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.

# # #

Media Contact: Nicole Chavez, 619-368-3259, nchavez@MotherToBaby.org.

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

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

MotherToBaby is the Leading National Resource on Exposures during Pregnancy and Breastfeeding

BRENTWOOD, TN – The non-profit Organization of Teratology Information Specialists (OTIS), which provides the MotherToBaby free service, receives new funding aimed at enhancing partnerships to address birth defects, infant disorders and related conditions, and the health of pregnant and postpartum people. The grant is supported by the Centers for Disease Control and Prevention (CDC).

The funding is a five-year award beginning October 1, 2023. “This remarkable funding is a testament to our tireless dedication to staying ahead of the curve when it comes to diseases, infections, and empowering the public with the latest information,” said Alfred Romeo, RN, PhD, President of MotherToBaby. “We are thrilled to collaborate with numerous organizations to amplify the impact of our vital work,” he added.

Great strides will be made under this grant, including collecting and disseminating data, developing and distributing data-driven resources, forging valuable partnerships, and fostering community engagement to raise awareness of the invaluable services provided by MotherToBaby.

“This support is a game-changer, enabling us to further equip pregnant and breastfeeding individuals with crucial information, especially during health crises like the recent COVID-19 pandemic,” Romeo emphasized. “The partnerships we build will help us navigate the next emerging issue affecting people who are pregnant and breastfeeding.”

MotherToBaby provides information on exposures, like medications, vaccines, diseases, herbal supplements, occupational exposures and more before and during a pregnancy as well as while breastfeeding. The service is provided through its no-cost helpline 866-626-6847, texting service 855-999-3525 and website www.MotherToBaby.org, where the public can live chat, e-mail an expert or browse a library of fact sheets in English and Spanish. Additionally, MotherToBaby hosts LactRx, a free app providing current information on the use of medications, vaccines, diagnostic agents, and drugs of misuse during breastfeeding. LactRx is available for iPhone

and Android.

More about OTIS and MotherToBaby

The Organization of Teratology Information Specialists (OTIS) is a professional scientific society made up of individuals engaged in assessing and evaluating risks to pregnancy and breastfeeding from environmental exposures. Members include, but are not limited to, specialists in the fields of obstetrics and gynecology, pediatrics, genetics, dysmorphology, perinatal epidemiology, teratology, behavioral teratology, pharmacy, genetic counseling, nursing, midwifery, maternal and child health, public health, and includes experts that provide MotherToBaby services and researchers that conduct MotherToBaby Pregnancy Studies. To learn more about MotherToBaby and OTIS, please visit www.MotherToBaby.org.

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

Pregnancy Outcomes

World Birth Defects Day is March 3 and MotherToBaby is a proud partner in two of the events scheduled for that day – the Facebook Live Event at 1p ET about the COVID-19 vaccine in pregnancy and breastfeeding featuring our own Sonja Rasmussen, MD, Lorrie Harris-Sagaribay, MPH, Kirstie Perrotta, MPH and our Past President Robert Felix. In addition, a #WorldBDDay Twitter chat is scheduled and, alongside the non-profit Family Voices, our Al Romeo, RN, PhD, will present a free webinar on lead exposure at 2p ET. We hope you'll mark your calendar for all of the events scheduled for March 3 and support World Birth Defects Day by taking part! Here is the full rundown of the activities outlined by our partners at the International Clearinghouse on Birth Defects Surveillance and Research:

LIVE EVENTS on March 3rd

Time	Event	How to Participate
8 AM EST / 2PM CET	**WHO WBDD webinar via Zoom:** Saving lives of babies with birth defects and improving their quality of life	1) Registration details will be made available soon.
11 AM EST/8 AM PST	**#WorldBDDay Twitter Chat:**Many birth defects. One voice	1) Promote event with sample tweets and promotional graphic-Eng, Span 2) Prepare responses and participate live or schedule tweets (script)

1PM EST/10AM PST	**Facebook Live Event: COVID-19 Vaccine in Pregnancy & Breastfeeding**	Follow MotherToBaby on March 3 to take part and ask questions! https://fb.me/e/A2mTOEya
2PM EST/11AM PST	**Free webinar on lead exposure in pregnancy**	Register at: http://bit.ly/FV_MTB_2021_Lead

Event Descriptions

WHO World Birth Defects Day Webinar via Zoom

8:00AM EST / 2:00PM CET

All children have the right to a healthy start in life. Babies born with birth defects are particularly at risk of death and lifelong disability. Many birth defects can be prevented and treated. But, when a baby is born with a birth defect, receiving the right care as soon as possible gives them the best chance to life and helps them reach their maximum potential. There is a need for strengthening healthcare services to meet the needs of babies born with a birth defect, in particular in low-and-middle income countries of Asia and Africa, where the health care systems are the weakest and the burden of birth defects is the highest. To promote quality of care and universal health coverage for children with birth defects, we must bring to light the human rights perspective and the need for advocacy.

With this webinar, we would like to commemorate World Birth Defects Day to raise awareness about **#ManyBirthdefects1Voice**. Registration details will be shared soon.

#WORLDBDDAY Global Twitter Chat

On March 3rd at 11:00AM EST, 5:00PM CET, join us during the Twitter Chat as one voice to raise awareness about birth defects. To prepare, get the bilingual script and questions here. Even if you cannot join us live, please schedule a tweet using #WorldBDDay at this time.



Facebook Live Event: COVID-19 Vaccine in Pregnancy & Breastfeeding

The event panel includes moderator Robert Felix, MD; and speakers Sonja Rasmussen, MD, Lorrie Harris-Sagaribay, MPH, and Kirstie Perrotta, MPH.

Follow MotherToBaby at https://fb.me/e/A2mTOEya



Lead Exposure Webinar

As parents or when planning to start a family, it's important to know and understand how to achieve the best care and health for children, but where do you begin? Right at home! Houses, especially older ones, can be a source of lead exposure. Although lead-based paint hasn't been sold since the late 70s, many older homes still have it. Learn about the available resources supporting families who are exposed to lead. On World Birth Defects Day March 3, join the free webinar presented by MotherToBaby and Family Voices on the impact of lead exposures during pregnancy, infancy and in childhood. Register here now.



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On March 3, join MotherToBaby, March of Dimes and dozens of organizations around the world for a World Birth Defects Day Twitter Chat. Ask questions about birth defects, pregnancy health and more. Include the hashtag #WorldBDDay in every tweet to take part!





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

Join MotherToBaby and partner organizations around the world for a special World Birth Defects Day Facebook and Instagram Live Chat March 3 at 10a PT/1p ET.

How to participate: Follow @MotherToBaby on Facebook or @mothertobabyotis on Instagram (or both). You might get a notification from Facebook or Instagram that the MotherToBaby page you follow is going live at the live broadcast start time. Alternatively, just go to MotherToBaby's profile on either Facebook or Instagram at the broadcast start time (10a PT/1p ET). You can also get a reminder for the live event by clicking "going" on the Facebook event created for it: https://www.facebook.com/events/213655426471361/

On Facebook, the live video should just be playing at the top of MotherToBaby's page. On Instagram, you will see a small badge around the story circles at the top of the screen that says "live." Tap to enter the live stream. The person streaming will know that you are tuning in.

With either platform, once you are watching the live stream, you can comment or ask questions, the same way you'd engage with a non-live post. MotherToBaby's president, Christina Chambers, PhD will be joined by Drs. Kenneth Lyons Jones, MD and Miguel Del Campo, MD to answer questions in English and Spanish about birth defects.

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