**Design of the Ocrelizumab Pregnancy Registry to Assess Maternal, Fetal and Infant Outcomes in Women With Multiple Sclerosis Who Were Exposed to Ocrelizumab During, or Within 6 Months Before, Pregnancy**

**D Wormser,¹ P Engel,² K Hahn,³ S Bader-Wedner,⁴ E-M Didden,⁵ J Evershed,⁶ M Garas,⁷ Q Wang,⁸ K Hellwig⁹

¹Hoffmann-La Roche Ltd, Basel, Switzerland; ²IQVIA, Paris, France; ³IQVIA, Cambridge, MA, USA; ⁴Roche Products Ltd, Welwyn Garden City, UK; ⁵St Joseph-Hospital, Ruhr University, Bochum, Germany

**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 safety profile of OCR in pregnancy and fetal outcomes has yet to be established.

**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.
  - The focus will be on selected adverse pregnancy outcomes (e.g., spontaneous abortions, stillbirths, elective or therapeutic terminations, prematurity, pre-eclampsia, preeclampsia, intrauterine growth retardation).

- **Data Sources**
  - Data will be obtained through questionnaires administered to patients and healthcare professionals (HCPs) (neurologist, obstetrician) during pregnancy and through at least 1 year after birth (pediatrician, obstetrician) at birth and through at least the first year of life of infants.

- **Study Design**
  - The registry will collect primary data from pregnant women with MS from the United States, Germany and other potential countries, who have been exposed to OCR during the 6 months prior to their LMP or at any time during pregnancy (Figure 1).

- **Eligibility Criteria**
  - Patients must meet the following criteria for study entry:
    - Currently pregnant
    - Diagnosed with MS
    - Completion of 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 at a significance level of 0.05 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 planned start date is mid-2019 and key study milestones are shown in Figure 3.

- **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 372) by providing detailed case information early after approval.

**ACKNOWLEDGMENTS**

The Ocrelizumab Pregnancy Registry is supported by Roche Products Ltd, Welwyn Garden City, UK, and funded by Hoffmann-La Roche Ltd, Basel, Switzerland.

**REFERENCES**