Significant and Clinically Meaningful Health-Related Quality of Life Improvements With Alemtuzumab in RRMS Patients in Clinical Practice: Interim Results From a Prospective, Non-Interventional, Real-World Study (PROMiS)

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OBJECTIVE

- To report an interim analysis on changes in patient-reported health-related quality of life (HRQL), function, and degree of disability over 8 months in patients with RRMS receiving alemtuzumab in clinical practice

CONCLUSIONS

- It will be important for patients to complete all the fulfills remission regimen (2 courses) to allow an accurate assessment of benefit

INTRODUCTION

- Progressive disability associated with MS has a substantial negative effect on patients' HRQL, including decreased mobility, physical functioning, and general sense of well-being
- Alemtuzumab is approved in >70 countries for patients with RRMS and is administered as 2 courses (Course 1: treatment initiation; Course 2: 12 months later)
- Recently, product labeling was updated to include additional courses as needed in the United States (no limit) and the European Union (up to 2 additional courses)
- In the CARE-MS I and II studies (NCT00530348; NCT00548405), 2 courses of alemtuzumab demonstrated significantly greater improvements in clinical and MRI outcomes versus various subcutaneous treatments in the SC IFNB-1a (NCT-SCIFNB-1a) over 2 years
- Over the additional 4 years in an extension study (CARE-MS extension [NCT00930553]), 60% of CARE-MS I and 50% of CARE-MS II patients did not receive residual alemtuzumab or other disease-modifying therapy (DMT) after the initial 2 courses
- HRQL improvements were also maintained over the additional 4 years in CARE-MS I and II patients
- In clinical trials, adverse events (AEs) in alemtuzumab-treated patients included infection-associated reactions (IAEs), infection, and autoimmune AEs (most commonly thyroid events and less frequently, immune thrombocytopenia and nephropathies [including anti-glomerular basement membrane disease])
- IAEs (predominantly mild or moderate, headache, rash, and pyrexia) were experienced by most patients, but decreased with the second treatment course and each additional course
- Infections occurred in <65% of alemtuzumab-treated patients in Year 1, and declined to <45% in Year 5; <95% were mild to moderate, and serious infections occurred in 1.0%–1.9% of patients per year
- Thyroid events were mostly mild to moderate, peaked in the third year after alemtuzumab initiation, and declined thereafter
- Real-world data on alemtuzumab use in clinical practice are limited

METHODS

- PROMiS is an ongoing 1-year, real-world, prospective, non-interventional, online PRO survey of adults with RRMS in the US who initiated treatment with alemtuzumab
- A 1-year follow-up survey will be carried out
- Patients were recruited from the MS One to One alemtuzumab patient support program under a separate protocol requiring informed consent
- Baseline demographics, disease characteristics, treatment history, and insurance type were collected

RESULTS

Survey Population

- The interim analysis included 171 patients (mean age 44.8 years; 72.5% female), of whom 97.5% had received another MS therapy before initiating alemtuzumab

Table 1. PROs Assessed in Alemtuzumab-Treated Patients

<table>
<thead>
<tr>
<th>PRO Assessment</th>
<th>PRO Questionnaire Included</th>
<th>N=171</th>
<th>Month</th>
<th>Mean (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSIS-29†</td>
<td>Multiple Sclerosis Impact Scale; 29 items grouped into a physical impact score (20 items) and a psychological impact score (9 items)</td>
<td>171</td>
<td>8</td>
<td>43.1 (40.2–46.0)</td>
<td>&lt;0.05 vs baseline</td>
</tr>
<tr>
<td>MSIS-12‡</td>
<td>Multiple Sclerosis Impact Scale; 12 items grouped into a physical impact score (10 items) and a psychological impact score (2 items)</td>
<td>171</td>
<td>8</td>
<td>24.4 (21.9–26.9)</td>
<td>&lt;0.05 vs baseline</td>
</tr>
<tr>
<td>MSPS-10</td>
<td>Multiple Sclerosis Patient Questionnaire (MS-10); 10 items (5 physical, 3 psychological, 2 social)</td>
<td>171</td>
<td>8</td>
<td>6.6 (5.6–7.6)</td>
<td>&lt;0.05 vs baseline</td>
</tr>
<tr>
<td>PDDS</td>
<td>Multiple Sclerosis Disability Scale (PDDS); 5 items</td>
<td>171</td>
<td>8</td>
<td>4.3 (3.7–4.8)</td>
<td>&lt;0.05 vs baseline</td>
</tr>
</tbody>
</table>

Figure 1. Mean MSIS-29 (A) Physical Impact Score and (B) Psychological Impact Score Improved From Baseline to Month 8

Table 2. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (SD)</td>
<td>44.8 (9.0)</td>
</tr>
<tr>
<td>Gender, %</td>
<td>21.1</td>
</tr>
<tr>
<td>Relapse in past year, %</td>
<td>32.2</td>
</tr>
<tr>
<td>MS disease, %</td>
<td>20.5</td>
</tr>
<tr>
<td>20.3</td>
<td></td>
</tr>
<tr>
<td>Any previous DMT, %</td>
<td>50.7</td>
</tr>
<tr>
<td>Inactive</td>
<td>2.3</td>
</tr>
<tr>
<td>Medicaid</td>
<td>3.4</td>
</tr>
<tr>
<td>Medicare</td>
<td>16.1</td>
</tr>
<tr>
<td>Private company</td>
<td>10.0</td>
</tr>
</tbody>
</table>

Figure 2. Mean Total MSIS Score Improved From Baseline to Month 8

Figure 3. Mean PDDS Score Improved From Baseline to Month 8

Statistical Analyses

- Pairwise t-tests (2-sided) were used to evaluate the statistical significance of change in each PRO score from baseline to each time assessment
- For the MSIS-29, clinically meaningful changes in mean scores were determined based on published reference data

Acknowledgments and Disclosures

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