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Utilization, safety, and tolerability of ocrelizumab: year 2 data from the Providence Ocrelizumab Registry

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Background: Ocrelizumab (OCR), a humanized anti-CD20 monoclonal antibody, was approved in the US in 2017 for the treatment of relapsing MS (RMS) and primary progressive MS (PPMS). The Providence OCR Registry was established to monitor long-term treatment and safety outcomes.
Objective: To evaluate OCR treatment outcomes using real-world data from a diverse, community-based MS population.
Methods: Adult MS patients who have been prescribed OCR were eligible. Chart reviews at OCR start date and then every 6 months were done by a trained RN. Expanded Disability Status Scale (EDSS) scores were determined by the treating provider on the start date and then yearly. **Results:** Of the 308 patients enrolled from March 2017 to March 2019, 72.6% were female; mean (SD) age was 51.9 (12.0) years; 76.3% had RMS, 14.3% had SPMS, and 9.4% had PPMS. Median baseline EDSS [interquartile range (IQR)] was 3.0 [2.0, 4.0], 6.5 [6.0, 7.5], and 6.5 [5.8, 7.1] respectively. The RMS cohort had an annualized relapse rate (ARR) of 0.34 prior to starting OCR. Among all patients who had > 1 dose of OCR (n=262), ARR was 0.10 with two patients having two relapses. Median EDSS scores at 12 months were 3.0 [2.0, 5.0] (n=98) for RMS patients, 6.5 [5.5, 7.5] (n=23) for SPMS, and 6.5 [5.0, 7.5] (n=13) for PPMS. Infusion reactions occurred in 33.6% of patients during dose one, becoming less frequent with subsequent doses (15.1%). Respiratory infections occurred in 32.1% of patients followed by urinary tract infections (UTI) (25.3%). Of the 22 hospitalizations that have occurred, 9 were due to infection, majority due to UTIs (89.9%) with four patients developing sepsis. Eighteen (81.8%) of these patients were 55 years or older. Twenty-two (7.1%) patients have stopped OCR with a median time to discontinuation [IQR] of 7.0 [4.6, 11.1] months; eleven patients stopped due to side effects, three patients stopped due to a relapse, and three patients died one each due to urosepsis, suicide, and respiratory distress. No significant changes in Beck Depression Inventory (BDI) or Modified Fatigue Impact Scale (MFIS) from baseline to 6 months including patients transitioning from natalizumab (n=12).
Discussion: Our study showed that OCR was effective in controlling relapse and disability worsening and reported similar rates of infusion reactions compared to earlier phase III clinical trials. Although only a small percentage of patients have stopped OCR, infections resulting in hospitalization are a concern, especially in older patients.