European Medicines Agency
*Evaluation of Medicines for Human Use*

London, 23 October 2008
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]**
**for**
**PREZISTA**

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

On 23 October 2008 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 Prezista. The Marketing Authorisation Holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted a change to an indication as follows:

Prezista, co-administered with 100 mg ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in treatment-experienced adult patients, including those that have been highly pre-treated.

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.

For information, the full indication for Prezista will be as follows[***]:

Prezista, co-administered with 100 mg ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in **treatment-experienced** adult patients, **including those that have been highly pre-treated.**

In deciding to initiate treatment with Prezista co-administered with 100 mg ritonavir careful consideration should be given to the treatment history of the individual patient and the patterns of mutations associated with different agents. Genotypic or phenotypic testing (when available) and treatment history should guide the use of Prezista.

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[*] 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.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu