ALEMTUZUMAB REDUCES DISEASE ACTIVITY IN TREATMENT-NAIVE PATIENTS WITH HIGHLY ACTIVE RELAPSING-REMITTING MULTIPLE SCLEROSIS

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INTRODUCTION: In treatment-naive relapsing-remitting MS (RRMS) patients [CARE-MS I (NCT00530348)], alemtuzumab significantly improved annualized relapse rate (ARR), magnetic resonance imaging (MRI) outcomes, and proportion of patients with no evidence of disease activity (NEDA) compared with subcutaneous interferon beta-1a (SC IFNB-1a), with manageable safety. Here we assess efficacy and safety of alemtuzumab versus SC IFNB-1a in CARE-MS I patients with highly active disease.

METHODS: CARE-MS I was a 2-year, randomized, rater-blinded study of alemtuzumab (12 mg intravenously in 2 annual courses) versus SC IFNB-1a (44 µg 3 times/week). Patients with highly active RRMS had ≥2 relapses the year before randomization and ≥1 baseline gadolinium (Gd)-enhancing lesion. MRI was performed annually. NEDA definition: absence of relapse, 6-month sustained accumulation of disability (Expanded Disability Status Scale score increase from baseline of ≥1.0 [≥1.5 if baseline EDSS=0]), new Gd-enhancing lesions, and new/enlarging T_2 hyperintense lesions.

RESULTS: Demographics were similar in alemtuzumab- (n=105) and SC IFNB-1a-treated (n=61) highly active patients. At Year 2, alemtuzumab reduced ARR by 51% versus SC IFNB-1a (*P*=0.0068). Alemtuzumab-treated patients had fewer Gd-enhancing, new/enlarging T_2, and new T_1 hypointense lesions, black hole conversions, and smaller reductions from baseline in brain parenchymal fraction (*P*0.05). Alemtuzumab-treated patients were more likely to achieve NEDA compared to SC IFNB-1a patients (25.5% versus 20.0%; *P*=0.0002). The adverse event profile of alemtuzumab was similar to the overall study cohort.

CONCLUSIONS: Alemtuzumab reduced disease activity versus SC IFNB-1a in treatment-naive patients with highly active RRMS, with a safety profile that was similar to the overall treatment group.