152 PREGNANCY OUTCOMES FROM TERIFLUNOMIDE CLINICAL STUDIES

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10.1136/jnnp-2014-309236.152

Introduction Teriflunomide is a once-daily oral immunomodulator approved for treatment of relapsing–remitting multiple sclerosis. Teriflunomide is the active metabolite of leflunomide, approved for treatment of rheumatoid arthritis since 1998. Evidence from animal models suggests a potential for fetal risk from teriflunomide.

Methods Reliable contraception was mandated during teriflunomide trials. Pregnant patients were to discontinue treatment and undergo an accelerated elimination procedure (cholestyramine or activated charcoal). Pregnancies were reported in the teriflunomide clinical database (cut-off October 2013).

Results Eighty-three pregnancies were reported in female patients and 22 in partners of male patients; 26 live births occurred in teriflunomide-treated women and 16 occurred in partners of male patients receiving teriflunomide. Newborns whose parents received teriflunomide had no structural defects or functional deficits at birth. The spontaneous abortion rate for female patients was 18.6%–within the range reported in the general population.

Conclusions Data from the clinical programme have shown no teratogenic signal for teriflunomide, consistent with findings of the Organization of Teratology Information Services (OTIS) registry, and >2.5 million patient-years of post-marketing data for leflunomide. Current pregnancy numbers are too small to draw firm conclusions. Additional data will be provided by teriflunomide pregnancy registries.