The European Agency for the Evaluation of Medicinal Products
Press office

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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products 23-24 March 2004

The Committee adopted 5 positive opinions on the initial marketing authorisation applications for:

- **Erbitux** (cetuximab), from Merck KGaA, for the treatment of metastatic colorectal cancer. EMEA review began on 21 July 2003 and the opinion was adopted on 24 March 2004, with an active review time of 201 days.
- **Lyrica** (pregabalin), from Pfizer, for the treatment of neuropathic pain and epilepsy. EMEA review began on 24 March 2003 and the opinion was adopted on 24 March 2004, with an active review time of 200 days.
- **Telzir** (fosamprenavir), from Glaxo Group Limited, intended for the treatment, with low dose of ritonavir, of human immunodeficiency virus type 1 (HIV-1) infected adults in combination with other antiretroviral medicinal products. EMEA review began on 20 January 2003 and the opinion was adopted on 24 March 2004, with an active review time of 201 days.
- **Yentreve** (duloxetine), from Eli Lilly and Company Ltd, for the treatment of stress urinary incontinence. EMEA review began on 24 February 2003 and the opinion was adopted on 24 March 2004, with an active review time of 178 days.
- **Ariclaim** (duloxetine), from Boehringer Ingelheim International GmbH, for the treatment of stress urinary incontinence. EMEA review began on 23 June 2003 and the opinion was adopted on 24 March 2004, with an active review time of 60 days.

Summaries of these opinions, including the full indications for each product, are available on the EMEA web site: http://www.emea.eu.int

The Committee also gave positive opinions on the extension of indication for two medicinal products that are already authorised in the EU:

- **Arava** (leflunomide), Aventis, to extend its use for the treatment of adult patients with active psoriatic arthritis (PsA). Arava was first authorised in the European Union on or 2 September 1999.
- **Cancidas** (caspofungin), Merck Sharp & Dohme, to include empirical therapy for presumed fungal infections (such as candida and aspergillus) in febrile, neutropaenic adult patients. Cancidas was first authorised in the European Union on 24 October 2001.
- **Ferriprox** (deferiprone), Apotex, to extend its use to include the treatment of patients with thalassaemia major when deferoxamine therapy is inadequate. Ferriprox was first authorised in the European Union on 25 August 1999.

Further information on this extension will be included in the public assessment report (EPAR) once the European Commission has granted final approval.

The Committee finalised its EU-wide review for **Lopid** (gemfibrozil) and associated product names from Pfizer. The referral was made by the European Commission in January 2003 under Article 30 of the Community Code on human medicines as part of the concerted action by EU regulatory authorities

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to harmonise the marketing conditions of a number of European brand leaders in major therapeutic areas.

The CPMP recommended that Lopid should be indicated as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) in the treatment of dyslipidaemia in mixed dyslipidaemia characterised by hypertriglyceridaemia and/or low HDL-cholesterol. In addition, the Committee recommended that Lopid should be indicated in primary hypercholesterolaemia, particularly when a statin is considered inappropriate or is not tolerated.

The Committee also recommended that Lopid should be indicated in primary prevention in the reduction of cardiovascular morbidity in males with increased non-HDL cholesterol and at high risk for a first cardiovascular event, particularly when a statin is considered inappropriate or is not tolerated.

A more detailed CPMP meeting report will be published shortly.

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