ALEMTUZUMAB-TREATED PATIENTS WITH ACTIVE RELAPSING-REMITTING MULTIPLE SCLEROSIS DEMONSTRATED SLOWING OF BRAIN VOLUME LOSS OVER 5 YEARS, WITH MOST PATIENTS NOT RECEIVING RETREATMENT FOR 4 YEARS

Krzysztof W. Selmaj¹, D. Alastair S. Compston², Massimo Filippi³, Gavin Giovannoni⁴, Hans-Peter Hartung⁵, Eva Havrdova⁶, Sven Schippling⁷, David H. Margolin⁸, Karthinathan Thangavelu⁸, Douglas L. Arnold^{9,10}

on behalf of the CARE-MS I and CARE-MS II Investigators

Medical University of Łódź, Łódź, Poland
²School of Clinical Medicine, University of Cambridge, UK
³San Raffaele Scientific Institute, Vita-Salute San Raffaele University, Italy
⁴Queen Mary University of London, Barts and The London School of Medicine, UK
⁵Heinrich-Heine University, Düsseldorf, Germany
⁶First Medical Faculty, Charles University in Prague, Czech Republic
⁷Neuroimmunology and Multiple Sclerosis Research, University Hospital Zurich and University of Zurich, Switzerland
⁸Sanofi Genzyme, Cambridge, USA
⁹NeuroRx Research, Montréal, Canada
¹⁰Montréal Neurological Institute, McGill University, Canada

kselmaj@afazja.am.lodz.pl

BACKGROUND: Patients with active relapsing-remitting multiple sclerosis (RRMS) who were treatment-naive (CARE-MS I; NCT00530348) or who had inadequate response (≥1 relapse) to prior therapy at baseline (CARE-MS II; NCT00548405) demonstrated significant slowing of brain volume (BV) loss over 2 years with alemtuzumab versus SC IFNB-1a. Slowing persisted through 4 years, despite most patients not receiving retreatment.

OBJECTIVE: To examine alemtuzumab's effect on BV over 5 years in patients in the CARE-MS extension (NCT00930553).

METHODS: Patients were randomised to 2 annual alemtuzumab courses (Months 0 and 12), with asneeded retreatment for relapse and/or magnetic resonance imaging disease activity, or another disease-modifying therapy (DMT). BV loss was measured annually by brain parenchymal fraction change.

RESULTS: 349 (95%) CARE-MS I and 393 (93%) CARE-MS II alemtuzumab patients entered the extension; 68% in CARE-MS I and 60% in CARE-MS II received no alemtuzumab treatment since Month 12, and 98% and 92% received no other DMT. Over 4 years, median annual rate of BV loss was reduced and remained low in CARE-MS I (Years 1–5: –0.59%, –0.25%, –0.19%, –0.15%, and –0.20%, respectively) and CARE-MS II (Years 1–5: –0.48%, –0.22%, – 0.10%, –0.19%, and –0.07%).

CONCLUSIONS: Slowing of BV loss with alemtuzumab was maintained over 5 years in patients with RRMS, despite most not receiving additional treatment beyond 12 months. 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.