22 January 2015
EMA/CHMP/38006/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dutrebis

lamivudine/raltegravir

On 22 January 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 Dutrebis, 150 mg lamivudine/300 mg raltegravir, film-coated tablet intended for the treatment of human immunodeficiency virus (HIV 1) infection in adults, adolescents, and children from the age of 6 years and weighing at least 30 kg. The applicant for this medicinal product is Merck Sharp & Dohme Limited. 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 substances of Dutrebis are lamivudine/raltegravir, antivirals for treatment of HIV infections, combinations (J05AR16). Lamivudine is substrate and competitive inhibitor of HIV reverse transcriptase and the main antiviral activity is through incorporation of the monophosphate form into the viral DNA chain, resulting in chain termination, while Raltegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle.

The benefits with Dutrebis are the improvement of the dosing regimen by reducing the daily pill burden, while retaining comparable efficacy as compared to dosing with the individual agents. The most common side effects observed during treatment with the individual components of Dutrebis are headache, nausea, malaise, fatigue, nasal signs and symptoms, diarrhoea and cough.

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

The approved indication is: "Dutrebis in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV 1) infection in adults, adolescents, and children from the age of 6 years and weighing at least 30 kg without present or past evidence of viral resistance to antiviral agents of the InSTI (Integrase Strand Transfer Inhibitor) and NRTI (Nucleoside Reverse Transcriptase Inhibitor) classes". It is proposed that Dutrebis be prescribed by physicians experienced in the management of HIV infection (see sections 4.2, 4.4 and 5.1).

[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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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.

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