28 April 2016
EMA/CHMP/267024/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Odefsey

emtricitabine / rilpivirine / tenofovir alafenamide

On 28 April 2016 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Odefsey, intended for the treatment of adults and adolescents infected with human immunodeficiency virus 1 (HIV 1). The applicant for this medicinal product is Gilead Sciences International Ltd.

Odefsey is a fixed-dose combination of three active substances, rilprivirine, emtricitabine and tenofovir alafenamide, and will be available as 25 mg/200 mg/25 mg film-coated tablets (ATC code: J05AR19). Emtricitabine and tenofovir alafenamide are substrates and competitive inhibitors of HIV reverse transcriptase. After phosphorylation, they are incorporated into the viral DNA chain, resulting in chain termination. Rilprivirine activity is mediated by non-competitive inhibition of HIV 1 reverse transcriptase.

The benefit with Odefsey is its ability to achieve an antiretroviral response with a once daily, single pill regimen. The most common side effects are nausea, insomnia and dizziness.

The full indication is: "Odefsey is indicated for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus 1 (HIV 1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine and with a viral load ≤ 100,000 HIV 1 RNA copies/mL (see sections 4.2, 4.4 and 5.1)." It is proposed that Odefsey 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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