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Pregnancy Outcomes in Ofatumumab-Treated Patients with Multiple Sclerosis

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Abstract Text:

Background: Ofatumumab, a fully human anti-CD20 monoclonal antibody with a 20 mg subcutaneous monthly dosing regimen, is approved for treating relapsing multiple sclerosis (RMS) in adults. As per ofatumumab's label, women of childbearing potential should use effective contraception during and for at least 6 months after discontinuation of ofatumumab treatment. Data on the effect of ofatumumab on pregnancy outcomes are currently limited in humans.

Objectives: To report the cumulative outcomes of pregnancy in women with RMS inadvertently exposed to ofatumumab during or prior to unplanned pregnancy from the Novartis Safety Database

Methods: Pregnancy outcomes in women with RMS exposed to ofatumumab during pregnancy or 6 months prior to last menstrual period will be analyzed from the Novartis Safety Database (includes cases from clinical trials and the post-marketing setting; data cut-off: Mar-25-2022). Maternal and infant outcomes including congenital anomalies, infections, vaccination, and developmental delay are being collected from the reporting of pregnancy up to 1 year of infant age.

Results: As presented previously with a cut-off date of Aug-31-2021, no congenital anomalies were reported in pregnant women exposed to ofatumumab during pregnancy or 6 months prior to last menstrual period and no reports of B-cell depletion, Immunoglobulin/hematological abnormalities, or serious infections in live births were reported. Updated pregnancy outcomes with a cutoff: Mar-25-2022 from clinical trials and post-marketing setting will be presented during the congress.

Conclusions: Reporting the latest data on pregnancy outcomes in women with exposure to ofatumumab will be helpful to healthcare professionals when treating MS in women of childbearing potential. A prospective observational registry on maternal and infant outcomes in women exposed to ofatumumab is also currently underway.

Title:
Pregnancy Outcomes in Ofatumumab-Treated Patients with Multiple Sclerosis

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Preferred Presentation Format:
Poster

Category:
Disease-modifying therapy

Has this abstract been presented/published elsewhere prior to this meeting?:
No

Have you simultaneously submitted this abstract to another organization for consideration?:
No

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?:
No

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