Improvements in Patient-Reported Treatment Satisfaction With Teriflunomide: Results From the Phase 4 Teri-PRO Study

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OBJECTIVE

• To report treatment satisfaction for patients enrolled in the 48-week phase 4 Teri-PRO (Teriflunomide Patient-Reported Outcome) study

METHODS

Study Design and Patients

— Teri-PRO was a prospective, global, multicenter, single-arm, open-label study
— The primary design and eligibility criteria have been presented previously in brief
— Patients ≥18 years of age with MS were recruited from sites in 30 countries, including the US, Canada, Europe, and Latin America
— In line with the clinical practice, there were no disease activity eligibility criteria for patient recruitment into the study
— Patients were prescribed teriflunomide (3 mg or 7 mg once daily) for 48 weeks in accordance with local labeling
— Patients who were switching from injectable DMTs could be classified into one of the following groups:
   - Patients with no DMT intake in the prior 2 years
   - Patients with DMT intake 6–24 months prior to study entry, subdivided into:
     - Patients with last DMT intake ≤6 months before study entry
     - Patients with last DMT intake >6 months before study entry
— Study Outcomes
   - The primary endpoint was global satisfaction with teriflunomide treatment, as measured by the TSQM; Version 1.4
   - Secondary endpoints included change in TSQM score from baseline to Week 48
   - The TSQM consists of 14 questions across 4 domains assessing the effects of treatment on patients’ daily lives and their satisfaction with therapy
— The use of patient-reported outcomes complements clinical assessment to provide a holistic view of the effects of treatment on patients’ daily lives and their satisfaction with therapy

RESULTS

Characteristics

Table 1. Demographics and Baseline Disease Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>47.1 (11.9)</td>
</tr>
<tr>
<td>Gender (female, n [%])</td>
<td>908 (90.8)</td>
</tr>
</tbody>
</table>
| Race | Hispanic (0.9)
| Asian | 1.2)
| Caucasian/White | 928 (92.8)
| Other | 1.2
| Time since most recent relapse onset, mean (SD), mo | 31.2 (46.5) |
| Time since most recent relapse response, mean (SD), mo | 6.4 (3.6) |
| Number of relapses within past 2 years, mean (SD) | 2.1 (3.5) |
| Baseline EDSS score, mean (SD) | 3.1 (2.0) |
| Previous DMT within past 6 months (switchers), n [%] | 938 (93.8) |
| Previous DMT within past 48 months (switchers), n [%] | 36 (3.6) |

CONCLUSIONS

• At Weeks 4 and 48, high levels of patient treatment satisfaction with teriflunomide were seen across all 75MS domains in the real-world Teri-PRO study
• In patients switching from other DMTs, statistically significant improvements in patient treatment satisfaction with teriflunomide were reported early at Week 8 and sustained throughout the course of the study across all 4 domains of the TSQM

In combination with other Teri-PRO outcomes, these treatment satisfaction results are consistent with results from the teriflunomide clinical trial program, and support the use of teriflunomide for relapse-remitting MS

Figure 1. Reasons for Treating Patients With Teriflunomide According to Physician

Figure 2. Last DMT Taken Before First Teriflunomide Intake by Patients Switching to Teriflunomide

Figure 3. Physician-Reported Reason for Treating With Teriflunomide Based on Last DMT Taken Patients Switching From Another DMT Within Past 6 Months

Table 2. Change From Baseline to Week 48 in Treatment Satisfaction

<table>
<thead>
<tr>
<th>Domain</th>
<th>n</th>
<th>Baseline</th>
<th>Week 48</th>
<th>Change from Baseline to Week 48</th>
<th>ES</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Satisfaction</td>
<td>997</td>
<td>29.8</td>
<td>60.1</td>
<td>30.3</td>
<td>0.68</td>
<td>0.0001</td>
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<td>Effectiveness</td>
<td>997</td>
<td>23.7</td>
<td>42.0</td>
<td>18.3</td>
<td>0.86</td>
<td>0.0001</td>
</tr>
<tr>
<td>Convenience</td>
<td>997</td>
<td>16.3</td>
<td>33.4</td>
<td>17.1</td>
<td>0.97</td>
<td>0.0001</td>
</tr>
<tr>
<td>Side Effects</td>
<td>997</td>
<td>17.9</td>
<td>34.2</td>
<td>16.3</td>
<td>0.88</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Figure 4. Treatment Satisfaction—Patients Switching From Another DMT

Figure 5. Change From Baseline to Week 48 in Treatment Satisfaction From Baseline DMT Within Prior 6 Months

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