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16 July 2013

Dr Tomas Salmonson
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of an Application for a Type II variation for Eviplera (emtricitabine / rilpivirine / tenofovir disoproxil) 200 mg/25 mg/245 mg Film-Coated Tablets, - **EMEA/H/002312/II/0023**

Dear Dr Tomas Salmonson,

I would like to inform you that Gilead Sciences International Ltd have taken the decision to withdraw the application for a new indication for Eviplera – to change the indication from the treatment of HIV-1 infection in treatment-naïve adult patients with a viral load ≤ 100,000 copies/ml to the treatment of HIV-1 infection in treatment-naïve adult patients with a viral load ≤ 500,000 copies/ml.

This withdrawal is based on the following reason: the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance.

The CHMP considered that the submitted study results did not support the expansion of the use of Eviplera to patients with viral load >100,000 to ≤ 500,000 copies/mL.

There are no consequences of the withdrawal on Gilead sponsored ongoing clinical trials and compassionate use programmes.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

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I agree for this letter to be published on the EMEA website.

Yours sincerely,

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