**Background**

Ocrelizumab (OCR) is a recombinant, humanized, monoclonal immunoglobulin G1 antibody that selectively targets CD20+ B cells. Immunoglobulins such as OCR do not cross the placenta during the first trimester of pregnancy, but transfer of OCR can occur thereafter.  

The safety profile of OCR has been investigated in multiple clinical trials and although the use of effective contraception was mandatory, 25 pregnancies have been reported in women with multiple sclerosis (MS) receiving OCR during these trials up to the end of January 2017. In 14 of these 25 pregnancies, the fetuses were considered to have been exposed to OCR.  

The small number of pregnancies and pregnancy outcomes that have been reported from clinical trials means the safety profile of OCR in pregnancy and fetal outcomes has yet to be established.

This study was designed as part of the post-marketing activities to provide information that will help to facilitate patients receiving OCR and clinicians when making decisions related to pregnancy.

**OBJECTIVE**

To assess maternal, fetal and infant outcomes in women with MS exposed to OCR during the 6 months prior to their last menstrual period (LMP) or at any time during pregnancy.

**METHODS**

**Study Objectives**

• This study will characterize pregnancy and infant outcomes of women with MS exposed to OCR during the 6 months prior to their LMP or at any time during pregnancy including:  
  — The frequency of selected adverse pregnancy outcomes (e.g., spontaneous abortions, stillbirths, elective and therapeutic terminations, preterm births, C-sections, and other infections)  
  — The frequency of selected adverse fetal/neonatal outcomes (e.g., major congenital malformations, small for gestational age, postnatal growth and development, adverse effects on immune system development) and birth and at least the first year of life of infants

**Eligibility Criteria**

• Patients must meet the following criteria for study entry:
  — Currently pregnant
  — Diagnosed with MS
  — Documented that the patient was exposed to OCR at any point starting from 6 months prior to LMP
  — The design of the pregnancy (e.g., pregnancy loss or live birth) must not be known

**Sample Size**

• Based on clinical, statistical and practical considerations, 92 pregnancy outcomes are required to achieve a minimum 90% power to detect a relative risk of 3 in major congenital malformations, major birth defects and preterm births relative to the baseline prevalence (Table 2).

**RESULTS**

• The total duration of participation is 21 months, and the study will last approximately 10 years.

• In-depth results will be communicated when sufficient patients have been accrued to allow meaningful analysis and final results will also be communicated to the MS communities.

**Conclusions**

• The Ocrelizumab Pregnancy Registry is a multicenter, prospective, observational study that will provide insights on the safety profile of ocrelizumab during pregnancy in a real-world setting and complement the multi-source post-marketing study (see poster 327/2) by providing detailed case information and followed up cases.

• This information is important for patients, clinicians and healthcare decision-makers and will support discussions with pregnant women with MS who are planning to become pregnant or may have been exposed to ocrelizumab before or during pregnancy.

**Acknowledgments**

REFERENCES


