new relapse or occurrence of a new MRI lesion across patient subgroups defined by gender, age, baseline MRI variables, and monofocal/multifocal status.
- These results were obtained despite premature termination of the study; therefore, the results may underestimate the true outcome.

Figure 1. Risk of Relapse Confirming Clinically Definite MS

- Teriflunomide 7 mg was significantly reduced by the risk of a new clinical relapse confirming CDMS compared with placebo (Figure 1).
- Teriflunomide 14 mg significantly reduced the risk of a new clinical relapse by 43% (P=0.0087).
- Teriflunomide 7 mg significantly reduced the risk of a new clinical relapse by 37% (P=0.0271).

Figure 2. Risk of Relapse or MRI Lesion

- Both doses of teriflunomide reduced the risk of a new clinical relapse or MRI lesion by 35% (P=0.0003).

Figure 3. Effect of Teriflunomide on Risk of Relapse Confirming Clinically Definite MS by Predefined Subgroups

- The effect of teriflunomide on relapse indicating conversion to CDMS and on neurological event consistent with demyelination (optic neuritis, spinal cord demyelination, transverse myelitis/cerebellar ataxia) occurring within 90 days of randomization. An MRI scan demonstrating ≥2 T2 lesions of ≥3 mm in diameter, characteristic of MS (i.e., lesion periventricular in location or oval in shape), was also required.

Methods

- Study Design and Patients
- Objectives
- INTRODUCTION
- RESULTS
- CONCLUSIONS
- REFERENCES