Patients With Highly Active RRMS Despite Prior Therapy Show Durable Improvement With Alemtuzumab Over 5 Years

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OBJECTIVE

- To evaluate 5-year efficacy in a subset of patients with RRMS and highly active disease at baseline who were treated with alemtuzumab in CARE-MS II

CONCLUSIONS

- Efficacy of alemtuzumab in patients with highly active RRMS despite an inadequate response to prior therapy was durable in the extension through Year 5 despite most not receiving treatment since Month 12 (4 years of no retreatment)

INTRODUCTION

- Highly active disease is defined as use of other DMTs was permitted at the investigator’s discretion

Study Design

- CARE-MS I study (NCT00548405); alemtuzumab demonstrated greater improvements in clinical and MRI outcomes over 2 years than SC IFNB-1a in patients with active RRMS and an inadequate response (≥1 relapse) to a prior therapy at baseline

- In the ongoing extension study (NCT00535533), alemtuzumab showed durable efficacy on clinical and MRI outcomes through Year 5, during which most patients did not receive alemtuzumab after the initial 2 courses in the core study, or another disease-modifying therapy (DMT)1,2

- Most patients showed improved or stable EDSS scores through retreatment since the initial 2 courses at core study baseline and 12 mg in 3 course at baseline 3 years after relapses

METHODS

- High activity disease definition: ≥2 relapses in the year prior to randomization and ≥1 Gd-enhancing lesion at core study baseline

Assessments

- Annualized relapse rate (ARR) and proportion of patients free of relapse

- EDSS score was assessed quarterly by blinded raters

RESULTS

Patients

- Of 435 patients treated with alemtuzumab 12 mg in CARE-MS I, 103 patients (24%) met highly active disease criteria at core study baseline

- 99 (97%) of the 103 highly active patients entered the extension study, 98 (97%) remained on study through Month 60 (Year 5) and 92 (92%) patients were on study through Month 12 and no other DMT

- 89 (91%) patients did not receive retreatment with alemtuzumab

Efficacy

- ARR remained low in each individual year of the extension study

- Mean EDSS score change from baseline to Year 5

- Patients with no evidence of 6-month CDW or those who achieved 6-month CDW and received no alemtuzumab

- Patients achieving 6-month CDL, %

Table 1. Disability Outcomes in the Highly Active Subgroup

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Highly Active Patients YS1,2</th>
<th>No. of Patients</th>
<th>Mean EDSS score change from baseline to Year 5</th>
<th>Patients with no evidence of 6-month CDW, %</th>
<th>Patients achieving 6-month CDL, %</th>
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<td>Patient</td>
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<td>M=month; Y=year</td>
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<td>Y0-5 (95% CI)</td>
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<td>76/101</td>
<td>+0.03</td>
<td>74.5</td>
<td>44.9</td>
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<td>77/101</td>
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<td>69/68</td>
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</table>

Figure 1. Durable Efficacy of Alemtuzumab on Relapses in Each Year of the Extension Study

Figure 2. Durable Efficacy on Disability Improvement in Each Year of the Extension Study

Figure 3. Most Patients Had No Evidence of Clinical Disease Activity in Each Year of the Extension Study

Figure 4. Most Patients Had No Evidence of MRI Disease Activity in Each Year of the Extension Study

Figure 5. Durable Efficacy of Alemtuzumab on EDSS in Each Year of the Extension Study

CONCLUSIONS

- Based on these findings, alemtuzumab may provide a unique treatment approach with durable efficacy in the absence of continuous treatment for patients with highly active RRMS

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References


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