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Pregnancy Outcomes in Patients Treated with Ocrelizumab

Celia Oreja-Guevara[1], Sibyl Wray[2], Regine Buffels[3], Dusanka Zecevic[3], Sandra Vukusic[4]

[1]Hospital Clinico San Carlos, Madrid, Spain, [2]Sibyl Wray MD Neurology PC, Knoxville, United States, [3]F. Hoffmann-La Roche Ltd, Basel, Switzerland, [4]Service de Neurologie et Sclérose en Plaques, Fondation EDMUS pour la Sclérose en Plaques, Hôpital Neurologique Pierre Wertheimer, Lyon, France

Background: Ocrelizumab (OCR) is a humanised anti-CD20+ monoclonal antibody approved for the treatment of relapsing and primary progressive forms of multiple sclerosis (MS) and has also been studied in clinical trials for rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE). As many patients with MS are women of reproductive age, pregnancy outcomes in OCR-exposed patients are important. B-cell levels in neonates exposed to OCR in utero have not been studied in trials, and the effect of OCR on the immune system of the newborn is unknown.

Method(s): Analysis includes pregnancies in women treated with OCR in clinical trials/post-marketing sources up to 31/03/2019. In the EU, women of childbearing potential are recommended to use contraception while receiving and for 12 months after the last OCR infusion; use of two contraceptive methods until 48 weeks after the last OCR infusion/until B-cell repletion (whichever longer) was required in trials. A foetus was considered to have in utero OCR exposure if the last infusion occurred within 3 months of conception or during pregnancy or if the date was unknown.

Result(s): As of 31/03/2019, a total of 362 pregnancies exposed to OCR (MS, N=267; RA or SLE, N=33; no reported indication, N=62) have been reported. Of these, 267 were MS patients (trials, N=78; post-marketing, N=189); 118 were considered to have foetal OCR exposure (N=47 with no foetal exposure; N=102 foetal exposure unknown). Preliminary outcomes of the 267 pregnancies in women with MS exposed to OCR at cut-off include 62 live births, 86 ongoing pregnancies, 25 elective abortions, 10 spontaneous abortions, 1 stillbirth, 3 ectopic pregnancies, 22 lost to follow-up and 58 unknown or not reported outcomes.

Conclusion: Reviewed cases to date do not suggest an increased risk of adverse pregnancy outcomes, including spontaneous abortions or malformations, with OCR treatment. The current update remains in line with previous reports. Data will continue to be collected and assessed as part of post-authorisation commitments.