22 September 2011
EMA/CHMP/724496/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Edurant

Rilpivirine Hydrochloride

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Edurant 25 mg film-coated tablet intended for the treatment of human immunodeficiency virus-1 (HIV-1) infection. The applicant for this medicinal product is Janssen-Cilag International N.V. 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 Rilpivirine Janssen-Cilag International NV is rilpivirine as hydrochloride, an antiviral for systemic use, NNRTI (non nucleoside reverse transcriptase inhibitor) (J05AG05). Rilpivirine activity is mediated by non competitive inhibition of HIV 1 reverse transcriptase.

The benefits with Edurant are its ability to reduce and maintain the amount of HIV in plasma (viral load) at a low level in patients with viral load ≤ 100,000 HIV 1 RNA copies/ml. The most common side effects are nausea, dizziness, abnormal dreams, headache and insomnia.

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

The approved indication is: Edurant, in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV 1) infection in antiretroviral treatment naïve adult patients with a viral load ≤ 100,000 HIV 1 RNA copies/ml. This indication is based on week 48 safety and efficacy analyses from two randomised, double blind, controlled, Phase III trials in treatment naïve patients and week 96 safety and efficacy analyses from a Phase IIb trial in treatment naïve patients (see section 5.1). As with other antiretroviral medicinal products, genotypic resistance testing should guide the use of EDURANT (see sections 4.4 and 5.1).

It is proposed that therapy with Edurant should be initiated by a physician experienced in the management of human immunodeficiency virus (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

[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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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 Edurant and therefore recommends the granting of the marketing authorisation.