Efficacy of Alemtuzumab Is Durable Over 6 Years in Patients With Active Relapsing-Remitting Multiple Sclerosis and an Inadequate Response to Prior Therapy in the Absence of Continuous Treatment (CARE-MS II)

H.P. Hartung[1], R. Alroughani[2], D. Brassat[3], S. Broadley[4], E. Havrdova[5], C. Oreja-Guevara[6], K. W. Selmaj[7], B. Singer[8], P.Vermersch[9], S. Wray[10], D. H. Margolin[11], K. Thangavelu[11], M. Chirieac[11], E. J. Fox[12]
[1]*Multiple Sc, Heinrich-Heine University, Germany*
[2]*Multiple Sc, Amiri Hospital, Kuwait*
[3]*Purpan Hospital and Mixed Unit of Research 1043, University of Toulouse, France*
[4]*School of Medicine, Gold Coast Campus, Griffith University, Australia*
[5]*First Medical Faculty, Charles University in Prague, Czech Republic*
[6]*Multiple Sc, University Hospital San Carlos, Spain*
[7]*Multiple Sc, Medical University of Lodz, Poland*
[8]*MS Center for Innovations in Care, Missouri Baptist Medical Center, USA*
[9]*Multiple Sc, University of Lille Nord de France, France*
[10]*Multiple Sc, Hope Neurology, USA*
[11]*Multiple Sc, Sanofi Genzyme, USA*
[12]*Multiple Sc, Central Texas Neurology Consultants, USA*

BACKGROUND: Patients with active RRMS and inadequate response to prior therapy (≥1 relapse after ≥6 months of treatment) had improved outcomes with alemtuzumab versus SC IFNB-1a over 2 years (CARE-MS II; NCT00548405). An extension (NCT00930553) demonstrated durable efficacy through 5 years in the absence of continuous treatment.
GOAL: Evaluate 6-year efficacy and safety of alemtuzumab in CARE-MS II patients.METHODS: Patients received 2 courses of alemtuzumab 12 mg (baseline: 5 days; 12 months later: 3 days) in CARE-MS II with as-needed alemtuzumab retreatment for relapse/MRI activity, or another DMT per investigator discretion, in the extension. Assessments: ARR; freedom from 6-month CDW (≥1-point EDSS increase [≥1.5-point if baseline EDSS=0]); 6-month CDI (≥1-point EDSS decrease [baseline score ≥2.0]); NEDA; AEs. RESULTS: Through 6 years, 344/393 (88%) patients remained on study. ARR remained low (Year 6: 0.15). 72% of patients were free from 6-month CDW; 43% achieved 6-month CDI. Mean EDSS increase from baseline was 0.10 (Years 0–6); 77% had improved or stable EDSS at Year 6. Most patients achieved annual NEDA (Year 6: 60%). 50% received no additional treatment after 2 initial courses of alemtuzumab. AEs decreased over time. Thyroid AEs peaked at Year 3 then declined. Infusion-associated reactions decreased with additional treatment courses. Serious AE rates, including infections, were low. CONCLUSION: Efficacy was maintained over 6 years with 50% of patients receiving no additional treatment after 2 initial alemtuzumab courses. Based on these findings, alemtuzumab may provide a unique treatment approach with durable efficacy in the absence of continuous treatment.