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Statement from the Southern African HIV Clinicians Society

Saturday, 19 May 2018

DTG in pregnancy

The Southern African HIV Clinicians Society (SAHCS) would like to inform all HIV-treating clinicians of the following important new information regarding dolutegravir (DTG).

Preliminary data from a study in Botswana have shown 0.9% of babies (4/426) born to women who were taking DTG when they conceived or early in the first trimester had neural tube defects (NTDs), compared with 0.1% of babies (14/11,173) of women taking other antiretrovirals (ARVs). No NTDs were observed in those pregnancies where DTG was initiated later in pregnancy. World Health Organization (WHO) and regulatory agencies have been informed and are evaluating these preliminary data. The Botswana Department of Health and Ethics Committee have recommended that the study should continue. Final study results are expected in 2019.

Reproductive toxicology studies have not shown any relevant findings. To date, other data on the use of DTG in pregnancy, including data from the Antiretroviral Pregnancy Registry (APR), clinical trials and post-marketing use, have not indicated a risk of NTDs.

WHO recommendations

WHO convened an expert guideline development meeting on 16-18 May 2018 to review all available DTG safety and efficacy data, including the Botswana data, and will release guidance on the role of DTG in antiretroviral therapy (ART) in the coming months.

In the interim, WHO advises the following:

- Follow the existing 2016 WHO Consolidated ARV Guidelines, which cautioned around insufficient data for using DTG in pregnancy/breastfeeding, and recommended efavirenz (EFV) with tenofovir and lamivudine/emtricitabine as the preferred option in pregnant women
- Pregnant women who are taking DTG should NOT stop their ART, and should speak with their healthcare provider for further guidance
- ART for women of childbearing age, including pregnant women, should include drugs for which adequate efficacy and safety are available. An EFV-based regimen is safe and effective for first-line ART.
- If other first-line ARVs cannot be used in women of childbearing age, DTG may be considered in cases where consistent contraception can be assured
- Programmes should continue strengthening pharmacovigilance including monitoring of birth outcomes.

SAHCS guidance (aligned with European Medicines Agency)

- Do not prescribe DTG for women of childbearing age who are trying to become pregnant
- Exclude pregnancy in women of childbearing age before starting DTG
- Advise women of childbearing age who are taking DTG to use effective contraception throughout treatment
- If pregnancy is confirmed in the first trimester while a woman is taking DTG, switch to an alternative treatment unless there is no suitable alternative.

While this is an early signal, it warrants careful pharmacovigilance, and further evaluation. As more information becomes available, we will update our guidance.

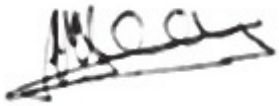
Links to statements from WHO, EMA and FDA for further detail:

http://www.who.int/medicines/publications/drugalerts/Statement_on_DTG_18May_2018final.pdf?ua=1

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/05/news_detail_002956.jsp&mid=WC0b01ac058004d5c1

https://www.fda.gov/Drugs/DrugSafety/ucm608112.htm

Yours sincerely



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