EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/CHMP/564327/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vitekta

Elvitegravir

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vitekta, 85 mg and 150 mg, film-coated tablets intended, in combination with other agents, for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults. The applicant for this medicinal product is Gilead Sciences International Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Vitekta is elvitegravir, an HIV-1 integrase strand transfer inhibitor (ATC Code J05AX11). Inhibition of integrase by elvitegravir prevents the integration of HIV-1 DNA into host genomic DNA, blocking the for formation of the HIV-1 provirus and propagation of the viral infection.

The benefits with Vitekta are its ability, in combination with other medicines, to reduce the viral load to undetectable levels (< 50 HIV-1 RNA copies/ml). The most common side effects are diarrhoea and nausea.

A pharmacovigilance plan for Vitekta will be implemented as part of the marketing authorisation.

The approved indication is: "coadministered with ritonavir-boosted protease inhibitor and with other antiretroviral agents, for the treatment of HIV-1 infection in adults who are infected with HIV-1 without known mutations associated with resistance to elvitegravir". It is proposed that Vitekta be prescribed by physicians experienced in the management of HIV infection.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Vitekta and therefore recommends the granting of the marketing authorisation.