The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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PRESS RELEASE

Committee for Proprietary Medicinal Products
Meeting of 24 to 26 July 2001

The CPMP adopted 3 opinions on initial marketing authorisation applications at this meeting:

- A positive opinion for Glivec (imatinib mesilate) from Novartis Europharm Ltd. indicated for the treatment of adult patients with Philadelphia chromosome (bcr-abl) positive chronic myeloid leukaemia (CML) in chronic phase after failure of interferon- alpha therapy, or in accelerated phase or blast crisis. Glivec was designated as an orphan medicinal product in Europe on 14 April 2001. This was an expedited procedure, with the EMEA review beginning on 27 March 2001 and the opinion adopted on 26 July 2001. The CPMP recommends the granting of a marketing authorisation under exceptional circumstances.
- A positive opinion for Caspofungin MSD (caspofungin) from Merck Sharp & Dohme (Europe) Inc. indicated for the treatment of invasive aspergillosis, a rare life threatening condition in immunocompromised patients. Review by the EMEA began on 31 October 2000 and the opinion adopted on 26 July 2001. The CPMP recommends the granting of a marketing authorisation under exceptional circumstances.
- A positive opinion for Travatan (travoprost) from Alcon Laboratories (UK) Ltd. intended for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma who are intolerant or insufficiently responsive to another intraocular pressure lowering medication, as monotherapy or as adjunctive therapy. Review by the EMEA began on 26 December 2000 and the opinion was adopted on 26 July 2001.

The CPMP upheld its April 2001 negative opinion for EVOXAC, following the withdrawal of the application and appeal by the applicant, Snow Brand France S.A.R.L. (CPMP/2203/00, 25 April 2001).

The summaries of opinion are available on the EMEA web site.

The Committee continued its discussions on the scientific review of cardiovascular risks of third generation oral contraceptives, in particular taking into account recently published information. These discussions will resume at the next CPMP meeting on 19-21 September 2001.

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 23 July 2001.

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