BRITISH COLUMBIA
CENTRE *for* EXCELLENCE
in HIV/AIDS

St. Paul's Hospital
613-1081 Burrard Street
Vancouver, BC
Canada V6Z 1Y6

Tel 604.806.8477
Fax 604.806.8464
www.cfenet.ubc.ca

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Dear Healthcare Provider:

RE: Safety of dolutegravir-containing products (Tivicay™, Triumeq™) in pregnancy and use in women of reproductive age

On June 7, 2018, Health Canada issued a warning regarding the possible risk of neural tube defects associated with dolutegravir use during early pregnancy. This warning was based on preliminary findings from an observational study in Botswana, which identified 4 of 426 infants (0.9%) with neural tube defects born to women who had been treated with dolutegravir at the time of conception, compared to 14 of 11,173 infants (0.1%) whose mothers took other antiretroviral medications. The manufacturer is continuing to monitor the results of this ongoing study.

At this time, pending additional information, healthcare providers are advised of the following cautions with use of dolutegravir in women of reproductive age:

- Avoid prescribing dolutegravir in women of reproductive potential who are not on a reliable method of birth control, or who are trying to become pregnant, when there are other reasonable treatment options.
- In women currently receiving dolutegravir, or for whom dolutegravir is being considered, weigh the risk versus benefit and ensure use of reliable contraceptive methods before initiating and during dolutegravir treatment. Rule out pregnancy before initiating dolutegravir, and counsel on the possible risk of neural tube defects in early pregnancy. Review pregnancy intention and contraceptive use regularly during therapy. If pregnancy is a possibility, including lack of reliable contraceptive use, consider switching to a non-dolutegravir containing regimen.
- If pregnancy is confirmed in a woman who is taking dolutegravir or who has a history of dolutegravir exposure at the time of conception and/or during the first trimester- Seek immediate expert advice from an HIV specialist and the Oak Tree Clinic at BC Women's Hospital and Health Centre 604-875-2212 to review pregnancy management and the antiretroviral regimen for potential modification. Women should not interrupt their antiretroviral therapy while awaiting expert HIV guidance.

- Due to the lack of safety information of new antiretroviral medications in pregnancy, caution should be exercised in prescribing any new antiretroviral agent in reproductive aged women with pregnancy potential, and should be avoided in the first trimester when possible.

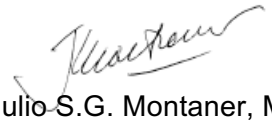
For additional information and guidance, please refer to the following:

- "Dolutegravir prescribing guidelines for pregnancy and women of reproductive potential" (May 31, 2018) developed by the Oak Tree Clinic in collaboration with the BC Centre for Excellence in HIV/AIDS (found at http://www.bcwomens.ca/health-professionals/professional-resources/hiv-aids-resources/hiv-aids-clinical-guidelines)
- Health Canada Advisory, Dear Healthcare Professional Letter "Tivicay™, Triumeq™, and Juluca™ (dolutegravir containing medicines) - Possible Risk of Neural Tube Defects" (June 7, 2018) (found at http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/66998a-eng.php)

The BC-CfE Pharmacovigilance Initiative conducts ongoing monitoring of adverse reactions to antiretroviral drugs in BC. Information about how to report an adverse drug reaction to the program can be found at http://www.cfenet.ubc.ca/hiv-drug-safety/report-drug-reaction.

Sincerely,

Val Montessori, MD, FRCPC
Co-Chair, Committee for Drug Evaluation and Therapy



Julio S.G. Montaner, MD, DSc (Hon), FRCPC, FCCP, FACP, FRSC
Director

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