European Medicines Agency
*Evaluation of Medicines for Human Use*

London, 23 April 2009
Doc. Ref. EMEA/CHMP/232469/2009

**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]**
**for**
**APTIVUS**

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

On 23 April 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 Aptivus. The Marketing Authorisation Holder for this medicinal product is Boehringer Ingelheim International GmbH.

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

Aptivus, co-administered with low dose ritonavir, is indicated for combination antiretroviral treatment of HIV-1 infection in highly pre-treated **adult- and adolescent-** patients **12 years of age or older** with virus resistant to multiple protease inhibitors. **Aptivus should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options.**

This indication is based on the results of two phase III studies, performed in highly pre-treated **adult patients** (median number of 12 prior antiretroviral agents) with virus resistant to protease inhibitors **and of one phase II study investigating pharmacokinetics, safety and efficacy of APTIVUS in mostly treatment-experienced adolescent patients aged 12 to 18 years** (see section 5.1).

In deciding to initiate treatment with Aptivus, 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 Aptivus. Initiation of treatment should take into account the combinations of mutations which may negatively impact the virological response to Aptivus, co-administered with low dose ritonavir (see section 5.1).

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.

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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.

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