ALEMTUZUMAB HAS DURABLE EFFICACY IN RELAPSING-REMITTING MULTIPLE SCLEROSIS PATIENTS: CARE-MS EXTENSION

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Two 2-year phase 3 trials comparing alemtuzumab to subcutaneous interferon beta-1a in RRMS patients who were treatment-naïve (CARE-MS I) and who had relapsed on prior disease-modifying therapy (CARE-MS II) found significant positive treatment effects for alemtuzumab on relapses (both studies) and accumulation of disability (CARE-MS II). An extension study is investigating the durability of alemtuzumab's efficacy. Disability was assessed quarterly by blinded raters with the Expanded Disability Status Scale (EDSS). Relapses were assessed as-needed by the treating neurologist. Patients originally treated with alemtuzumab also received safety monitoring and were eligible to receive additional alemtuzumab upon evidence of resumed disease activity. Re-treatment courses were 12 mg/day alemtuzumab intravenously infused once daily for 3 days. Year 1 extension data are reported. 349 CARE-MS I and 386 CARE-MS II alemtuzumab patients enrolled in the extension. Annualized relapse rates during Extension Year 1 were 0.24 for CARE-MS I and 0.25 for CARE-MS II alemtuzumab patients. Mean EDSS scores for CARE-MS I were Baseline: 2.0; Month 24: 1.9; Extension Baseline: 1.8, and Extension Year 1: 1.9. Mean EDSS scores for CARE-MS II was Baseline: 2.7; Month 24: 2.5; Extension Baseline: 2.5, and Extension Year 1: 2.6. Re-treatment data will be presented. Safety experience during the extension was consistent with previously reported adverse events, including thyroid, immune thrombocytopenia, and autoimmune nephropathies. Efficacy was maintained through the first year of the extension study. Low annualized relapse rates were observed for alemtuzumab patients from both studies. EDSS remained stable in the patients during Extension Year 1.