European Medicines Agency
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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
14-17 November 2005

Initial marketing authorisations

The Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions on initial marketing authorisation applications for:

- **Cubicin** (daptomycin), Chiron Corporation Ltd. Cubicin is indicated for the treatment of complicated skin and soft-tissue infections in adults. EMEA review began on 20 December 2004 with an active review time of 211 days.
- **Kiovig** (human normal immunoglobulin (IVIg)), Baxter AG. Kiovig is intended as replacement therapy for immunodeficiency and for immunomodulation in immune-mediated diseases. EMEA review began on 18 October 2004 with an active review time of 204 days.

Scientific opinion in the context of cooperation with the Word Health Organization (WHO)

The CHMP gave for the first time scientific opinions in the context of cooperation with the WHO for medicinal products intended exclusively for markets outside of the European Union. **Lamivudine GSK 150 mg film-coated tablets** and **Lamivudine/Zidovudine GSK film-coated tablets**, both from Glaxo Group Limited, are intended as part of an antiretroviral combination therapy for the treatment of human immunodeficiency virus (HIV) infected children and adults.

Extensions of indications

The Committee adopted a positive opinion on the extension of indication for **Hycamtin** (topotecan), from SmithKline Beecham plc, to add treatment of relapsed small cell lung cancer in patients for whom re-treatment with the first-line regimen is not considered appropriate. Hycamtin, which was first authorised in the EU on 12 November 1996, is currently indicated for the treatment of patients with metastatic carcinoma of the ovary after failure of first-line or subsequent therapy.

New contraindication

The Committee recommended to add a contraindication for **Regranex** (becaplermin), from Janssen-Cilag International NV, that it should not be used in patients with clinically infected ulcers. Regranex, which was first authorised in the EU on 29 March 1999, is currently indicated, in association with other good wound care measures, to promote granulation and thereby the healing of full-thickness, neuropathic, chronic, diabetic ulcers less than or equal to 5 cm^2.

Summaries of opinion for all the above-mentioned products are available here.

A more detailed CHMP meeting report will be published shortly.

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