Topiramate Exposure and Birth Defect Data to be Presented at the 29th International Epilepsy Congress

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MOUNTAIN VIEW, Calif., July 20, 2011 /PRNewswire/ -- VIVUS, Inc. (NASDAQ: VVUS [1]) today announced that on August 31, 2011, during the late breaking poster session at the 29th International Epilepsy Congress (IEC) in Rome, Italy, Dr. Alison Pack, Associate Professor of Clinical Neurology, Department of Neurology, Columbia University Medical Center, will present the results of a retrospective study of medical claims data on oral clefts (OC) and major congenital malformations (MCMs) associated with *in utero* topiramate exposure. The IEC is one of the largest international gatherings of medical professionals focused on the management of patients with epilepsy.

The study was conducted using medical claims and pharmacy prescription data from the Wolters Kluwer Pharma Solutions Source® Lx Patient Longitudinal Database, which identified 778 mother-infant dyads exposed to topiramate within 10 months prior to giving birth. The study also included two non-topiramate-exposed control groups: one comprised of 3,431 dyads exposed to other antiepileptic drugs (AEDs) during pregnancy and a second of 2,307 dyads with a diagnosis of epilepsy, but no exposure to topiramate during pregnancy. In all cohorts, known or suspected teratogens, including valproate, and phenytoin were excluded. The risk of OC and MCM due to topiramate exposure was calculated in comparison to the other AED exposed and the non-topiramate exposed Epilepsy groups. The results are as follows: Topiramate Group

AED Group

Epilepsy GroupFrequency of:Oral cleft

0.26%

0.20%

0.30%Major malformations

4.11%

3.50%

4.72%The relative risk (95% CI) for the topiramate group vs. other AEDs group for OCs was 1.26 (0.26-6.05) and the relative risk of MCMs was 1.18 (0.80-1.72). For the topiramate vs. the non-topiramate exposed Epilepsy group, the relative risk '/>"/>

SOURCE [2]

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