OBJECTIVE

To evaluate patient-reported quality of life outcomes, measured by the Multiple Sclerosis International Quality of Life (MusiQoL) questionnaire, during the 48-week Teri-PRO (Teriflunomide Patient-Reported Outcomes) study.

INTRODUCTION

Teriflunomide is a once-daily oral immunomodulator approved for the treatment of relapsing-remitting MS in 69 countries. Approximately 55,000 patients have been treated with teriflunomide as of April, 2016, with total exposure to the 14-mg dose approaching 70,000 patient-years.

Teriflunomide also has a manageable, well-characterized safety and tolerability profile,11 confirmed over the long-term extension studies.12

In MS, long-term preservation or improvement of quality of life should be regarded as an important indicator of therapeutic success; as it reflects important aspects of the patient’s life, including perceptions of treatment benefit and functional signs of disease worsening.13

The phase 4 TERI-QOL (NCT01895339) evaluated patient treatment satisfaction with teriflunomide using patient-reported outcomes, as well as efficacy, safety and tolerability, in routine clinical practice.

Quality of life was evaluated as a secondary outcome in this study.

Teriflunomide outcomes, including treatment satisfaction (primary outcome), patient-reported disability, and safety and tolerability, are described in Poster EP1484 (Coye et al12) and posters P646 (Gold et al13) and P648 (Coye et al12), respectively, at this congress.

METHODS

Study Design and Patients

Teri-PRO was a prospective, global, multicenter, single-arm, open-label study. Patients with MS were recruited from sites in the US, Canada, Europe, and China, patients in the US were treated with teriflunomide 7 or 14 mg (dosing determined by the treating neurologist), while those in the rest of the world were treated with teriflunomide 14 mg, according to local labeling.

The full study design and eligibility criteria have been presented previously,114 and are briefly described in abstract EP1484 at this congress.

Quality of Life Secondary Endpoints

Quality of life, as measured by the MusiQoL scale,14 included 31 questions, divided into 9 dimensions: Activities of Daily Living, Psychological Well-being, Symptoms, Relationships With Friends, Relationships With Family, Sexual Life, Coping, Rejection, and Relationship With Healthcare System.

Higher scores reflect higher quality of life in that dimension.

MusiQoL has been validated in 20 countries and 14 languages, in relapsing-remitting, secondary progressive, and progressive relapsing MS, as well as in clinically isolated syndrome. It has shown high levels of internal consistency, reproducibility, and test-retest reliability.15

Patients’ leisure activity, as measured by the Stern Leisure Activity Scale16

- Consists of 13 questions assessing the patient’s participation in leisure activities such as walking, reading, or visiting during the last month. Each point is given for participation in each of the 13 activities, and an aggregate score is obtained.
- A score 6 or higher is considered as low leisure activity and a score >8 as high leisure activity.

Timing of Assessments

- MusiQoL and Stern Leisure Activity Scale scores were assessed at baseline and Week 48 (or end of treatment).

Analysis Population

All patients who received ≥1 dose of teriflunomide were included in the analyses.

Effect Size

- Effect size (ES), potentially useful in evaluating whether differences in groups over time are clinically meaningful and related to patients, was defined as the change from baseline divided by the standard deviation of the change.
- ES for the quality of life endpoints was calculated for the full group of patients, but not for those switching from another disease-modifying therapy (DMT) within 6 months of study entry.
- Clinical significance was defined as per the ES limits set out by Cohen:17 -0.2, negligible; 0.2 to <0.5, small; 0.5 to 0.8, moderate; and >0.8, high.

Statistical Analysis

- In a post hoc analysis, P values were derived from an ANCOVA model of change from baseline adjusted for baseline score and baseline Expanded Disability Status Scale score categorized as <3.5 or ≥3.5.
- Demographics and baseline disease characteristics are reported in poster P646 (Gold et al13).

RESULTS

A total of 1001 patients were included in the Teri-PRO study and 1000 were treated, most received teriflunomide 14 mg (n=928, 92.8%), with only a small number receiving teriflunomide 7 mg (n=73, 7.2%, US only).

- Demographics and baseline disease characteristics are reported in poster P646 (Gold et al13).

MusiQoL

- There was a statistically significant increase in MusiQoL total score from baseline to Week 48 in the full group of patients, although the ESS was negligible according to Cohen’s criteria (Figure 1).

- MusiQoL subscale scores either remained stable or showed a statistically significant increase from baseline to Week 48 in all but 1 of the 9 MusiQoL subscales (Figure 2).

- A small but statistically significant reduction was seen in the Relationships With Family subscale.

In patients switching from another DMT within 6 months (n=159), the total MusiQoL score remained stable over the course of the study, with a small (but statistically nonsignificant) increase in the total score at Week 48 (81.5% v baseline 76.7; 4.8); MusiQoL subscale scores either remained stable or increased from baseline to Week 48 in 8 out of 9 MusiQoL subscales (Figure 2).

- Statistically significant improvements were observed in the Activities of Daily Living, Psychological Well-being, Symptoms, and Coping subscales.

Stern Leisure Activity Scale

- Scores in the Stern Leisure Activity Scale remained high and stable over the course of the study, with mean SD confidence interval values of 7.30 (7.16, 7.44) and 7.40 (7.24, 7.56) at baseline and Week 48, respectively, representing a mean increase of 0.07 (0.04, 0.10) (Figure 3).

- In patients switching from another DMT within 6 months of study entry, the Stern score also remained stable over the course of the study, with mean SD confidence interval values of 7.38 and 7.44 at baseline and Week 48, respectively (P value nonsignificant).

References

18. RG: This poster was reviewed by Larisa Miller, PharmD, of Sanofi Genzyme. Post hoc statistical analyses in this poster were provided by Karthinathan Thangavelu, PhD, of Sanofi Genzyme.
19. RG: Sanofi Genzyme, Chilly-Mazarin, France; Sanofi Genzyme, Chilly-Mazarin, France; Employee of Sanofi Genzyme.
20. Employee of Lincoln, mandated by Sanofi.
21. RG: This poster was reviewed by Larisa Miller, PharmD, of Sanofi Genzyme. Post hoc statistical analyses in this poster were provided by Karthinathan Thangavelu, PhD, of Sanofi Genzyme.
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