The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 22 to 24 July 2003

Five opinions were adopted for initial applications for marketing authorisation:

- A positive opinion for **Dukoral** (vibrio cholerae and recombinant cholera toxin B-subunit), from SBL Vaccin AB, intended for the active immunisation against Vibrio cholerae. EMEA review began on 26 March 2002 and the opinion was adopted on 24 July 2003, with an active review time of 200 days.
- A positive opinion for **Emend** (aprepitant), from Merck Sharp & Dohme, intended for prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy (EMEND is given as part of combination therapy). EMEA review began on 18 November 2002 and the opinion was adopted on 24 July 2003, with an active review time of 182 days.
- A positive opinion for **Emtriva** (emtricitabine), from Gilead Science International Ltd, intended for the treatment of HIV-1 infected adults and children in combination with other antiretroviral agents. EMEA review began on 6 January 2003 and the opinion was adopted on 24 July 2003, with an active review time of 170 days.
- A positive opinion for **Xagrid** (anagrelide), from Shire Pharmaceutical Contracts Ltd, intended for the reduction of platelet counts in essential thrombocythaemia patients. EMEA review began on 22 April 2002 and the opinion was adopted on 24 July 2003, with an active review time of 179 days. Xagrid was designated an orphan medicinal product on 29 December 2000 and is the **thirteenth orphan medicinal product** to receive a positive CPMP opinion.
- A negative opinion for **Yondelis** (trabectedin), from PharmaMar S.A, intended for the treatment of patients with advanced soft tissue sarcoma, having failed anthracyclines and ifosfamide, or having failed ifosfamide and unsuitable to receive anthracyclines. The EMEA review began on 20 November 2001and the opinion was adopted on 24 July 2003, with an active review time of 207 days. Yondelis was designated as an orphan medicinal product on 30 May 2001.

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

The Committee also gave positive opinions for a number of new indications for medicinal products that are already authorised in the EU:

- Extension of indication for **Bondronat** (ibandronic acid) from Roche Registration Ltd to include prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases. Bondronat was first authorised in the European Union on 25 June 1996.
- Extension of indication for **Synagis** (palivizumab) from Abbott Laboratories to include use in children less than 2 years of age and with haemodynamically significant congenital heart disease. Synagis was first authorised in the European Union on 13 August 1999.
- Extension of indication for **Zerit** (stavudine) from Bristol Myers Squibb Pharma EEIG to include HIV infected paediatric patients below 3 months of age. Zerit was first authorised in the European Union on 08 May 1996.
- Extension of indication for **Zyprexa** and **Zyprexa Velotab** (olanzapine) from Eli Lilly to include prevention of recurrence in patients with bipolar disorder whose manic episode has responded to olanzapine treatment. Zyprexa was first authorised in the European Union on 27 September 1996 and Zyprexa Velotab was first authorised in the European Union on 3 February 2000.

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

A more detailed CPMP meeting report will be published shortly.

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