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# Safety of ocrelizumab in multiple sclerosis: Updated analysis in patients with relapsing and primary progressive multiple sclerosis

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## Introduction:

The long-term benefit–risk profile of ocrelizumab (OCR) in patients (pts) with multiple sclerosis (MS) can be evaluated by regular safety reporting of clinical trial (CT) and post-marketing (PM) data. Safety/efficacy of OCR have been characterised in Phase II (NCT00676715) and Phase III (NCT01247324; NCT01412333; NCT01194570) trials and related open-label extension (OLE) periods, in relapsing-remitting MS, relapsing MS (RMS) and primary progressive MS (PPMS). It is important to understand the long-term safety profile of OCR.

## Objectives/Aims:

To understand the consistency of the safety profile by examining longer-term safety from OCR CT and OLE periods over >10-year follow-up period (up to November 2022).

## Methods:

Safety outcomes are reported for the OCR all-exposure population from 12 ongoing or completed CTs in MS. Rates per 100 patient years (PY) are presented.

## Results:

For more than 10 years of follow-up, 6,155 pts with MS received OCR treatment in 12 CTs (28,269 PY of exposure; November 2022). Reported rates per 100 PY (95% CI) were: Adverse events (AEs), 230.32 (228.55–232.09); infections, 71.24 (70.26–72.23); serious AEs, 7.97 (7.64–8.30); serious infections (SIs), 3.04 (2.84–3.25); malignancies, 0.49 (0.41–0.58); SIs leading to treatment withdrawal, 0.14 (0.10–0.19); and AEs leading to treatment discontinuation, 1.08 (0.96–1.21). As of March 2023, over 300,000 pts with MS initiated OCR globally in the PM setting. Data remain generally consistent with those observed in CTs despite the burden of the pandemic in a more heterogeneous population.

## Conclusion:

AE rates in the OCR all-exposure population remain generally consistent with the controlled treatment period in RMS/PPMS populations. SI and malignancy rates remain within the range reported for pts with MS in real-world registries. COVID-19 did not lead to increased treatment withdrawal. For more than 10 years of continuous 6-monthly treatment with OCR, no new or unexpected safety signal was seen in pts treated with OCR in ongoing CTs. The benefit–risk profile of OCR continues to be stable and consistent with previous observations over >10 years of treatment. Regular reporting of longer-term safety data will continue.

## Disclosures:

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