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Subcutaneous Ocrelizumab in Patients With Multiple Sclerosis: Results of the Phase III OCARINA II Study

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Supplementary Materials

Results
Treatment and study withdrawal[a]

Patients originally randomized and ongoing in the OCR SC treatment period	OCR IV/SC (n=114/118)[b]	OCR SC/SC (n=115/118)
Discontinued treatment	4	3
Reasons for discontinuation:		
Pregnancy	1	1
Lack of efficacy	0	1
Withdrawal by subject	1	1
Physician decision	2[c]	0
Discontinued from the study	3	2
Reasons for discontinuation:		
Pregnancy	0	1
Lack of efficacy		
Withdrawal by subject	1	1
Physician decision	2	0

At CCOD, one patient from each arm were ongoing in the SFU period, and no patients had completed the SFU

Overall, the treatment withdrawal rate was low and similar between both arms

[a]The first patient was enrolled on May 3, 2022 and the CCOD was on March 10, 2023 where none of the patients had completed the SFU; [b]Of the 118 patients randomized to the OCR IV/SC arm, three patients did not receive OCR SC treatment; [c]One patient randomized to the IV/SC arm who experienced infections (one SAE of cellulitis Staphylococcal and two SAEs of SC abscess) withdrew from treatment during the controlled period. The SAEs were not considered related to OCR treatment. The patient was withdrawn due to the physician decision (participant's safety concerns with recurrent MSSA skin infection).
CCOD, clinical cut-off date; IV, intravenous; MSSA, methicillin-susceptible Staphylococcus aureus; OCR, ocrelizumab; SAE, serious adverse events; SC, subcutaneous; SFU, safety follow-up.