European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 July 2009
Doc. Ref. EMEA/CHMP/471151/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
ISENTRESS

International Nonproprietary Name (INN): ***raltegravir***

On 23 July 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Isentress. The Marketing Authorisation Holder for this medicinal product is Merck Sharp & Dohme Ltd.

The CHMP adopted a change to an indication as follows***:

Isentress is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients.

This indication is based on safety and efficacy data from two double-blind, placebo-controlled trials of 48 weeks duration in treatment-experienced patients **and one double-blind, active-controlled trial of 48 weeks duration in treatment-naïve patients**.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*** The text in bold represents the new or the amended indication.

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