Infusion-Related Reactions With Ocrelizumab in the Phase III Double-Blind, Double-Dummy, Interferon β-1a–Controlled OPERA I and OPERA II Studies

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DISCLOSURES

• The incidence of IRRs was assessed in patients with RMS in a pooled safety analysis of OPERA I and OPERA II

RESULTS

• IRRs with ocrelizumab administration were most frequent with the first infusion and decreased in incidence and severity with subsequent doses

• The incidence of IRRs was assessed in patients with RMS in a pooled safety analysis of OPERA I and OPERA II

• The most frequent (>10%) IRR symptoms reported by the 11 patients who withdrew from treatment were rash, pruritis, throat irritation, dyspnea, and headache

• Patients were assigned (1:1) to ocrelizumab (OCR) arm (600 mg; biweekly) vs interferon β-1a (IFN β-1a) arm (44 µg, subcutaneous) every 21 days or subcutaneous (SC) IFN β-1a 44 µg three times weekly

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• Premedication was recommended to lower the incidence and severity of IRRs; most IRRs were generally manageable with infusion adjustments

• Optional prophylactic treatment with an analgesic/antipyretic such as acetaminophen/paracetamol (1 g) and/or an IV or oral antihistaminic such as diphenhydramine (25-100 mg) was offered to all patients

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• To reduce the incidence of potential IRRs, all patients received prophylactic treatment with methylprednisolone (100 mg), administered by slow IV infusion (while patients were in the clinic) and 24 hours post-infusion (while patients were not in the clinic; Table 1)

• The most frequent (>10%) IRR symptoms in the OCR group were pruritis, throat irritation and flushing (Table 1)

• The incidence of IRRs was assessed in patients with RMS in a pooled safety analysis of OPERA I and OPERA II

• IRRs were to be treated symptomatically with oral acetaminophen/paracetamol (1 g) and intramuscular or slow IV antihistamines such as diphenhydramine (25-100 mg)

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• Simple rash occurring at the site of the drug injection was typically managed with the use of a topical corticosteroid and discontinuation of treatment

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