21 November 2013
EMA/CHMP/636968/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tivicay

dolutegravir

On 21 November 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 Tivicay, 50 mg, Film-coated tablet intended for the treatment of Human Immunodeficiency Virus (HIV). The applicant for this medicinal product is ViiV Healthcare. 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 Tivicay is dolutegravir, an antiviral for systemic use (ATC code: J05AX12). Dolutegravir 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 benefit with Ticivay is the efficacy demonstrated in adult patients with and without resistance to the integrase inhibitors class (documented or clinically suspected) and in adolescents without resistance to the integrase inhibitors class. The most common side effects for Tivicay are diarrhoea (16%), nausea (15%) and headache (14%).

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

The approved indication is: "*Tivicay is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age*". It is proposed that Tivicay be prescribed by physicians experienced in the treatment 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 Tivicay and therefore recommends the granting of the marketing authorisation.