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Abstract Title: Evaluating Ofatumumab Excretion in Breastmilk of Women With RMS: Phase 4 Study Design

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Kerstin Hellwig*[1], Xiaofang Shi[2], Igor Vostiar[3], Xixi Hu[4], Riley Bove[5]

[1]St. Josef Hospital, Ruhr University Bochum, Department of Neurology, Bochum, Germany, [2]China Novartis Institutes for BioMedical Research Co., Ltd, Shanghai, China, [3]Novartis Pharma AG, Basel, Switzerland, [4]Novartis Pharmaceutical Corporation, East Hanover, New Jersey, United States, [5]UCSF Weill Institute for Neuroscience, University of California San Francisco, San Francisco, California, United States

Introduction:
Women with relapsing forms of multiple sclerosis (RMS) are at increased risk of relapses after giving birth. Therefore, disease control with an effective MS disease-modifying therapy (DMT) in post-partum women is important. For women who wish to initiate/resume treatment with DMT and breastfeed at the same time, understanding the extent of drug excretion in milk is important. Currently no data are available on whether ofatumumab (OMB) is excreted in human milk. Excretion of antibodies (IgG) after the first few days post-partum is low and given low systemic exposure of OMB, the concentration in breastmilk is estimated to be very low (0.5-1 ng/mL) and not pharmacologically relevant. However, generation of data on the excretion of OMB in breastmilk of lactating women with RMS is still important to confirm this.
Objectives/Aims:
To present the study design of a Phase 4 study to evaluate OMB excretion in mature breastmilk of lactating women with RMS who initiate/re-initiate treatment with OMB post-partum.
Methods:
This is a multicentre, prospective, open-label, post-marketing study in adult lactating women with RMS. Women who delivered term infants (≥37 weeks gestation) and plan to initiate/re-initiate OMB or have been initiated/re-initiated on OMB in accordance with the local label between 2 to 24 weeks post-partum will be included. The study consists of two parts: core part (up to 4 weeks of screening period and up to 12 weeks of sampling period) and safety follow-up part (additional 9 months, with 3-monthly visits). The primary endpoint is the OMB concentration in mature breastmilk at the following time points: (pre-dose) on the day of the second (or later) maintenance dose, then 7, 14, 21 and (pre-dose) 28 days after the maintenance dose. Key secondary endpoints include other pharmacokinetic parameters (Cmax, AUC, and milk/plasma ratio, etc.), and AEs in lactating women receiving OMB and their breastfed infants. Data will be analysed through descriptive summary statistics.
Results:
Approximately 20 lactating women with RMS initiating/re-initiating OMB post-partum are planned to be enrolled. Primary analyses will provide data on detectable concentration of OMB in breast milk over 28 days.
Conclusion:
This study will generate information about OMB excretion in mature breastmilk, and these data will help inform treatment decisions for women with RMS who wish to breastfeed and their treating physicians.

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