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BREAKING BARRIERS IN MS

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Cumulative Pregnancy Outcomes in Patients With Multiple Sclerosis Following Maternal Exposure to Ofatumumab: Results From the Novartis Safety Database

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Abstract:
Background: Ofatumumab, a fully human anti-CD20 monoclonal antibody with a monthly dosing subcutaneous regimen, is approved for treating relapsing multiple sclerosis (RMS) in adults. B-cell-depleting therapies are large immunoglobulin (Ig) G1 monoclonal antibodies, which are minimally transferred across the placenta. Maternal transfer of Ig is negligible during the first trimester, whereas highest exposure occurs after week 32 during fetal growth. The FDA and EMA labels of ofatumumab both state that women of childbearing potential should use effective contraception during and for at least 6 months after discontinuation of treatment. Pregnancy outcome data from multiple sclerosis (MS) clinical trial patients treated with ofatumumab are currently limited.
Objectives: To report the latest cumulative pregnancy outcomes data in women with RMS treated with ofatumumab during or in the 6 months prior to pregnancy.
Methods: The Novartis Safety Database (pharmacovigilance system) includes cases from clinical trials and the post-marketing setting collected via the global non-interventional **PR**egnancy outcomes **I**ntensive **M**onitoring (PRIM) study. Data from spontaneously reported pregnancies in the real world and clinical trials are collected using a set of targeted and structured checklists. Pregnancy outcomes in women with MS treated with ofatumumab during pregnancy or 6 months prior to their last menstrual period were analyzed (cutoff date: September 25, 2023). Data on pregnancy and infant outcomes including congenital anomalies, infections, vaccinations, and developmental delays were collected from the reporting of pregnancy up to 12 months postpartum.

Results: As of September 25, 2023, 279 prospective pregnancies (30 from clinical trials and 249 from the post-marketing setting) with maternal exposure to ofatumumab were identified in the Novartis Global Safety Database. Among these, pregnancy outcomes were known for 55 cases leading to 57 infant/fetus outcomes (2 pregnancies involving twins). The outcomes consisted of 29 livebirths (including 1 minor malformation [congenital hydronephrosis] and 1 set of twins), 12 induced terminations (1 case of trisomy 18 and no reported abnormalities or reason for termination provided in the remaining 11 outcomes), 4 ectopic pregnancies, 11 spontaneous abortions, and 1 abortion (not further specified), respectively.
Conclusions: Reporting the latest data on pregnancy outcomes following treatment with ofatumumab will provide updated information to healthcare professionals and might help in making informed decisions in managing women of childbearing potential living with MS. Given limited data, conclusions cannot be made on the generalizability of the current observations. In addition to the PRIM initiative, a prospective observational exposure registry on maternal and infant outcomes in women with MS treated with ofatumumab is currently underway (NCT05634967).

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