24 September 2015
EMA/628515/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Genvoya

elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Genvoya, intended for the treatment of HIV infection. The applicant for this medicinal product is Gilead Sciences International Ltd.

Genvoya will be available as a fixed-dose combination of four active substances, elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide, and will be available as 150 mg/150 mg/200 mg/10 mg film-coated tablets (ATC code: J05AR18).

Elvitegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration that is essential for the HIV replication cycle. 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. Cobicistat enhances the systemic exposure of elvitegravir and has no direct antiviral effect.

The benefits with Genvoya are its ability to achieve a potent antiretroviral response in a once daily, single pill regimen. The most common side effect is nausea. Genvoya was associated with low impact on renal safety and bone mineral density compared to the licensed tenofovir disoproxil.

The full indication is: "Genvoya 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 any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir (see sections 4.2 and 5.1)." It is proposed that Genvoya 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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