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### **Pregnancy Outcomes Following Exposure to Ofatumumab in Patients with MS: Results from the Prim Study**

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#### **Abstract Text:**

##### **Background:**

Ofatumumab, a fully human anti-CD20 monoclonal antibody with a monthly dosing s.c. regimen, is approved for treating relapsing multiple sclerosis (RMS) in adults. Although no pregnancy test is recommended for ofatumumab unlike another anti-CD20 antibody, the EMA and FDA labels recommend that women of childbearing potential use effective contraception during treatment and for at least 6 months after discontinuation of ofatumumab. Pregnancy outcome data from MS clinical trial patients exposed to ofatumumab are currently limited and further information is needed.

##### **Objectives:**

To report the latest cumulative pregnancy outcome data in women with MS exposed to 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 exposed to ofatumumab during pregnancy or 6 months prior to their last menstrual period (LMP) were analyzed (cutoff date: September 25, 2022). 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, 2022, a total of 118 pregnancies (28 from clinical trials and 90 from the post-marketing setting) were reported in the Novartis Safety Database with maternal exposure during pregnancy. Of these, 104 were prospective and 14 were retrospective cases. Most of the mothers were exposed to ofatumumab peri-conception or during the 1<sup>st</sup> trimester. At the time of cut-off, pregnancy outcomes were known in 42 pregnancies (n=44 fetus/infant outcomes due to two sets of twins). Among these 44 fetus/infant outcomes, 30 were prospective and includes: 16 live births, 8 induced termination, 1 ectopic pregnancy, and 5 spontaneous abortions. Cases reported retrospectively have inherent reporting bias toward abnormal outcomes and will be presented separately. No congenital anomalies or serious infections were reported in the 16 live births. Information regarding B-cell depletion, immunoglobulin/hematological abnormalities and vaccination status in the infants was not available at the time of this analysis.

**Conclusions:**

The limited number of cases retrieved so far in conjunction with the number of pregnancies with pending outcome, does not yet allow for conclusion on the generalizability of the observations made so far. Larger studies are required. In addition to the PRIM initiative, a prospective observational exposure registry on maternal and infant outcomes in MS patients exposed to ofatumumab is also currently underway (NCT05634967).

**Title:**

Pregnancy Outcomes Following Exposure to Ofatumumab in Patients with MS: Results from the Prim Study

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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?:**

Yes

**Simultaneous submission details:**

This abstract has also been submitted to 75th AAN Annual Meeting will be held from April 22-27, 2023. Kindly note that abstract submitted to AAN does not have detailed results (Data) while this abstract has detailed data involving pregnancy outcomes with ofatumumab.

**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

**Category:** Disease-modifying therapy

**Keywords:**

Ofatumumab, Pregnancy Outcomes, PRIM Study

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