## SOME DISEASE MODIFYING THERAPIES ARE SAFE DURING PREGNANCY AND BREASTFEEDING (YES) Magnhild Sandberg-Wollheim Sweden

Multiple Sclerosis (MS) affects women in their childbearing ages. Consequently pregnancy is a common topic during clinic visits. There is no evidence that MS increases the risk of spontaneous abortion of congenital defects. Some studies – but not all – have shown that caesarian delivery was more common in women with MS and neonates were small for gestational age compared to the general obstetric population. With the availability and use of disease-modifying agents, patients have to take into consideration not only the burden of MS when considering pregnancy but also the possible harm of stopping treatment and the risk to the foetus if continuing with therapy.

For obvious reasons studies cannot be undertaken to evaluate the risk to the foetus of exposure to a disease-modifying treatment. Therefore, regulatory authorities have restricted the use of disease-modifying therapies during pregnancy. But data on exposed pregnancies are emerging from various sources. Information has been collected on pregnancies that occurred in treatment trials, pregnancies that have been reported in post-marketing, and pregnancies that have been included in various registries. Overall information is now available on several disease-modifying treatments, in particular on interferon beta but to some extent also on natalizumab. Data on glatiramer acetate are scarce and data on interferon beta 1b have not been reported.

In assessing the risk, several factors have to be taken into account: prospective data carry more weight than retrospective data, pregnancy outcomes must be reported with correct terms, date of conception and duration of exposure have to be calculated correctly, and reports should preferably be medically confirmed.

Data from available sources on subcutaneous interferon beta 1a, intramuscular interferon beta 1a, and natalizumab can be summarized as follows: the rate of spontaneous abortion was not increased versus the general population; the majority of pregnancies exposed to disease-modifying treatments were associated with normal live births; the majority of congenital anomalies occurred singly. Women who stopped disease-modifying therapy as soon as pregnancy was recognized were not at increased risk of adverse pregnancy outcomes. These data should be considered when women with MS are planning a pregnancy while on treatment with disease-modifying therapy.