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### **Pregnancy Outcomes in Patients with Multiple Sclerosis Following Exposure to Ofatumumab**

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#### **Abstract Text:**

**Background:** Ofatumumab, a fully human anti-CD20 monoclonal antibody, is approved for the treatment of relapsing multiple sclerosis (RMS) in adults. As per the ofatumumab label, females of childbearing potential should use effective contraception during and for at least 6 months after discontinuation of treatment. Data on the effect of ofatumumab on pregnancy outcomes are limited in humans. Based on the current knowledge, the maternal-fetal transfer of IgG during the first trimester is minimal and fetal IgG concentration starts to rise from the second trimester. Furthermore, in cynomolgus monkeys, exposure to ofatumumab during gestation did not cause maternal toxicity and there were no adverse effects on the pre- or postnatal development.

**Objectives:** To report pregnancy outcomes from the Novartis Safety Database in women with RMS inadvertently exposed to ofatumumab during pregnancy.

**Methods:** Pregnancy outcomes data from women with RMS exposed to ofatumumab during pregnancy or 6 months prior to last menstrual period were analyzed from clinical trials, and real-world setting in the Novartis Safety Database (cutoff: August 31, 2021). Maternal and infant outcomes including birth defects, congenital anomalies, infections, vaccination, and developmental delays were collected from the reporting of pregnancy up to 1 year of infant age.

**Results:** As of cutoff date, 32 pregnancies with ofatumumab (ASCLEPIOS I/II, n=4; ALITHIOS, n=14; MIRROR, n=7; post-marketing, n=7) were reported in women with MS; of which 5 were ongoing and in 4 pregnancies, information on the outcomes was not reported. The remaining 23 pregnancies had the following outcomes: therapeutic/induced abortions (n=6), spontaneous abortion (n=5), early intrauterine fetal demise at ~8.5 weeks gestation and patient underwent therapeutic abortion (n=1; not suspected to be related to ofatumumab by the treating physician), and 11 live births of normal babies. Based on followed-up data (up to 1 year of infant age), no B-cell depletion, immunoglobulin/hematological/fetal abnormalities, and serious infections were reported.

**Conclusions:** In this analysis, no birth defects or congenital anomalies were reported in 23 pregnant women exposed to ofatumumab with known outcomes. There were no reports of B-cell depletion, immunoglobulin/hematological abnormalities, or serious infections in live births to date. Sharing the up-to-date data on pregnancy and infant outcomes with ofatumumab is helpful in counseling women with MS of childbearing potential. A prospective observational registry on maternal and infant outcomes in women exposed to ofatumumab is currently being planned.

**Title:**

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**Category:**

Disease-modifying therapy

**Would you give CMSC and International Journal of MS Care the first preference to any article that is submitted for publication based on this abstract presentation?:**

Yes

**Late Breaking Reason:**

We aimed to present most recent data with a data cut-off of 31-Aug-2021 on pregnancy and infant outcomes with ofatumumab, which would be helpful for physicians in counseling women with MS of childbearing potential.

**Category:** Disease-modifying therapy

**Keywords:**

Disease-modifying treatments in MS and Pregnancy, Ofatumumab

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