**INTRODUCTION**

- Teriflunomide is a once-daily oral immunomodulator approved for the treatment of relapsing forms of MS in over 80 countries, including the United States and those of the European Union, for the treatment of relapsing forms of MS in over 80 countries, including the United States and those of the European Union.

- The efficacy and safety of teriflunomide have been established in patients with relapsing forms of MS in clinical trials programs, including a phase 3 study and the Phase 2 and Phase 3 TEMSO and TOWER studies.

- Patients who received one or more previous disease-modifying therapies (DMTs) prior to study entry were eligible to participate.

- In the Phase 2 TEMSO and TOWER studies, patients with relapsing MS (EDSS score ≤5.5; ≥2 relapses in the previous 3 years and ≥1 relapse during the year prior to study entry were eligible to participate.

- In all trials, patients were not eligible to enroll if they had received prior or concurrent treatment with cladribine, mitoxantrone, or other immunosuppressant agents.

- Here, we evaluate the efficacy and safety of teriflunomide in subgroups of patients 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**

**Phase 2, TEMSO and TOWER Study Designs and Patients**

- Complete study designs, methods, and inclusion criteria for the Phase 2 study and the Phase 3 TEMSO and TOWER studies have been published previously.

- In the Phase 2 study, patients with relapsing MS (Expanded Disability Status Scale [EDSS] score ≤6, ≥2 relapses in the previous 3 years and ≥1 relapse during the year prior to study entry were randomized 1:1:1 to receive placebo, teriflunomide 7 mg, or teriflunomide 14 mg for up to 36 weeks.

- In TEMSO and TOWER, patients with relapsing MS (EDSS score ≤5.5; ≥2 relapses in the previous 2 years or ≥1 relapse in the preceding year) were randomized 1:1:1 to receive placebo, teriflunomide 7 mg, or teriflunomide 14 mg for up to 108 weeks (TEMOS) or up to 48 weeks (TOWER).

**TENERE Study Design and Patients**

- The complete study design, methods and inclusion criteria for the TENERE study have been published previously.

- Patients with relapsing MS (EDSS score ≤5.5; ≤60 years of age, relapse-free for at least 30 days prior to randomization) were randomized 1:1:1 to receive teriflunomide 7 mg, or teriflunomide 14 mg or placebo for 108 weeks.

- Patients who were randomized to FIZ in the core period, but who entered the extension and were treated with teriflunomide 14 mg, were included in Group 2 (Table 1).

- Adjusted ARR was derived using Poisson regression.

**Statistical Analysis**

- P-values from patients from the intention to treat (ITT) study populations were included in these analyses.

- Adjusted annualized relapse rates (ARRs) were compared between patients receiving placebo and patients treated with teriflunomide 7 mg or teriflunomide 14 mg, using the relative rate (RR) analysis to adjust for the relative small sample size according to the subgroups of prior MS treatment status defined in Table 1.

- Adjusted ARR was derived using Poisson regression.

**RESULTS**

**Study Population**

- There were 2483 patients in the pooled population, of whom 1883, 348 and 122 were in Group 1, 2 and 3, respectively.

- Demographics and baseline disease characteristics for the pooled study population are shown in Table 2.

- Patients were predominantly white females and the mean age ranged from 37 to 39 years in the different groups. Average disease duration was longer in patients in Groups 1 and 2 compared with Group 1.

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