**Poster Presentations**

**Friday, June 4 (6:30 pm - 8:00 pm)**

**(S26) THE BETASERON (INTERFERON BETA-1B) PREGNANCY REGISTRY**

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**Background:** The United States–based Betaseron (interferon beta-1b) Pregnancy Registry was initiated in April 2006 by Bayer HealthCare Pharmaceuticals following FDA requirements issued to all disease-modifying therapy (DMT) manufacturers.

**Objectives:** The Registry aims to monitor women with multiple sclerosis (MS) whose pregnancies were exposed to Betaseron to examine rates of birth defects, spontaneous abortions (SAs), and other pregnancy outcomes. **Methods:** This prospective, observational registry enrolls pregnant women exposed to Betaseron around the time of conception and/or during pregnancy but prior to prenatal screening that identifies potential abnormalities. Women are followed throughout pregnancy; their infants are followed until the 4-month pediatrician visit. The plan is to enroll 420 women exposed to Betaseron to reach 340 evaluable cases or to enroll patients until January 2011, whichever comes first. **Results:** As of December 31, 2009, 81 cases were enrolled. All women were exposed to Betaseron during their first trimester except for one woman with a third-trimester exposure. The Registry has collected pregnancy outcomes data on 69 of the 81 pregnancies; 7 are pending outcome information; 5 were either lost to follow-up or not valid. Of the 69 pregnancies with known outcomes, 59 (85.5%) resulted in live births, 8 (11.6%) resulted in SA (the National Center for Health Statistics reports an SA rate of 16% in the general population), and 2 (2.9%) resulted in stillbirths. Among the live-born infants, birth defects were reported in three: a case of trisomy 21 considered unlikely to be related to drug exposure; a case of multiple hemangiomas, which was not defined specifically enough to assess causality from drug exposure; and a case with cardiovascular defects, in which exposure was not temporally related to the development of the heart defects, and hip dysplasia, a defect with sufficiently ambiguous pathogenesis that temporality could not be ruled out. **Conclusions:** Preliminary data do not suggest an increased risk for negative pregnancy outcomes; however, caution is urged until the study is completed. This study highlights the difficulties encountered by registries of this nature in enrolling patients to reach valid conclusions. To report a pregnancy exposure, contact the Registry at 800-478-7049 (www.BetaseronPregnancyRegistry.com).

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**Keywords:** disease-modifying treatment in MS