European Medicines Agency
Press office

London, 27 June 2005
Doc. Ref. EMEA/207407/2005

PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
20-23 June 2005

Initial marketing authorisation

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

- **Tarceva** (erlotinib), from Roche Registration Ltd, for the treatment of locally advanced or metastatic non-small cell lung cancer. EMEA review began on 20 September 2004 with an active review time of 193 days.
- **Vasovist** (gadofosveset), from Schering AG, for diagnostic use in contrast enhanced magnetic resonance angiography for visualization of abdominal or limb vessels in patients with suspected or known vascular disease. EMEA review began on 21 June 2004 with an active review time of 182 days.
- **Xyrem** (sodium oxybate), from UCB Pharma Ltd, for the treatment of cataplexy in patients with narcolepsy. Xyrem is the **twenty-first orphan medicinal product** to receive a positive opinion. EMEA review began on 29 March 2004 with an active review time of 198 days.

Extensions of Indications and other recommendations

- The Committee gave positive opinions for **Humira** and **Trudexa** (adalimumab), Abbott Laboratories, to extend the indication to include treatment in combination with methotrexate of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. Further positive opinions were given to extend the indication to include the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. Humira was first authorised in the European Union on 8 September 2003. Trudexa was first authorised in the European Union on 1 September 2003.
- The CHMP recommended the approval of **Bondenza** (ibandronic acid) and **Bonviva** (ibandronic acid) 150 mg film-coated tablets indicated for the treatment of osteoporosis. This higher strength is for once monthly administration compared to once daily previously authorised.

The CHMP also recommended changes to the product information for **Infergen** (interferon alfacon-1) and **Refacto** (moroctocog alfa). Details of these changes are given in the summaries of opinion for these products.

Summaries of opinion are available for all products mentioned in this press release and can be found here.

The CHMP concluded an arbitration procedure for two generic medicinal products containing **lanzoprazole** (Lansopon Lansoprazole Hexal,), with the recommendation to harmonise the summaries of product characteristics of these products. The procedure was initiated under Article 29(2) of the Community code on human medicines (Directive 2001/83/EC as amended) because of differences in the indication and posology section between the summaries of product characteristics (SPCs) of the reference product and the SPCs of the generic products.

The CHMP concluded its review of COX-2 inhibitors. A separate statement was issued and can be found [here]

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A more detailed CHMP meeting report will be published shortly.

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