Taking Vedolizumab in Pregnancy Did Not Increase the Risk of Birth Defects or Adverse Pregnancy Outcomes

LA JOLLA, CA – Vedolizumab (sold under the trade name Entyvio®) is a medication that is used to treat Crohn's disease and ulcerative colitis, which are two forms of inflammatory bowel disease (IBD). For women who became pregnant while taking vedolizumab, there are limited data on whether this medication could affect the pregnancy and the developing baby. Our study sought to examine this question by evaluating the safety/risk of vedolizumab use in pregnant women who were participating in MotherToBaby Pregnancy Studies.

What did we study? From 2015 to 2022, we enrolled 275 pregnant women in the United States and Canada; 99 of the women had IBD and reported taking vedolizumab sometime during their pregnancy, 76 women had IBD but were being treated with other biologic medications, and the remaining 100 women did not have IBD and were not exposed to vedolizumab or other biologic medications.

We interviewed the mothers up to three times during their pregnancy and once at the end of their pregnancies. We also collected information from the medical records of both mom and baby. Finally, a subset of the babies was examined by one of our study doctors. We then compared the three groups of women by looking at several pregnancy and birth outcomes, including pregnancy loss, preterm birth, and birth defects.

What did we find? We found no meaningful differences in the rates of pregnancy loss, preterm birth, or birth defects between the groups. There were also no meaningful differences between the groups on infant growth measures at birth and at 1 year of age.

What's the takeaway? Taking vedolizumab in pregnancy did not increase the chance of birth defects or other adverse pregnancy outcomes. Our study provides additional reassuring evidence for women with IBD who take vedolizumab during pregnancy.

Reference:

Chambers CD, Johnson DL, Luo Y, Xu R, Adam MP, Braddock SR, Jones KL; OTIS Collaborative Research Group. Birth Outcomes in Women Who Have Taken Vedolizumab in Pregnancy: Results from the Vedolizumab Pregnancy Exposure Registry. Am J Gastroenterol. 2025 Jun 11. doi: 10.14309/ajg.0000000000003593. Epub ahead of print. PMID: 40498121.

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Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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PRESS RELEASE

Brentwood, TN — MotherToBaby, a service of the Organization of Teratology Information Specialists (OTIS), today announced the launch of two brand new resource hubs—a dedicated webinar repository and a collection of downloadable infographics—to equip healthcare providers with evidence-based tools for patient education and clinical practice. The announcement coincides with National Birth Defects Awareness Month (NBDAM), observed every January.

Each year, approximately 1 in 33 babies in the United States is born with a birth defect. Birth defects are a leading cause of infant mortality. National Birth Defects Awareness Month, led by the National Birth Defects Prevention Network (NBDPN), underscores the importance of prevention, education, and support for families.

The new MotherToBaby Webinar Repository houses on-demand presentations featuring nationally recognized experts discussing timely topics related to exposures during pregnancy and breastfeeding, from medication safety to infectious disease risks. All webinars are free to view, evidence-based, and designed for providers who counsel patients on exposure risks and benefits.

In addition, the MotherToBaby Infographics Library offers visually engaging, easy-to-share graphics covering common questions about exposures—from vaccines and radiation to environmental concerns. These materials can be shared directly with patients, used in presentations, or integrated into community outreach.

“Healthcare providers are often the first line of support when families have questions about exposures during pregnancy or breastfeeding,” said Lorrie Harris-Sagaribay, MPH, President of OTIS/MotherToBaby. “We created these webinars and infographics to make their jobs easier—delivering evidence-based information in formats that are quick to access, simple to share, and easy for patients to understand. Our goal is to help prevent birth defects and improve outcomes by ensuring accurate, trusted information reaches the providers and families who need it most.”

By aligning this launch with National Birth Defects Awareness Month, MotherToBaby highlights the critical role of

healthcare providers in advancing prevention and education. The organization encourages providers to explore the webinars and infographics, and to share them with patients and colleagues.

More about MotherToBaby

MotherToBaby, a service of the non-profit Organization of Teratology Information Specialists (OTIS), is dedicated to providing no-cost evidence-based information to pregnant and breastfeeding people, healthcare professionals, and the general public about medications and other exposures during pregnancy and while breastfeeding. Talk directly to the experts behind the most up-to-date research by calling (866) 626-6847, texting (855) 999-3525, or via live chat and email on www.MotherToBaby.org. MotherToBaby is recommended by many agencies, including the Centers for Disease Control and Prevention (CDC).

MotherToBaby is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an annual award totaling $1,200,000 with zero percentage financed with non-governmental sources. MotherToBaby is also supported by the Centers for Disease Control and Prevention (CDC). The contents of this release are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, CDC, HHS or the U.S. Government. To learn more about MotherToBaby and OTIS, please visit www.MotherToBaby.org.

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