

## **Teriflunomide (Aubagio®) International Pregnancy Registry: Enrollment Update**

### **Teriflunomide Pregnancy Registry Enrollment**

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### **BACKGROUND**

Teriflunomide is a once-daily oral immunomodulator approved for treatment of relapsing-remitting MS in 70 countries, with more than 74,000 patients currently being treated worldwide.

Teriflunomide is contraindicated in pregnancy based on embryo-fetal toxicity in rats and rabbits.

Despite the requirement for effective contraception during teriflunomide clinical trials, pregnancies did occur. There were no signs of structural or functional deficits in newborns, and data from the clinical program, although limited, showed no signal for human teratogenicity.

### **OBJECTIVES**

The International Teriflunomide Pregnancy Exposure Registry will compare rates of birth defects (congenital malformations, fetal deaths, termination due to fetal abnormality) in teriflunomide-exposed pregnant women with those reported by European Surveillance of Congenital Anomalies (EUROCAT).

### **METHODS**

The registry is a voluntary, multinational, prospective, observational, exposure-registration study.

Pregnant MS patients with teriflunomide exposure (any dose, any time after Day 1 of last menstrual period until pregnancy end) can enroll. National Coordinators liaise with healthcare professionals to collect information on teriflunomide-exposed pregnancies and coordinate patient enrollment.

Target recruitment is 196 women to achieve 104 live births, providing 80% power to detect 3.95-fold increase in risk ratio of birth defects associated with teriflunomide exposure vs EUROCAT. Pregnancy outcome data including birth defects and infant characteristics during the first year of life will be collected.

### **RESULTS**

As of April 26, 2017, 14 patients have been recruited from 7 European countries. Six healthy babies have been born with no abnormality reported. One patient had an elective termination that was not motivated by an abnormal result of a prenatal test or by any concerns regarding potential birth defect.

## **CONCLUSIONS**

This registry aims to provide data on pregnancy outcomes and infant development during the first year of life from teriflunomide-exposed pregnancies and will help physicians to provide better counseling for women exposed to teriflunomide during pregnancy.

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