Teriflunomide (Aubagio®) International Pregnancy Registry: Enrollment Update

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OBJECTIVE

• To provide an enrollment update for the International Teriflunomide Pregnancy Exposure Registry. Table 1 outlines the primary and secondary objectives of the registry.

INTRODUCTION

Teriflunomide is a once-a-day oral immunomodulator approved for relapsing-remitting MS in 80 countries. As of October 2017, over 80,000 patients are being treated with teriflunomide, with a total real-world exposure of approximately 162,000 patient-years since approval.

Teriflunomide elimination can be accelerated in patients by the stopping of teriflunomide-treatment.

Patient Follow-up

Teriflunomide-exposed pregnant women with MS who:

• Are not participating in a teriflunomide clinical trial at time of pregnancy
• Provide written informed consent
• Receive healthcare in the participating countries (shown above)

Outcomes

Pregnancy outcomes in addition to infant characteristics during the first year of life are being collected (Table 3)

CONCLUSIONS

• The International Teriflunomide Pregnancy Exposure Registry will provide outcomes on teriflunomide-exposed pregnancies, in addition to infant development during the first year of life
• Findings from this registry, together with those of the US and Canadian Teriflunomide Pregnancy Exposure Registry, will inform HCPs when counseling women exposed to teriflunomide during pregnancy

RESULTS

• Patient enrollment commenced in early 2015 and is planned to continue until December 2019
• Interim data from a cutoff date of April 26, 2017, have been collected from the registry

• Fourteen patients have been recruited from 7 countries: 4 each from France and Spain; 2 from Germany; and 1 each from Austria, Denmark, and Greece, and Italy
• Outcomes are available for 2 pregnancies
• Six healthy babies have been born, with no abnormalities reported to date
• One patient in Spain had an elective termination that was not motivated by the result of a prenatal test or by any suspicion of a potential birth defect

Statistical Registry:

The registry includes 196 pregnant women, projected to result in 104 live births; this sample size is estimated to provide an 80% power to detect a 3.95-fold increase in risk ratio of birth defects associated with teriflunomide exposure vs EUROCAT.

Analyses will be based on prospective cases of women with teriflunomide exposure during pregnancy prior to the knowledge, or perceived knowledge, of pregnancy outcome (ie, structural defect or genetic abnormality noted on a prenatal test), and will be conducted in 3 populations:

• Primary analysis population: all teriflunomide-exposed pregnant women with available pregnancy outcomes and birth-deficit status of any live-born infants available at birth (1 or 1-year follow-up).
• Used for evaluation of primary objective and rate of birth defect (secondary objective)

• Pregnant women population: Eligible pregnant women with pregnancy outcomes available.

• Live infant population: All live-born infants from the pregnant women population.

• Exclusions of T1 pregnancy data will be classified by gestational week and trimester

REFERENCES