ECTRIMS 2024
Copenhagen, Denmark
Annual Congress | 18-20 September 2024
Pre-Day | 17 September 2024
Patient Community Day | 20 September 2024
40TH ANNIVERSARY

Abstract Number: 1193/P085

Pregnancy and infant outcomes in women with multiple sclerosis receiving ocrelizumab: Analysis of approximately 4,000 pregnancies to date

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Introduction:

A significant proportion of people with multiple sclerosis (MS) are women of childbearing age and the number of those exposed to ocrelizumab (OCR) close to pregnancy is increasing. Currently, OCR labelling advises contraception during treatment and for 6–12 months thereafter; however, an increasing number of pregnancies are occurring in this interval.

Objectives/Aims:

To report pregnancy and infant outcomes among women with MS exposed to OCR before or during pregnancy and/or breastfeeding.

Methods:

Pregnancies from the Roche safety database were analysed. Maternal OCR exposure was defined as ≥1 infusion; *in utero* exposure was defined as an infusion ≤3 months (M) prior to the last menstrual period (LMP) or during pregnancy. Foetal death was termed spontaneous abortion (SA) if <22 complete gestational weeks (GW), or stillbirth if later. Live births (LB) were preterm if <37 complete GW. Major congenital anomalies (MCA) were classified via EUROCAT 1.5. Infant exposure through breastfeeding was recorded if lactating mothers received OCR postpartum.

Results:

As of 12 July 2023, 3,244 cumulative MS pregnancies were reported; 2,444 were reported prospectively, 793 retrospectively, seven unspecified. A total of 855 prospective pregnancies were considered *in utero* exposed; most occurred ≤3M before LMP (n=572), followed by first (n=258) and later trimesters (n=25). Amongst prospectively reported pregnancies with known outcomes (n=1,144), 83.6% resulted in LB. *In utero* exposed and non-exposed groups had similar proportions of LB (84.2% vs 88.3%), full-term (65.7% vs 70.9%) and preterm (9.5% vs 8.7%) LB, and SA (7.4% vs 9.1%). Elective abortions were more frequent in the exposed group (7.4% vs 1.7% in the non-exposed group). The proportion of LB with MCA was similar between the exposed

and non-exposed group (2.1% vs 1.9%) and remained within epidemiological background. Of 122 infants with breastfeeding exposure, 27 were also exposed *in utero*. As of 28 March 2024, approximately 4,000 cumulative MS pregnancies were reported. Updated pregnancy outcomes and 1-year infant outcomes will be presented.

Conclusion:

This is the largest dataset of pregnancy outcomes for an anti-CD20 therapy in MS.*In utero* exposure to ocrelizumab, primarily occurring ≤3M before the LMP and first trimester, did not increase the risk of adverse pregnancy or infant outcomes compared with the epidemiological background of both MS and the general population. Counselling remains an important approach to ensure optimal outcomes for mothers and infants.

Disclosures:

R Dobson received research support from Multiple Sclerosis Society UK, Horne Family Foundation, Barts Charity, Merck, Biogen and Celgene; consultancy fees from F. Hoffmann-La Roche Ltd, Novartis, Sandoz and Biogen (all payments made are institutional and used to support research/educational activities); honoraria for lectures, speaking etc. from Biogen, F. Hoffmann-La Roche Ltd, Sanofi-Genzyme, Merck, Novartis, Janssen and Teva; support for attending meetings and/or travel from Novartis, Biogen and Janssen (all payments made are institutional and used to support research/educational activities); and is part of the Association of British Neurologists MS Advisory Group and NHS England Clinical Reference Group. S Vukusic received grants and research support from Biogen, Novartis, Merck-Serono, F. Hoffmann-La Roche Ltd and Sanofi-Genzyme; consultancy fees from F. Hoffmann-La Roche Ltd, Biogen, Bristol Myers Squibb/Celgene, Janssen, Novartis, Merck-Serono, Sandoz, Sanofi-Genzyme and Teva; and payment/honoraria for lectures, speaking etc. from F. Hoffmann-La Roche Ltd, Biogen, Bristol Myers Squibb/Celgene, Novartis, Merck-Serono, Sandoz, Sanofi-Genzyme and Teva. R Bove received consultancy fees from Alexion, EMD Serono, Horizon, Janssen and TG Therapeutics; and is funded by the National Multiple Sclerosis Society Harry Weaver Award, National Institutes of Health and Department of Defense, as well as Biogen, Eli Lilly and F. Hoffmann-La Roche Ltd. K Hellwig received grant/contract support, consultancy fees, honoraria and/or compensation from the Federal Innovationsfonds, National MS Society in Germany, Almirall, Bayer, Biogen, Sanofi, Teva, Bristol Myers Squibb/Celgene, Janssen, Hexal, F. Hoffmann-La Roche Ltd, Novartis and Merck. KM Krysko received grants from MS Canada; a contract for a study site from Roche; speaking or consultancy fees from Biogen, EMD Serono, Novartis and F. Hoffmann-La Roche Ltd; and served as an advisory board member for Biogen, EMD Serono, Novartis and F. Hoffmann-La Roche Ltd; and a scientific advisory committee member for Bristol Myers Squibb. C Pietrasanta received consultancy fees from F. Hoffmann-La Roche Ltd. T McElrath received research support from the National Institutes of Health and NX Prenatal Inc.; compensation for service on the scientific advisory boards of Mirvie Inc., F. Hoffmann-La Roche Ltd and Momenta Pharmaceuticals, Inc.; and consultancy fees from F. Hoffmann-La Roche Ltd and Comanche Biopharma. L Craveiro is an employee of and a shareholder in F. Hoffmann-La Roche Ltd. G Ferreira is a consultant for F. Hoffmann-La Roche Ltd. D Goncalves Pereira Alves is an employee of and a shareholder in F. Hoffmann-La Roche Ltd. D Zecevic is an employee of and a shareholder in F. Hoffmann-La Roche Ltd. C-J Lin is an employee of and a shareholder in F. Hoffmann-La Roche Ltd. N Pasquarelli is an employee of and a shareholder in F. Hoffmann-La Roche Ltd. C Oreja-Guevara received honoraria for consulting and serving on advisory boards from Biogen Idec., F. Hoffmann-La Roche Ltd, Genzyme, Merck, Novartis and Teva.