DURABLE EFFECT ON DISEASE-FREE OUTCOMES WITH ALEMTUZUMAB: 3-YEAR FOLLOW-UP OF THE CARE-MS STUDIES

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INTRODUCTION: Alemtuzumab demonstrated superior efficacy versus subcutaneous interferon beta-1a (SC IFNB-1a), with a consistent and manageable safety profile, in active relapsing-remitting multiple sclerosis (RRMS) patients who were treatment-naive (CARE-MS I; NCT00530348) or had inadequate efficacy response to prior therapy (CARE-MS II; NCT00548405). Alemtuzumab patients were more likely than SC IFNB-1a patients to have no evidence of disease activity (NEDA) after 2 years. This analysis examined the proportion of patients who received alemtuzumab at the beginning of CARE-MS studies that achieved NEDA after 3 years.
METHODS: Alemtuzumab-treated (12 mg/day intravenously on 5 consecutive days; 3 consecutive days 1 year later) patients continued in an extension (NCT00930553) and were offered retreatment on evidence of disease activity. Clinical activity (≥1 relapse, or 6-month sustained accumulation of disability [Expanded Disability Status Scale score increase from baseline of ≥1.0; ≥1.5 if baseline EDSS=0]), magnetic resonance imaging (MRI) activity (≥1 new gadolinium-enhancing or new/enlarging T_2 hyperintense lesion), and NEDA (absence of clinical and MRI activity) were assessed at Year 3.
RESULTS: 349 CARE-MS I and 393 CARE-MS II alemtuzumab patients entered the extension; 18% and 20% were retreated in Year 3. Most were free of clinical (83% and 76%) and MRI (72% and 68%) activity, and achieved NEDA (64% and 55%) in Year 3. Similar proportions of patients met the NEDA definition in Years 2 and 3.
CONCLUSIONS: Similar proportions of alemtuzumab patients achieved NEDA from Year 2 to 3, and most received no retreatment in Year 3, supporting the durable efficacy of alemtuzumab in RRMS.