European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 April 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISTAION SUMMARY OF POSITIVE OPINION*
for
PREZISTA

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

On 23 April 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending an extension 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 extension adopted by the CHMP is to add two new strengths (75 and 150 mg film-coated tablets) to the existing product range.

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

Prezista, co-administered with low dose ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in **antiretroviral** treatment **(ART)** experienced adult patients, including those that have been highly pre-treated, and for the treatment of HIV-1 infection in **ART**-experienced **children and adolescents from the age of 6 years and at least 20 kg body weight**.

In deciding to initiate treatment with Prezista co-administered with low dose 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.

* 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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