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Title: Pregnancy and Infant Outcomes with Interferon Beta: Data from the European Interferon Beta Pregnancy Registry and Population Based Registries in Finland and Sweden

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Introduction: Women with multiple sclerosis (MS) are often diagnosed and treated at childbearing age. Until recently, data on MS and interferon beta (IFN β) exposure during pregnancy has been limited. To address this lack of evidence, a European IFN β pregnancy registry was established and a population-based cohort study was conducted on data from two Nordic health registers (Finland and Sweden).

Objective: Assess the prevalence of pregnancy and infant outcomes in IFN β exposed women with MS from European IFN β pregnancy registry and Nordic health registers.

Methods: In the European IFN β pregnancy registry, women identified themselves to Marketing Authorization Holders (Bayer, Biogen, Merck, Novartis) or healthcare professionals as pregnant and exposed to IFN β since shortly before last menstrual period (LMP) or during pregnancy. In Nordic countries, data were retrospectively analysed from national health registers recording births. Women treated with IFN β during pregnancy or ≤ 3 months prior to LMP were considered exposed. Pregnancy outcomes included congenital anomalies, spontaneous abortions, elective terminations, ectopic pregnancies, stillbirths and live births. Prevalence of pregnancy outcomes in women exposed

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to IFN β in the European registry are presented alongside Nordic data, and a cohort of women with MS diagnosis unexposed to treatment from the Nordic dataset.

Results: Overall, 948 and 875 pregnancy reports with exposure to IFN β and known pregnancy outcomes were collected from the European registry (Eur) and Nordic registers, respectively. Prevalence of spontaneous abortions (10.7% Eur; 7.9% and 11.1% Nordic), congenital anomalies in live births (2.1% Eur; 1.8% and 3.3% Nordic) and ectopic pregnancies (0.4% Eur; 1.5% and 2.9% Nordic) were calculated in exposed and non-exposed cohorts, respectively. Additional analyses on pregnancy outcomes will be presented.

Conclusions: The European IFN β pregnancy registry showed no evidence that IFN β exposure before conception and/or during pregnancy adversely affected pregnancy or infant outcomes; consistent with the Nordic registers.

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Disclosures:

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YG is an employee of Novartis Pharma AG

MS is an employee of Merck KGaA, Darmstadt, Germany

CP is an employee and stockholder of Biogen

AA is an employee of Bayer AG

JK is an employee of Synteract GmbH

PH is a member of the European Interferon Beta Pregnancy Study Group

PK is an employee of StatFinn and EPID Research which performs commissioned pharmacoepidemiological studies for several pharmaceutical companies

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SB is an employee at the Centre for Pharmacoepidemiology, which receive grants from several entities including pharmaceutical companies

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AO has nothing to disclose

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