# The Vedolizumab Pregnancy Exposure Registry: An OTIS Pregnancy Study Update

**Chambers CD[1,2], Adams J[4], Xu R[2,3], Johnson DL[1], Luo Y[1], Jones KL[1], and the OTIS Collaborative Research Group**

[1] Department of Pediatrics [2] Herbert Wertheim School of Public Health and Longevity Science,
[3]Department of Mathematics, University of California San Diego, La Jolla, CA, USA, [4]Department of Psychology, University of Massachusetts

*Disclosures:* Dr. Chambers receives research funding from the following industry sponsors and a foundation: Amgen Inc.; AstraZeneca; Celgene; GlaxoSmithKline; Janssen Pharmaceuticals; Pfizer, Inc.; Regeneron; Hoffman La-Roche-Genentech; Genzyme Sanofi-Aventis; Takeda Pharmaceutical Company Limited; Sanofi; UCB Pharma, USA; Sun Pharma Global FZE; Gilead; and the Gerber Foundation.

## Background

Vedolizumab is a gut-selective immunoglobulin (Ig) G1 monoclonal antibody that binds to α4β7 integrin; it is approved for the treatment of moderately to severely active Crohn's disease (CD) and ulcerative colitis (UC) in the U.S. and elsewhere. Published studies on the effect of vedolizumab in human pregnancy are limited. Data from the ongoing Vedolizumab Pregnancy Exposure Registry (NCT02678052) in the U.S. and Canada have been collected by the MotherToBaby Pregnancy Studies conducted by the Organization of Teratology Information Specialists (OTIS).

This prospective observational pregnancy cohort study planned to enroll and analyze the outcomes of 100 vedolizumab-exposed (Vedo) participants compared to 100 disease-matched (DM) and 100 healthy comparison (HC) participants.

## Methods

Pregnant women treated with vedolizumab for UC or CD with at least one dose in the first trimester were enrolled in the Vedo group.

Pregnant women with UC or CD but no exposure to vedolizumab were enrolled in the DM group.

Pregnant women with no exposure to any biologic during pregnancy and not diagnosed with an auto-inflammatory or other exclusionary disease were enrolled in the HC group.

Data were collected from telephone interviews and maternal and pediatric medical records; live-born children were followed to one year of age with a dysmorphological examination and developmental screening. The Short Quality of Life in Inflammatory Bowel Disease Questionnaire (SIBDQ) was administered to women with CD or UC.

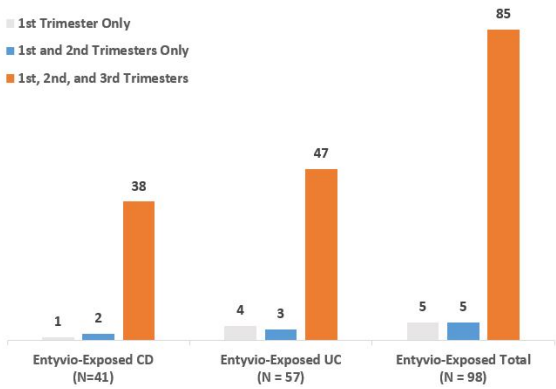
## Results

Between December 2015 and March 2022, outcomes were collected for 301 women, 98 in the Vedo group, 104 in the DM group, and 99 in the HC group. SIBDQ mean scores were similar in the Vedo group, 5.8 (SD 1.0) and the DM group, 5.9 (SD 1.0). Preliminary descriptive outcome data are shown in Table 1.

In the **Vedo group 7.3% of pregnancies resulted in a fetus or infant with a major birth defect,** compared to **6.8% in the DM group,** and **4.7% in the HC group.**

***No pattern of major birth defects was identified in the Vedo group.***

| | Vedo-Total (N=98) | DM-Total (N=104) | HC-Total (N=99) |
|---|---|---|---|
| Pregnancies ending with live born infant - n/N (%) | 93/98 (94.9) | 99/104 (95.2) | 85/99 (85.9) |
| Spontaneous abortion – N (Left Truncation Accounted Rate[a]) | 3 (8.7%) | 3 (6.1%) | 1 (6.4%) |
| Termination - n/N (%) | 0/98 (0.0) | 0/104 (0.0) | 0/99 (0.0) |
| Stillbirth - n/N (%) | 0/98 (0.0) | 1/104 (1.0) | 0/99 (0.0) |
| Lost to follow-up (LTFU) - n/N (%) | 2/98 (2.0) | 1/104 (1.0) | 13/99 (13.1) |
| Preterm delivery – N (Rate[b]) | 13 (14.5%) | 6 (6.1%) | 6 (7.2%) |
| Birth weight full term infants – mean g (SD) | 3410.4 (436.7) | 3428.8 (454.0) | 3308.1 (432.3) |
| Number of pregnancies with major birth defects among all pregnancies excluding LTFU – n/N' (%) | 7/96 (7.3) | 7/103 (6.8) | 4/86 (4.7) |
| Serious infections in live born infants up to 1 year of age – n/N'(%)[c] | 3/97 (3.1) | 2/99 (2.0) | 1/88 (1.1) |
| Ages and Stages Screening at 1 year of age with concern – n/N' (%)[c] | 10/66 (15.2) | 20/87 (23.0) | 11/59 (18.6) |




a Spontaneous abortion rate computed using Fleming-Harrington estimate at 20 weeks' gestation, accounting for left truncation because women can enroll at various times in gestation
b Computed using Fleming-Harrington estimate at 37 weeks' gestation
c Includes twins
% = (n/N') * 100. N' at each category: Number of pregnancies meeting the criteria specified in the row title

## Discussion

**The proportion of pregnancies with vedolizumab exposure resulting in a major birth defect are similar to proportions in the disease comparison group, and did not represent a specific pattern.** The Vedolizumab Pregnancy Exposure Registry is ongoing with formal statistical analysis planned once the study is completed in 2023.