Dear Healthcare Professional,

NEW STUDY SUGGESTS RISK OF BIRTH DEFECTS IN BABIES BORN TO WOMEN ON HIV MEDICINE DOLUTEGRAVIR (TIVICAY)

The Food and Drugs Authority (FDA) will like to bring to your attention safety information relating to dolutegravir (Tivicay) in an ongoing observational study in Botswana which found that babies born to women treated with dolutegravir developed cases of neural tube defect (NTD). Preliminary results from the ongoing study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.

Dolutegravir is an antiretroviral medicine approved by the FDA under the brand name Tivicay for use in combination with other antiretroviral medicines to treat HIV, the virus that can cause acquired immunodeficiency syndrome (AIDS). Dolutegravir works by blocking integrase, an HIV enzyme, to prevent the virus from multiplying and can reduce the amount of HIV in the body.

The FDA would like to recommend the following precautionary measures for immediate implementation:

1. Dolutegravir HIV medicines should not be prescribed to women seeking to become pregnant.

2. Pregnancy should be excluded in women of child bearing potential before starting dolutegravir.

3. Women who can become pregnant should use effective contraception while taking dolutegravir medicines.

4. If pregnancy is confirmed in the first trimester while a woman is taking dolutegravir, treatment should be switched to an alternative treatment unless there is no suitable alternative.

This safety concern was identified from a preliminary analysis of the Tsepamo study, in Botswana, where 4 NTD cases out of 426 pregnancies on dolutegravir were observed.
representing an incidence of 0.9% compared with an expected background rate of 0.1%. The study is ongoing and final results are expected in about a year.

The FDA will like to advice healthcare professionals to report adverse drug reactions to dolutegravir and all other medicines to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh/ or call mobile number, 024 431 0297 or send an email to drug.safety@fdaghana.gov.gh.

Yours faithfully,

Signed

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER