• 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. As of August 2016, >95% of patients enrolled in the Phase 2 and Phase 3 TEMSO, TOPIC, TOWER and TENERE studies, with a total real-world exposure of approximately 186,000 patient-years as of 2014.

• The efficacy and safety of teriflunomide have been established in patients with relapsing MS (RMS) in three Phase 2 studies and the Phase 3 TEMSO, TOPIC, TOWER and TENERE studies, and in patients with a first clinical episode suggestive of MS in the Phase 2 TOWER study. The studies demonstrated a decreased risk of relapse, disability increase and lower mean annualised relapse rates (ARRs) compared with placebo (0.55 vs 0.81; 0.30 vs 0.48; 0.25 vs 0.36). Additionally, significantly fewer patients receiving teriflunomide 14 mg versus placebo demonstrated disability increase (7.4% vs 21.3%; P=0.04) (Figures 1a–1d).

• In the Phase 2 trial, patients treated with teriflunomide 14 mg had fewer combined major adverse events (AEs) per person-year compared with placebo (2.9 vs 4.5; P=0.02), and fewer serious AEs (0.5 vs 0.9; P=0.04), and lower mean annualised relapse rates (ARRs) compared with placebo (0.55 vs 0.81; P=0.001). In the Phase 3 TOWER study, a maximum of 106 weeks, 56% (34/61) of patients receiving teriflunomide 14 mg versus placebo demonstrated disability increase (17.2% vs 28.0%; P=0.03) (Figures 2a and 2b).

• In the Phase 2 trial, teriflunomide 14 mg was found to significantly reduce ARR by 31.5% (P=0.001), 31.9% (P=0.001), 36.8% (P=0.001), respectively, compared with placebo. Nine per cent of patients experienced a relapse and disability worsening (longest 12 weeks) with teriflunomide 14 mg compared with placebo (7.6% vs 14.8% at 12 weeks, respectively) (Table 1).

• In TOWER, TENERE and TOPIC studies (in which patients were enrolled in the enrolled in the core studies), the relapse rate and disability worsening (longest 12 weeks) with teriflunomide 14 mg vs placebo were lower in the extension studies. The relapse rate was lower in the extension studies compared with the core studies (0.05 vs 0.20; 0.20 vs 0.35; 0.30 vs 0.35) (Table 1).

• The overall proportion of patients remaining free from relapse during the course of the core and extension studies was 0.41 (0.36, 0.45) (Figure 2c).

• The proportion of patients remaining free from relapse during the last year of follow-up was 0.75 (0.73, 0.77) (Figure 2d).

• The proportion of patients treated with teriflunomide for up to 12.8 years demonstrated disability increase (7.4% vs 21.3%; P=0.04) (Figures 1a–1d).

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