DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857
HIV/AIDS Bureau

MAY 23 2018

Dear Ryan White HIV/AIDS Program Colleagues:

On May 18, 2018, the U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication on the potential risk of antiretroviral medication dolutegravir (DTG) associated neural tube birth defects.[1] Dolutegravir is used in combination with other antiretroviral drugs and is available as a single agent under the brand name Tivicay, and as part of combination tablets with other antiretrovirals under the brand names Juluca and Triumeq.

This FDA alert comes after preliminary results of an ongoing observational study in Botswana. The study showed that infants born to women who were taking dolutegravir as part of their antiretroviral therapy regimen when becoming pregnant had an increased risk of neural tube birth defects. Neural tube birth defects are abnormalities that are the result of improper formation of the brain, spine, or spinal cord early in pregnancy. The preliminary data has not shown neural tube birth defects in infants born to women who started dolutegravir during pregnancy

The study is ongoing and the FDA will release more information when it becomes available. Further information is expected over the next nine to twelve months.

In response to the FDA alert, interim guidance has been issued by the HHS Antiretroviral Guidelines Panels regading dolutegravir (DTG).[2] The Office of AIDS Research Advisory Council will be reviewing for proposed guideline changes. The interim recommendations of the Panels are as follows[3]:

- Health care providers are encouraged to counsel women of childbearing age with HIV currently receiving DTG about this newly identified potential risk.
- Pregnant women with HIV who are currently taking DTG should not stop their ARV therapy and should speak with their health care provider for additional guidance.
- Women of childbearing age with HIV who desire to become pregnant should discuss alternative ARV regimen options with their health care provider.
- Women of childbearing age with HIV who are not planning to become pregnant may be on DTG-based regimens provided their pregnancy test before initiation of therapy is negative, and they consistently use a reliable contraceptive method.
- Health care providers are encouraged to report all pregnancy data to the Antiretroviral Pregnancy Registry (1-800-258-4263; http://www.apregistry.com).

1. https://www.fda.gov/Drugs/DrugSafety/ucm608112.htm
2. The Panel on Antiretroviral Guidelines for Adults and Adolescents, the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV, and the Panel on Treatment of Pregnant Women Living with HIV and Prevention of Perinatal Transmission.
3. https://aidsinfo.nih.gov/news/2094/statement-on-potential-safety-signal-in-infants-born-to-women-taking-dolutegravir.

Updates to the HHS treatment guidelines are anticipated as more information becomes available. It is important to use the HHS guidelines to drive HIV care and treatment as we focus on the Goals to End the HIV Epidemic and provide optimal care and treatment for all people living with HIV. We encourage you to be alert for HHS guideline updates (from *AIDSinfo)* and to share this information with providers. You can sign up for AIDS*info* At-a-Glance to stay up to date on the latest HIV news and to receive notice of new and updated AIDS*info* features (https://aidsinfo.nih.gov/e-news).

Sincerely,

/s/

Laura Cheever, MD, ScM
Associate Administrator and
Chief Medical Officer
HIV/AIDS Bureau