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Novel Assessment of Real-world Effectiveness of Ocrelizumab for Treatment of Patients with Relapsing and Primary Progressive Multiple Sclerosis: Design of a Multicenter Non-interventional Study (musicale Study)

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Background: Ocrelizumab is a monoclonal antibody which selectively targets CD20+ b cells and is approved for the treatment of relapsing (RMS), and primary progressive multiple sclerosis (PPMS). The efficacy and safety of ocrelizumab have been studied in one phase ii and three phase iii randomised controlled clinical trials. However, long-term data from real-world settings, in particular capturing patient-reported outcomes (PROS), are still missing. The objective is to report the design of the musicale study, a multicentre non-interventional prospective study, which will evaluate the effectiveness of ocrelizumab in patients with RMS and PPMS when used in clinical practice.
Methods: Over 1,000 patients with RMS or PPMS for whom ocrelizumab has been newly prescribed from 20 countries are planned for enrolment. Patients will receive ocrelizumab according to the approved label and will be managed as per routine clinical care over four years. The real-world effectiveness of ocrelizumab will be evaluated using several PROS: Symptomscreen, multiple sclerosis impact scale-29, fatigue scale for motor and cognitive functions, abilhand and work productivity and activity impairment in multiple sclerosis. The costs of all healthcare and other resource utilisations related to MS will also be assessed using a MS resource use questionnaire. Satisfaction with treatment will be captured using a treatment satisfaction questionnaire for medication. Various conventional clinical and imaging outcomes will also be collected, including the number and character of MS relapses, the expanded disability status scale, and MRI outcomes as per routine care. Safety and tolerability will be evaluated by adverse event reporting at each visit.
Results: Patient recruitment will begin in november 2018 with interim analyses reported approximately each year.
Conclusions: The study results are expected to provide meaningful patient-related information on the real-world effectiveness of ocrelizumab in RMS and PPMS patients and help establish correlation between relevant PROS and conventional clinical endpoints.