Registry-based, Prospective, Observational Study to Assess Maternal, Fetal, and Infant Outcomes Following Exposure to Migraine Treatments, Including Galcanezumab

Sara A. Ephross[1], Krista M. Schroeder[2], Nicole A. Kellier-Steele[2], Angie O. Graves[1], Mark E. Bangs[2], Russell M. Nichols[2], Lynn V. Do[2], Paula M. Hauck[2], Jan L. Brandes (Presenter)[3]

[1]Syneos Health, Morrisville, NC, USA; [2]Eli Lilly and Company, Indianapolis, IN, USA; [3]Nashville Neuroscience Group, Department of Neurology, Vanderbilt University, Nashville, TN, USA

OBJECTIVE

- The objective of the pregnancy registry study is to compare maternal, fetal, and infant outcomes among pregnant women with migraine exposed to galcanezumab to those exposed or not exposed to other migraine medications
- The objective of this poster is to increase awareness of the registry

STUDY DESIGN

- Study aims to enroll 420 mothers with live births into each of the following groups:
  - Women with migraine exposed to galcanezumab up to five months before or during pregnancy
  - Pregnant women with migraine exposed to other migraine preventative medications
  - Pregnant women with migraine not exposed to migraine preventative medications
- Information on mother and fetus/infant (e.g., demographics, medical history, exposures, pregnancy outcomes) will be collected at multiple time points throughout pregnancy and to 1 year after delivery

KEY OUTCOME

- The primary outcome to be assessed in the Lilly Migraine Pregnancy Registry is the frequency of major congenital malformations; however, additional maternal, fetal, and infant outcomes will also be evaluated (to 1 year of age)

CONCLUSIONS

Conclusions

- Real-world studies are needed to evaluate the utilization and safety of new migraine medication exposures during pregnancy
- This registry is part of a larger effort towards this goal
- Sufficient enrollment of pregnant women exposed and not exposed to galcanezumab and other migraine medications will enable execution of comparative safety studies

Limitations

- Potential inability to enroll enough patients for a well powered comparative analysis
- Potential bias towards those who are receiving care from a health care provider despite self-enrollment possibilities

Eligible women may self-enroll or be enrolled by their Health Care Provider into the Lilly Migraine Pregnancy Registry via website (coming soon) or by calling via phone (1-833-464-4724)

Background

- Migraine affects primarily women and is most prevalent during child-bearing years
- Based on a parallel conducted administrative claims database study (Healthcore Integrated Research Database), 0.03% (91 of 362,658) evaluable pregnancies were exposed to galcanezumab from launch through June 2020. Therefore, exposure is expected to be rare and it is imperative that every effort be made toward maximizing enrollment
- Data from preclinical studies, clinical trials, and spontaneous reports on outcomes of pregnancies exposed to galcanezumab are limited
- Thus, there is a need to study utilization and safety of galcanezumab when taken during pregnancy

Additional Background Information on Pregnancy Data from Past Galcanezumab Trials

Table 1: Outcomes After Maternal Exposure to Galcanezumab (migraine clinical trials)

Outcome	Number of Events (n)	Percent (%) of Total Female Exposure[a]
Normal Outcome	10	0.46
Premature birth	2	0.09
Abortion spontaneous (n=2); abortion missed (n=1)	3	0.14
Elective termination	1	0.05
Lost to follow-up	5	0.23
Overall exposure via mother	**21**	**0.96**

Abbreviation: n = number of patients within each specific category.
[a] Total Female Exposure = 2183.
Note: Data is from migraine trials. As of 04 September 2018, there were no women who became pregnant during their participation in a phase 3 cluster headache study.

Preclinical Exposure to Galcanezumab

- Embryofetal development studies conducted in rats and rabbits at exposures greater than expected clinically revealed no evidence of harm to the developing fetuses.
- In offspring exposed to galcanezumab in utero and through lactation at exposures greater than expected clinically in the prenatal and postnatal development study in rats, there were no effects on
  - survival
  - growth
  - sexual maturation
  - behavior, or
  - reproduction.

Disclosures: Krista M. Schroeder, Nicole A. Kellier-Steele, Mark E. Bangs, Russell M. Nichols, Lynn V. Do, and Paula M. Hauck are employees of Eli Lilly & Company; Sara A. Ephross and Angie O. Graves are employees of Syneos Health, Jan Brandes received research grants, is a part of advisory boards, and/or is a lecturer for Allergan, Teva, Amgen, Eli Lilly & Company, Lundbeck, National Headache Foundation, and Impel. Previously presented at HEADACHE UPDATE 2021; Diamond Headache Clinic Research & Educational Foundation (DHCREF); Lake Buena Vista, FL, USA; July 15 - 18, 2021

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IHS 2021