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Alemtuzumab provides durable improvements in clinical outcomes in treatment-naive patients with active relapsing-remitting multiple sclerosis over 6 years in the absence of continuous treatment (CARE-MS I)

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Background: In the phase 3 CARE-MS I clinical trial (NCT00530348), alemtuzumab significantly reduced annualised relapse rate (ARR), MRI disease activity, and brain volume loss versus subcutaneous interferon beta-1a over 2 years in patients with active relapsing-remitting multiple sclerosis (RRMS) who were treatment-naive at baseline (BL). An extension study (NCT00930553) has shown durable efficacy through 5 years in the absence of continuous treatment.

Goal: To evaluate 6-year clinical efficacy and safety of alemtuzumab in patients who were treatment-naive at BL.

Methods: In CARE-MS I, patients received 2 courses of alemtuzumab 12 mg (Month 0: 5 days; Month 12: 3 days). At the end of Year 2, patients who completed the study could enter the extension, with as-needed alemtuzumab for relapse or MRI activity. Another disease-modifying therapy could be provided per investigator discretion. Assessments: ARR, proportion of patients free from 6-month confirmed disability worsening (CDW; ≥1-point Expanded Disability Status Scale [EDSS] increase [≥1.5-point if BL EDSS=0]), with 6-month confirmed disability improvement (CDI; ≥1-point EDSS decrease [BL score ≥2.0]), no evidence of disease activity (NEDA), and adverse events (AEs).

Results: Through 6 years, 325/349 (93%) patients who enrolled in the extension remained on study. ARR remained low through the extension (0.12 at Year 6). Through 6 years, 77% of patients were free from 6-month CDW and 34% achieved 6-month CDI. Proportions of patients with stable or improved EDSS remained high through the extension (81% at Year 6); the majority of patients achieved NEDA annually in the extension (57% at Year 6). These efficacy results were achieved with most patients (63%) receiving no additional treatment after their initial 2 courses of alemtuzumab. The overall rate of AEs decreased over time. The rate of thyroid AEs peaked at Year 3 and subsequently declined. Infusion-associated reactions decreased with additional treatment courses. The serious AE rate was low, including the rate of serious infections, which declined throughout the extension.

Conclusion: Clinical efficacy of alemtuzumab was maintained for 6 years in patients who were treatment-naive, despite most receiving no additional treatment since the initial 2 courses of alemtuzumab. Based on these findings, alemtuzumab may provide a unique treatment approach with durable efficacy in the absence of continuous treatment for RRMS patients.

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