Pregnancy Outcomes in Patients Treated
With Ocrelizumab

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INTRODUCTION AND PURPOSE
• Ocrelizumab (OCR), a humanized monoclonal antibody that selectively targets CD20+ B cells, is approved for the treatment of relapsing forms of multiple sclerosis (MS) and primary progressive multiple sclerosis (PPMS)
• A total of 4,611 patients have received OCR in clinical trials (as of 7 January 2019)
• Ongoing ocrelizumab Phase II, III and IIIb studies and their respective open-label extensions
• Near-complete elimination
• 17 (36)
• 33 (32)
• 1 (<1)
• Thirteen pregnancies (12 with foetal exposure) resulted in live births
• Twenty-nine pregnancies had an unknown outcome or were lost to follow-up (foetal

OBJECTIVE
• To report pregnancy, fetal, neonatal and infant outcomes in female patients who became pregnant while receiving OCR and post-marketing analyses in multiple sclerosis (MS) up to 31 March 2019

METHODS
Study Design
• This analysis includes OCR-exposed women with MS recorded from clinical trials and post-marketing experience.
• The database includes information from all sources and includes:
• Clinical trials of all pregnancy cases (including nonpregnant women) and all cases with serious adverse events
• Ocrelizumab exposure in patients with MS or PPMS

RESULTS
Overall Patient Exposure
• As of 31 March 2019, 382 pregnancies exposed to OCR have been reported (Figure 1)

Figure 2. Overview of outcomes in live births

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Table 1. Outcomes of maternal exposure pregnancies in patients with MS

REFERENCES
• Retrieved cases are suggested of an ocrelizumab-related increased risk of adverse pregnancy / fetal outcomes
• The current update on pregnancy outcomes remains in line with previous reports

CONCLUSIONS
• The database includes information from all sources and includes:
• Clinical trials of all pregnancy cases (including nonpregnant women) and all cases with serious adverse events
• Ocrelizumab exposure in patients with MS or PPMS
• Pregnancy outcomes, including information about child health up to 1 year after birth, have been collected in ongoing OCR studies and the OCR pregnancy registry and post-marketing experience will continue to be collected and assessed
• Prospective and retrospective pregnancy reports were included in this analysis
• Material exposure was defined as occurring at least one OCR infusion at any time point before or after conception

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DISCLOSURES
• All authors have read the final manuscript and are submitting the work on behalf of the authors
• The authors have no financial interests or other relationships to disclose

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A total of 4,611 patients have received OCR in clinical trials (as of 7 January 2019)
• Approximately 5137 patients have received OCR in the post-marketing setting (as of 31 March 2019)
• Estimated patient exposure from clinical trials and the post-marketing setting are 14,229
• and 43,227 patient-years, respectively
• A significant proportion of patients eligible for treatment with OCR will be of reproductive age
• Mean age of OCR treatment was approximately 30 years
• Ongoing ocrelizumab Phase II, III and IIIb studies and their respective open-label extensions
• Near-complete elimination
• 17 (36)
• 33 (32)
• 1 (<1)
• Thirteen pregnancies (12 with foetal exposure) resulted in live births

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Figure 2. Overview of cumulative maternal exposure pregnancy exposures

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• Prospective and retrospective pregnancy reports were included in this analysis
• Material exposure was defined as occurring at least one OCR infusion at any time point before or after conception
• An embryo/foetus was considered exposed to OCR

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