

Efficacy of a third course of alemtuzumab in patients with active relapsing-remitting multiple sclerosis who experienced disease activity after the initial two courses: pooled analysis of CARE-MS I and II

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Background: Alemtuzumab improved efficacy outcomes in 2-year (y), phase 3 trials vs SC IFNB-1a in RRMS patients (CARE-MS I: treatment-naïve [NCT00530348]; CARE-MS II: inadequate response to prior therapy [NCT00548405]). Patients continuing in an extension (NCT00930553) demonstrated durable 6-y efficacy; 27% (pooled CARE-MS I/II) received only 1 alemtuzumab retreatment (Course 3 [C3]) through Y6. Goal: Evaluate alemtuzumab retreatment efficacy in pooled CARE-MS I/II patients who received C3. Methods: Patients received 2 courses of alemtuzumab 12 mg/day (baseline: 5 days; Month 12: 3 days) in CARE-MS I/II, and could receive as-needed alemtuzumab retreatment (for relapse/MRI activity) or another DMT (investigator discretion) in the extension. Assessments: annualized relapse rate (ARR); mean EDSS change; improved/stable EDSS; 6-month confirmed disability improvement (CDI). Patients receiving >C3 or another DMT were excluded. Conclusion: A third alemtuzumab course effectively reduced relapses and improved disability without further treatment. These data support administering C3 in patients with disease activity to achieve durable disease control.