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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
17-20 January 2005

The Committee adopted one positive opinion on an initial marketing authorisation application for **Aclasta** (zoledronic acid), from Novartis Europharm Ltd, for the treatment of Pagets disease of the bone. EMEA review began on 17 May 2004 with an active review time of 181 days. A summary of this opinion, including the full indication for the product, is available on the EMEA web site: http://www.emea.eu.int

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

- **Pegasys** (peginterferon alfa-2a), Roche Registration Ltd, to extend its use to the treatment of chronic hepatitis B. Pegasys was first authorised in the European Union on 20 June 2002 for the treatment of chronic hepatitis C.
- **Thyrogen** (thyrotrophin alfa), Genzyme B.V., to extend its use to pre-therapeutic stimulation in low-risk post-thyroidectomy patients maintained on hormone suppression therapy for the ablation of thyroid remnant tissue in combination with 100 mCi radioactive iodine. Thyrogen was first authorised in the European Union on 9 March 2000.

A summary of opinion for these two products is available on the EMEA web site: http://www.emea.eu.int. The initiative to publish summaries of opinion for post-authorisation applications is part of the further implementation of the Agency's transparency policy adopted by its Management Board in October 2003.

As part of the ongoing review of **COX-2 inhibitors**, the Committee heard presentations and held discussions with Pfizer, Merck Sharp & Dohme and Novartis. A separate statement has been issued and is available on the EMEA web site.

The CHMP concluded a Community-wide review of **Rigevidon** (levonorgestrel and ethinylestradiol) , a generic oral contraceptive from Medimpex France SA. The referral was initiated by the Netherlands under Article 29 (2) of the Community code on human medicines (Directive 2001/83/EC as amended) on 29 July 2004 because of concerns whether the normally accepted range for proving bioequivalence is sufficient to demonstrate safety and efficacy of Rigevidon. After reviewing relevant data, the Committee concluded that there was no objection for granting a marketing authorisation for Rigevidon.

The CHMP began Community referrals under Article 29(2) of the Community code on human medicines (Directive 2001/83/EC as amended) for five generic medicinal products containing **lanzoprazole**. Concerns were raised by Germany and Portugal because of differences in the dosage and indications between the summaries of product characteristics of the reference products and the SPCs of the generic products.

A more detailed CHMP meeting report will be published shortly.

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