European Medicines Agency
*Evaluation of Medicines for Human Use*

London, 20 November 2008
Doc.Ref. EMEA/CHMP/618601/2008

**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**POST-AUTHORISTAION SUMMARY OF POSITIVE OPINION***
**for**
**PREZISTA**

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

On 20 November 2008 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 a new strength (400 mg film-coated tablets) to the existing product range.

This new strength will be used in a new indication.

The new indication adopted by the CHMP is: PREZISTA 400 mg, 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 therapy (ART) naïve adults.

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 extension 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.

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