The European Agency for the Evaluation of Medicinal Products

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# PRESS RELEASE
# Committee for Proprietary Medicinal Products
# Meeting of 19 to 21 February 2002

The CPMP adopted 5 opinions on initial marketing authorisation applications at this meeting:

- A positive opinion for **EVRA** (norelgestromin – ethinyl estradiol) from Janssen Cilag International N. V. presented as a transdermal patch intended for female contraception for women of fertile age. EMEA review began on 27 March 2001 and the opinion was adopted on 21 February 2002, with an active review time of 175 days.

- A positive opinion for **Tracleer** (bosentan) from Actelion Registration Ltd indicated for the treatment of pulmonary arterial hypertension to improve exercise capacity and symptoms in patients with grade III functional status. EMEA review began on 27 February 2001 and the opinion was adopted on 21 February 2002, with an active review time of 173 days. Tracleer was designated an orphan medicinal product on 14 February 2001. This is the fifth orphan medicinal product to receive a positive opinion for marketing authorisation from the CPMP.

- Positive opinions for the double application **Memantine-Merz Pharmaceuticals GmbH** (memantine hydrochloride) from Merz Pharmaceuticals GmbH, and **Ebixa** (memantine hydrochloride) from Lundbeck A/S indicated for the treatment of patients with moderately severe to severe Alzheimer's disease**.** EMEA review for Memantine Hydrochloride Merz & Co began on 26 September 2000 and for Ebixa on 22 October 2001. The opinion was adopted on 21 February 2002, with an active review time of 208 and 62 days respectively.

- A positive opinion for **Opatanol** (olopatadine) from Alcon Laboratories (UK) Ltd indicated for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis. EMEA review began on 27 March 2001 and the opinion was adopted on 21 February 2002, with an active review time of 218 days.

Summaries of these opinions are available on the EMEA web site: http://www.emea.eu.int

The CPMP also gave a positive opinion for a new indication for **Glivec** (imatinib mesylate) from Novartis Europharm Ltd for the treatment of adult patients with unresectable and/or metastatic gastrointestinal stromal tumours (GIST)**.** Glivec was first authorised in the European Union on 7 November 2001 and orphan medicinal product status for GIST was granted on 20 November 2001. EMEA review began on 14 December 2001.

The CPMP initiated a Community-level review on the risk-benefit of bupropion containing medicinal products (Corzen, Quomem, Zyban, Zyntabac) authorised under the mutual recognition procedure, following a referral by Germany under Article 36 of the Community Code on human medicines (ex-Article 15a of Council Directive 75/319/EEC).

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 18 February 2002.

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