QL02

Baseline Characteristics of Patients Enrolled in the Teri-PRO Phase 4 Study in the United States vs Canada, Europe, and Latin America

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INTRODUCTION

- Teriflunomide is a once-daily oral immunomodulator approved for relapsing-remitting MS
- Teriflunomide has demonstrated consistent efficacy in patients with relapsing forms of MS[1–3] and in patients who experienced a first clinical episode suggestive of MS[4] in placebo-controlled clinical trials. It also has a well-characterized and manageable safety and tolerability profile[1–4]
- Patient-reported outcomes (PROs) are important measures that complement clinical evaluations and are applied to evaluate experience and satisfaction of patients with their treatment; consequently, PRO measures also provide insight into patients' health-related quality of life
- The ongoing phase 4 Teri-PRO (**Teri**flunomide **P**atient-**R**eported **O**utcomes; NCT01895335) study is evaluating the efficacy and tolerability of and satisfaction with teriflunomide in clinical practice
  - Patients entering Teri-PRO were recruited across sites in North America, Europe, and Latin America

OBJECTIVES

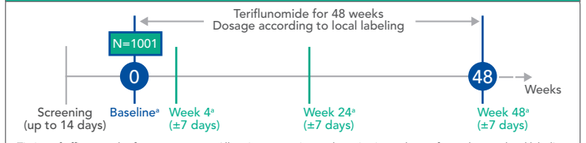
- To describe demographics and baseline disease characteristics of patients enrolled in Teri-PRO in the United States and the rest of the world (ROW), including Canada, Europe, and Latin America

METHODS

Study Design and Patients

- Teri-PRO is a global, prospective, single-arm, multicenter, open-label study (**Figure 1**)

Figure 1. Teri-PRO Study Design[5]



[a]Timing of efficacy and safety assessments. All patient screening and monitoring to be performed as per local labeling. Patients continuing treatment after Teri-PRO will have the opportunity to switch to commercial teriflunomide.

- Patients with relapsing forms of MS (N=1001) aged ≥18 years were recruited across sites in the United States, Canada, Europe (Austria, Belgium, Finland, France, Germany, Greece, Italy, Norway, Spain, Sweden, and the United Kingdom), and Latin America (Chile)[5]
- Reflecting the routine clinical practice setting, there were no disease activity eligibility criteria; full exclusion criteria have been presented previously[5]
- Patients were prescribed teriflunomide 14 mg or 7 mg once daily for 48 weeks according to local labeling; in the United States, where the 7-mg dose is available, choice of dose was determined by the treating neurologist
- Patients could enter Teri-PRO, regardless of previous use of disease-modifying therapy (DMT) and were classified into the following groups:
  - Patients with no DMT intake in the past 2 years
  - Patients with last DMT intake within 2 years of study entry
    - Patients with last DMT intake 6–24 months before study entry
    - Patients with last DMT intake within 6 months of study entry (considered "switchers")

Study Outcomes

- The primary endpoint of Teri-PRO is global satisfaction with teriflunomide treatment at Week 48 (or end of treatment [EOT] if treatment was discontinued before Week 48), as measured by the Treatment Satisfaction Questionnaire for Medication (TSQM, version 1.4)[6]
- Secondary endpoints include:
  - Change in TSQM from baseline to Week 4 and from baseline to Week 48 (or EOT) in patients switching from another DMT
  - Change in TSQM from Week 4 to Week 48 (or EOT) in patients with no DMT intake in the past 2 years
  - Changes from baseline in other PROs[5]
  - Clinical outcomes, including treated relapses, time to first treated relapse, and Expanded Disability Status Scale (EDSS) score
  - Occurrence of adverse events

Timing of Assessments

- All efficacy and safety measures will be assessed at baseline and at Week 48/EOT. The following measures will also be assessed at other times:
  - TSQM: Week 4 and Week 48/EOT in all patients, and baseline, Week 4, and Week 48/EOT in patients switching from another DMT
  - Treated relapses: Baseline and Weeks 4, 24, and 48/EOT
  - Adverse events: Reported at each visit

Analysis Population

- All patients who receive ≥1 dose of teriflunomide are included in the efficacy and safety analyses

RESULTS

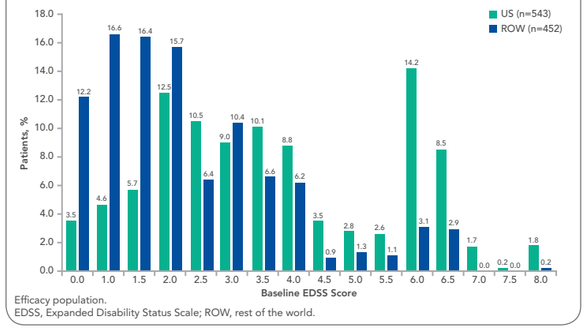
- Teri-PRO enrollment is complete; 1001 patients were included in the study and 1000 patients were treated
- In the United States:
  - Patients were enrolled between June 21, 2013, and June 24, 2014, inclusive
  - Of 611 US patients screened, 545 were included in Teri-PRO. Teriflunomide 14 mg and 7 mg were prescribed to 473 patients (86.8%) and 72 patients (13.2%), respectively
- In the ROW (Canada, Europe, and Latin America):
  - Patients were enrolled between March 3, 2014, and November 27, 2014, inclusive
  - Of 491 ROW patients screened, 456 were included in Teri-PRO and 455 were prescribed teriflunomide 14 mg
- Demographic and baseline disease characteristics are detailed in **Table 1**
  - Patients in the US group were generally older than those in the ROW (mean age 50.6 vs 42.9 years, respectively) and had a longer duration of disease (14.7 vs 11.3 years, respectively)
  - The ROW group contained a higher proportion of Caucasian/white patients (98.9%) compared with the US group (89.7%)
  - The median time since most recent relapse was longer in the ROW group (14.7 months) compared with the US group (10.1 months)
- The frequency distribution of EDSS scores at baseline is shown in **Figure 2**
  - Baseline EDSS scores were generally lower for ROW patients compared with US patients
- Regardless of the location of participating patients, the most frequent reason given by physicians for choosing treatment with teriflunomide was the convenience associated with oral therapy; this was followed by side effects/risk of side effects with previous DMT (**Figure 3**)
- For both the US and the ROW, most patients (n=385, 70.6% and n=327, 71.9%, respectively) were treated with ≥1 DMT within the last 2 years before study entry (**Table 1**)

Table 1. Patient Demographic and Baseline Disease Characteristics

Characteristic	United States (n=545)	ROW (n=455)	All (N=1000)
Age, mean (SD), y	50.6 (10.5)	42.9 (10.1)	47.1 (11.0)
Female, n (%)	414 (76.0)	344 (75.6)	758 (75.8)
Race, n (%)			
Asian	0	3 (0.7)	3 (0.3)
Black	49 (9.0)	1 (0.2)	50 (5.0)
Caucasian/white	489 (89.7)	450 (98.9)	939 (93.9)
Other	7 (1.3)	1 (0.2)	8 (0.8)
Time since first symptom of MS, mean (SD), y	14.7 (9.8)	11.3 (8.9)	13.2 (9.5)
Time since most recent relapse onset, mo			
Median (min:max)	10.1 (0.0:372.2)[a]	14.7 (0.1:358.0)[b]	12.4 (0.0:372.2)[c]
Mean (SD)	32.1 (51.8)[a]	29.7 (39.9)[b]	31.0 (46.6)[c]
Number of relapses within past 2 years, n (%)			
0	196 (36.1)[d]	163 (35.8)	359 (36.0)[e]
1	182 (33.5)[d]	154 (33.8)	336 (33.7)[e]
2	77 (14.2)[d]	85 (18.7)	162 (16.2)[e]
3	36 (6.6)[d]	37 (8.1)	73 (7.3)[e]
≥4	52 (9.6)[d]	16 (3.5)	68 (6.8)[e]
Baseline EDSS score, median (min:max)	3.5 (0.0:8.0)[d]	2.0 (0.0:8.0)[f]	2.5 (0.0:8.0)[g]
Previous DMT within past 2 years, n (%)			
No	160 (29.4)	128 (28.1)	288 (28.8)
Yes	385 (70.6)	327 (71.9)	712 (71.2)
Not within past 6 months	69 (12.7)	50 (11.0)	119 (11.9)
Switchers[h]	316 (58.0)	277 (60.9)	593 (59.3)

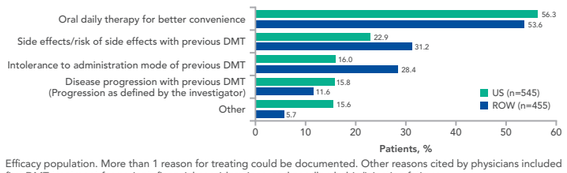
[a]n=518; [b]n=451; [c]n=969; [d]n=543; [e]n=998; [f]n=452; [g]n=995; [h]defined as patients with last prior DMT administration date within 6 months before first teriflunomide intake. Efficacy population.
DMT, disease-modifying therapy; EDSS, Expanded Disability Status Scale; ROW, rest of the world; SD, standard deviation.

Figure 2. Frequency Distribution of EDSS Scores at Baseline for US and ROW Patients



Efficacy population.
EDSS, Expanded Disability Status Scale; ROW, rest of the world.

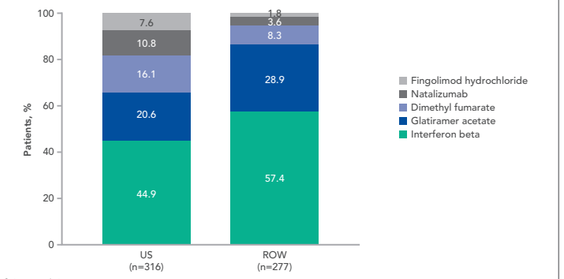
Figure 3. Reasons for Treating Patients With Teriflunomide According to Physicians for US and ROW Patients



Efficacy population. More than 1 reason for treating could be documented. Other reasons cited by physicians included first DMT treatment for patient, financial considerations, and needle phobia/injection fatigue.
DMT, disease-modifying therapy; ROW, rest of the world.

- For patients who switched to teriflunomide within 6 months of discontinuing another DMT in both the US and ROW (n=316, 58.0% and n=277, 60.9%, respectively), the most common prior therapies before study entry included interferon beta-1a, glatiramer acetate, and dimethyl fumarate (**Figure 4**)

Figure 4. Last DMT Taken Before First Teriflunomide Intake by Patients With Last DMT Intake Within 6 Months of Study Entry



Safety population.
DMT, disease-modifying therapy; ROW, rest of the world.

CONCLUSIONS

- Comparison of baseline characteristics of patients enrolled in Teri-PRO indicates some differences between US patients and those from other regions, which may reflect differences in prescribing practices and overall disease management
- Teri-PRO will provide valuable information on the use of teriflunomide in clinical practice, including patient treatment satisfaction, safety, and efficacy. This real-world experience will complement existing data from phase 2 and 3 clinical trials

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Disclosures

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Disclaimer

Teriflunomide is approved in many countries, including the US and the European Union, for the treatment of relapsing multiple sclerosis or relapsing-remitting multiple sclerosis. This material may contain information that is outside of the approved labeling in some countries.

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