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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 Text:

Background: Ofatumumab (OMB), 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 G1 monoclonal antibodies that are minimally transferred across the placenta. The US Food and Drug Administration and European Medicines Agency labels of OMB state that women of childbearing potential should use effective contraception during and for ≥6 months after treatment discontinuation. Pregnancy outcome data from clinical trial patients with MS treated with OMB are currently limited.

Objectives: To report the latest cumulative pregnancy outcomes data in women with RMS treated with OMB during or in the 6 months prior to pregnancy.

Methods: The Novartis Safety Database includes cases from clinical trials and the postmarketing setting collected via the global noninterventional **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 OMB during pregnancy or in the 6 months prior to their last menstrual period were analyzed (cutoff date: Sep 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: 279 prospective pregnancies (30 from clinical trials and 249 from the postmarketing setting) with maternal exposure to OMB 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 OMB will provide updated information to health care professionals and might help in making informed decisions in managing women of childbearing potential living with MS. Given the limited data, conclusions cannot be made on the generalizability of the current observations.

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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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