Design of a study to evaluate the safety of administering ocrelizumab per a shorter infusion protocol in patients with primary progressive multiple sclerosis and relapsing multiple sclerosis

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Introduction

Ocrelizumab (OCR) is an intravenously-administered humanised $CD20^+$ B cell-selective monoclonal antibody approved for the treatment of relapsing (RMS) and primary progressive (PPMS) multiple sclerosis. Infusions of OCR are approximately 2.5–3.5 hours in duration. In Phase III studies of OCR in patients with RMS (OPERA I [NCT01412333], OPERA II [NCT01247324]) and PPMS (ORATORIO [NCT01194570]), infusion-related reactions (IRRs) were a common but manageable adverse event.

Objective

To describe an open-label, non-randomized study evaluating IRRs with OCR infused over a shorter time period.

Methods

This study includes patients aged 18–55 years with RMS or PPMS (2017 McDonald criteria) and an Expanded Disability Status Scale score of 0–6.5; those who previously experienced a serious or life-threatening IRR with OCR are excluded. Patients will be divided into two cohorts. Cohort 1 will include patients who completed one or two doses of OCR as per US prescribing information (PI) prior to enrolment; these patients will receive their second or third dose of OCR 600 mg administered over a reduced infused time of 2 hours. Patients in Cohort 2 received the first 300-mg infusion of OCR Dose 1

over 2.5 hours, per US PI, prior to enrolment; the second infusion of Dose 1 (300 mg) will be administered over 1.5 hours. The primary endpoint is the rate and frequency of National Cancer Institute Common Terminology Criteria for Adverse Events v4.0 Grade 3 and 4 IRRs in Cohort 1; secondary endpoints include rate and frequency of IRRs Grades 1-4 in both cohorts.

Results

Enrolment began in the second half of 2018 with a planned total of 150 patients (Cohort 1: 100; Cohort 2: 50). The study is currently ongoing; updated status will be reported.

Conclusions

This study will provide information on the safety (i.e., IRRs) and tolerability of administering OCR per a shorter infusion protocol.

Disclosures

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