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POSTER PRESENTATION

Pregnancy Outcomes in Patients With Multiple Sclerosis Following Exposure to Ofatumumab

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INTRODUCTION

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.

AIM

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.

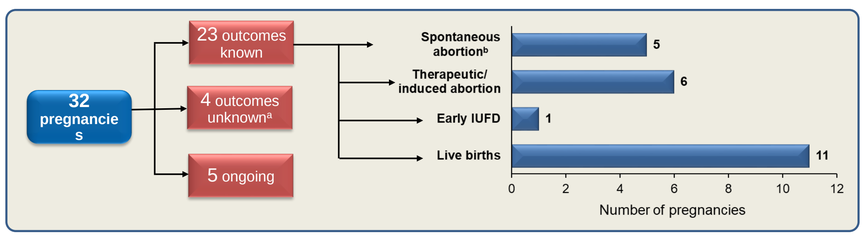
The following maternal and infant outcomes were collected from the reporting of pregnancy up to a maximum of 1 year of infant age

Pregnancy outcomes[a]
- therapeutic/induced abortion
- spontaneous abortion
- IUFD includes still birth
- live birth

Infant outcomes
- birth defects
- congenital anomalies
- infections
- vaccination and
- developmental delays

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.

The study was supported by Novartis Pharma AG, Switzerland. Detailed author disclosures will be provided in the subsequent presentation.

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.

DISCLOSURES

Bassem Yamout has served on advisory boards for Sanofi, Bayer, Roche, Merck and Biogen. He received honoraria as speaker from Sanofi, Bayer, Roche, Merck, Biogen, Pfizer and Lundbeck. He received research grants from Novartis and Biogen. He served on steering committees for Merck.

Kerstin Hellwig has received compensation for serving as a consultant or speaker, or the institution she works for has received research support from Bayer, Schering Healthcare, Teva, Sanofi Aventis, Biogen Idec, Merck Serono, and Novartis.

Riley Bove has received research support and/or served on Advisory Boards and/or steering committees of Alexion, Biogen, EMD Serono, Genzyme Sanofi, Novartis, and Roche Genentech.

Pranava Katkuri, Ulf Schulze Topphoff, Dee Stoneman, Ronald Zielman and Ratnakar Pingili are all employees of Novartis.

Maria Houtchens has received consulting fees from Biogen, EMD Serono, Sanofi-Genzyme, Mallinckrodt, and Roche and research support from Biogen, EMD Serono, and Sanofi-Genzyme.

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BIBLIOGRAPHY

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