

ALEMTUZUMAB DEMONSTRATES PERSISTENT CLINICAL EFFICACY OUTCOMES OVER 5 YEARS IN PATIENTS WITH ACTIVE RELAPSING-REMITTING MULTIPLE SCLEROSIS, WITH MOST NOT RECEIVING RETREATMENT: CARE-MS I AND II EXTENSION STUDIES

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BACKGROUND: Patients with active relapsing-remitting multiple sclerosis (RRMS) who were treatment-naïve (CARE-MS I; NCT00530348) or with inadequate response (≥ 1 relapse) to prior therapy (CARE-MS II; NCT00548405) had improved outcomes with alemtuzumab versus SC IFNB-1a over 2 years.

OBJECTIVE: To examine alemtuzumab's efficacy and safety over 5 years in CARE-MS patients.

METHODS: Patients received 2 courses of alemtuzumab 12 mg (Months 0 and 12), with as-needed retreatment for disease activity, or another disease-modifying therapy (DMT). Annualised relapse rate (ARR), 6-month confirmed disability progression (≥ 1 -point Expanded Disability Status Scale [EDSS] increase [≥ 1.5 -point if baseline EDSS=0]), and 6-month sustained reduction in pre-existing disability (SRD; ≥ 1 -point EDSS decrease [baseline ≥ 2.0]) were assessed.

RESULTS: 349 (95%) and 393 (93%) CARE-MS I and II patients entered extension (NCT00930553), respectively; 68% and 60% received no alemtuzumab since initial 2 courses; 98% and 92% received no other DMT. ARRs remained low from Year 3 (0.19 and 0.22) to Year 5 (0.15 and 0.18). Through Years 0–5, 80% and 75% were free from 6-month confirmed disability progression, and 33% and 43% achieved 6-month SRD. Infusion-associated reactions and infections were reduced versus core studies, and serious adverse events (AE) were low. Thyroid AEs peaked at Year 3, then declined.

CONCLUSIONS: Alemtuzumab improved relapse and disability outcomes over 5 years despite most patients not receiving retreatment. Based on these findings, for the majority of RRMS patients, alemtuzumab may provide an innovative treatment approach with efficacy persisting through 5 years in the absence of continued treatment and associated treatment burden.

Study supported by Sanofi Genzyme and Bayer Healthcare Pharmaceuticals.