Infusion-Related Reactions With Ocrelizumab in the Phase III Studies

J de Seze,¹ SL Hauser,² L Kappos,³ X Montalban,⁴ C Pozzilli,⁵ C Chognot,⁶ L Julian,⁷ H Koendgen,⁸ H Zheng,⁹ JS Wolinsky⁸

¹University of Strasbourg, Strasbourg, France; ²University of California, San Francisco, San Francisco, CA, USA; ³University Hospital Basel, University of Basel, Basel, Switzerland; ⁴Vall d’Hebron University Hospital, Barcelona, Spain; ⁵Sapienza University of Rome, Rome, Italy; ⁶F. Hoffmann-La Roche Ltd, Basel, Switzerland; ⁷Genentech, Inc., South San Francisco, CA, USA; ⁸University of Texas Health Science Center at Houston, Houston, TX, USA

BACKGROUND

• The efficacy and safety of ocrelizumab (OCR) in Phase III studies in patients with relapsing multiple sclerosis (RMS) (OPERA I/II (NCT01127524) and OPERA II (NCT01143236) and primary progressive multiple sclerosis (PPMS) (ORATORIO (NCT01738546) and ORATORIO II) have been reported previously.

METHODS

Studies

• OPERA I and OPERA II (Pooled analyses): Patients with RMS were randomized 1:1 to receive double-blind, double-dummy treatment for 126 weeks with either OCR 600 mg IV every 6 weeks or IFN β-1a 44 μg subcutaneously (SC) every 4 weeks (Figure 1).

For OPERA I/II and ORATORIO study design (Figure 1), scan here.

Results

• The majority of IRRs in patients within the OCR treatment groups (Pooled analyses and OPERA II [per-protocol]) were mild to moderate in severity and manageable with pretreatment and symptomatic management

DISCUSSIONS

• Among OCR recipients who experienced an IRR on Day 1 within OPERA I and OPERA II (Pooled analyses) n/N=275/623 (44.3%) and n/N=154/266 (57.7%), 66.7% of patients within the OCR pooled analyses (n=100) and 64% of patients within ORATORIO (n=70) had a subsequent IRR

Figure 2. IRR frequencies

Table 1. IRR frequencies by dose and pretreatment

Figure 3. IRR frequencies by dose and intensity

Figure 4. OCR-related IRR frequency and intensity by pretreatment

Acknowledgments

Conflict of interest: C. Pozzilli, L. Julian, H. Zheng and JS Wolinsky: consulting and/or speaking fees from Genentech/Roche. C. Chognot is an employee of F. Hoffmann-La Roche Ltd. L. Julian is an employee of Genentech, Inc. H. Zheng is an employee of Genentech, Inc. J.S. Wolinsky has received personal compensation for the development of research materials, travel, accommodations, or meal expenses. E. Levy, K. Kappos, G. Magliulo, C. Pozzilli, L. Julian, H. Zheng, and JS Wolinsky have no conflicts of interest to report.