Brain MRI Activity and Atrophy in Ocrelizumab-Treated Relapsing Multiple Sclerosis Patients in the Open-Label Extension of the Pooled OPERA Trials

A Traboulsee, DL Arnold, L Kappos, SL Hauser, X Montalban, JS Wolinsky, V Levesque, PVilloslada, SBelachew, FMF Model, SHubeaux, ABaro-Or

University of British Columbia, Vancouver, BC, Canada; McGill University, Montreal, QC, Canada; Neurology Research, Montreal, QC, Canada; University Hospital Basel, University of Basel, Basel, Switzerland; University of California, San Francisco, San Francisco, CA, USA; Division of Neurology, University of Toronto, Toronto, ON, Canada; Vall d’Hebron University Hospital, Barcelona, Spain; McGovern Medical School, UTHouston, Houston, TX, USA; Genetech, Inc, South San Francisco, CA, USA; Hoffman-LaRoche Ltd., Basel, Switzerland; University of Pennsylvania, Philadelphia, PA, USA

Background: Ocrelizumab (OCR) is a human monoclonal antibody that selectively targets CD20+ B cells, while preserving the capacity of mature B cells to maintain humoral immunity.

Methods: In two identical Phase III, randomized, double-blind, double-dummy studies (OPERA I [NCT02382532] and OPERA II [NCT02382540]), patients with relapsing-remitting, secondary progressive, and primary progressive multiple sclerosis (MS) received OCR 600 mg or IFN β-1a 44 µg SC weekly for 2 years (Phase 1: 24–48 weeks) and then were randomized in a 2:1 ratio to continue in the open-label extension (OLE) phase for 1 additional year in those who had completed 2 years of the double-blind (DB) phase. Among patients switching from IFN β-1a to OCR, the adjusted mean of percentage change in gray matter volume (GMV) was −0.3 (p = 0.6) at OLE Week 46 (Year 3/OLE Year 1) and −0.7 (p = 0.1) at OLE Week 94 (Year 4/OLE Year 2) (Figure 4). Among patients receiving continuous OCR, the adjusted mean of percentage change in GMV was −0.7 (p < 0.001) at OLE Week 46 (Year 3/OLE Year 1) and −1.3 (p < 0.001) at OLE Week 94 (Year 4/OLE Year 2) (Figure 4).

Conclusions: Overall, 86% of patients who entered the OLE phase of the OPERA studies completed Year 2 of the OLE, with a similar percentage completing Year 3. Ocrelizumab was well tolerated and maintained its safety and efficacy profile in comparison with IFN β-1a.

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