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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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

World-Renowned UC San Diego Epidemiologist Leads Groundbreaking Study

SAN DIEGO, CA – Recruitment is underway for a groundbreaking new study on the treatment of lupus during pregnancy. The observational research, led by world-renowned UC San Diego epidemiologist Christina Chambers, PhD, MPH, is the first of its kind for the non-profit MotherToBaby, a CDC-recommended organization that provides evidence-based information on medications, diseases, vaccines, herbal supplements and more during pregnancy and breastfeeding.

The study will recruit 400 pregnant people over a five-year period to evaluate use of the lupus drug Benlysta® (belimumab) in pregnancy. Benlysta® is used to treat the most common type of lupus, systemic lupus erythematosus (SLE), as well as lupus nephritis. Currently, there is limited information on the drug's use in pregnancy.

The study will be MotherToBaby's first to focus on a treatment specifically for lupus, and participants will be enrolled into the MotherToBaby Pregnancy Studies research program. Chambers, who is the lead investigator for MotherToBaby Pregnancy Studies, Co-Director of the Center for Better Beginnings, and Chief of the Environmental Science and Health Division in the UC San Diego Department of Pediatrics, noted that, "lupus can raise the risk of pregnancy complications, so it's important for both the mom and her developing baby that this condition be well-managed during pregnancy. So, when treatments for lupus like belimumab are available, we want to do our best to gather information about those pregnancies where this medication has been used."

The study is enrolling pregnant and recently pregnant people with exposure to Benlysta® and will provide critical information on the use of this medication during pregnancy. Participants will not be asked to change any part of their health care routine, including medications, nor will they be asked to travel.

More about MotherToBaby Pregnancy Studies

MotherToBaby Pregnancy Studies are conducted by the non-profit Organization of Teratology Information Specialists (OTIS) and coordinated at the Center for Better Beginnings at UC San Diego. 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 include experts that provide MotherToBaby services and researchers that conduct MotherToBaby Pregnancy Studies.

MotherToBaby is a suggested resource by many federal 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 award totaling $6,000,000 with zero percentage financed with non-governmental sources. 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, HHS or the U.S. Government. To learn more about MotherToBaby and OTIS, please visit **MotherToBaby.org**.

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

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

March 23, 2020

LA JOLLA, CA –A new study conducted by birth defects research experts from the non-profit Organization of Teratology Information Specialists (OTIS) launches to examine the short and long-term effects of the novel COVID-19 virus in pregnancy and breastfeeding. The observational study will consist of phone calls over the course of volunteers' pregnancies and post-delivery, and/or breastmilk samples, as well as a release of medical records related to the pregnancy and the infant's development.

OTIS is the scientific non-profit society that provides the no-cost MotherToBaby information service and enrolls women through the MotherToBaby Pregnancy Studies.

"Women and their health care providers need answers as quickly as possible regarding the effects of COVID-19 during pregnancy and while breastfeeding," said the Principal Investigator, Christina Chambers, PhD, MPH, OTIS/MotherToBaby president and professor of pediatrics at UC San Diego (pictured right). "We know that pregnant and breastfeeding moms are contracting COVID-19, but the fact of the matter is that we know very little about its short and long-term effects on a developing baby," she added. "We hope pregnant women see the importance in helping the world understand this novel virus and consider volunteering for the study."



The study is open to pregnant and breastfeeding women in the United States and Canada with known or suspected COVID-19 infection. The MotherToBaby Pregnancy Studies Research Center is located at the University of California San Diego.

Pregnant women and breastfeeding mothers can enroll in the study at the following link https://mothertobaby.org/join-study/ or by calling MotherToBaby Pregnancy Studies at (877) 311-8972. Learn more about the ongoing observational study at https://mothertobaby.org/ongoing-study/coronavirus-covid-19/.

Health care providers can refer pregnant and breastfeeding patients with known or suspected COVID-19 infection at the following link https://mothertobaby.org/healthcare-professional-referral-form/ or by calling MotherToBaby Pregnancy Studies at (877) 311-8972.

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. MotherToBaby is a suggested resource by many federal agencies including the Centers for Disease Control and Prevention (CDC). To learn more about ongoing MotherToBaby Pregnancy Studies, call (877) 311-8972, email MotherToBaby@ucsd.edu or visit www.MotherToBaby.org.

The study launched March 23, 2020. Interviews with Christina Chambers, PhD, MPH are now being

scheduled. Interested media, please call 619-368-3259 or email nchavez@mothertobaby.org.

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

602 Pregnancies Examined by the Non-Profit Organization of Teratology Information Specialists

LA JOLLA, CA –A new study conducted by birth defects experts from the Organization of Teratology Information Specialists (OTIS) suggests adalimumab use in pregnancy was not associated with an increased risk for adverse outcomes examined, such as major structural birth defects, spontaneous abortion and preterm delivery. The findings were published today in the Public Library of Science (PLOS) One Journal.

The prospective research study conducted by OTIS examined 602 pregnancies that occurred between 2004 – 2016 in women across the U.S. and Canada. Researchers enrolled pregnant women into the observational cohort study who had or had not taken adalimumab for their autoimmune disease, as well as generally healthy pregnant women for comparison. OTIS is the scientific non-profit society that provides the no-cost MotherToBaby information service and enrolls women through the MotherToBaby Pregnancy Studies Research Center at the University of California San Diego. Financial support for the adalimumab study was provided by AbbVie.

“Many women hoping to start a family rely on adalimumab to control symptoms related to crippling autoimmune diseases such as rheumatoid arthritis or Crohn’s Disease,” said lead study author Christina Chambers, PhD, MPH, OTIS/MotherToBaby president and professor of pediatrics at the University of California, San Diego. “The fact that this

study showed no increased risk in adverse birth outcomes with the use of adalimumab in pregnancy is important since not a lot of research was previously available on this particular medication."

The study also found that regardless of whether they took adalimumab or not, pregnant women with rheumatoid arthritis or Crohn's Disease were at an increased risk of preterm birth (delivery before 37 weeks of pregnancy).

"Studies on medication use in general are lacking when it comes to understanding their effects on pregnancy, making it difficult for pregnant women and their healthcare providers to make informed decisions," said Dr. Chambers. "We are proud to add valuable information to the literature and encourage more pregnant women to consider volunteering for critical observational studies."

For more information on all of the current MotherToBaby Pregnancy Studies, please visit https://mothertobaby.org/pregnancy-studies/.

More about OTIS and MotherToBaby

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