



London, 19 December 2002

Doc. Ref: EMEA/CPMP/6589/02

## PRESS RELEASE

### European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 17 to 18 December 2002

- The Agency's scientific committee, the CPMP, adopted a positive opinion for **Forsteo** (teriparatide) from Eli Lilly, which is intended for the treatment of established osteoporosis in postmenopausal women. EMEA review began on 19 June 2001 and the opinion was adopted on 18 December 2002, with an active review time of 207 days. A summary of this opinion is available on the EMEA web site: <http://www.emea.eu.int>
- The CPMP revised its opinions of 25 July 2002 for valdecoxib containing medicines **Bextra** (Pharmacia-Pfizer EEIG), **Valdyn** (Pharmacia Europe EEIG) and **Kudeq** (Pfizer Limited). The revision follows the EMEA public statement of 22 October 2002 on reports of serious hypersensitivity reactions and serious skin reactions in some patients treated with valdecoxib, which is now reflected in the revised product literature.

The opinions for **Valdecoxib Pfizer Ltd** (Pfizer Limited) and **Valdecoxib Pharmacia Europe EEIG** (Pharmacia Europe EEIG) were not revised because they have been withdrawn by the applicants since the initial opinion.

- The Committee also gave a positive opinion to extend the indication for **Forcaltonin** (recombinant salmon calcitonin) from Unigene UK Ltd to include the product's use in the prevention of acute bone loss due to sudden immobilisation (such as patients with recent bone fractures). Forcaltonin was first authorised in the European Union in January 1999. Further information on this extension will be included in the public assessment report (EPAR) once the European Commission has granted final approval.
- The Committee concluded its Community-wide review for the centrally authorised medicinal products containing desloratadine (**Azomyr**, **Opulis**, **Alex**, **Aerius** and **Neoclarityn**) from SP Europe. Desloratadine is the major metabolite of loratadine. The CPMP considered that the benefit/risk balance of desloratadine containing medicinal products remains favourable. The scientific assessment of the safety signal of hypospadias following use of loratadine during pregnancy concluded that, based on the available data, a causal relationship could neither be confirmed nor excluded. As a precautionary measure the product information for desloratadine will be revised to state that the use of desloratadine during pregnancy is not recommended. The separate referral procedure for loratadine containing medicinal products is still ongoing as the Committee is also assessing other aspects of the safety and efficacy of these nationally approved products.

A more detailed CPMP meeting report will be published shortly, including details from the MRFG meeting of 16 December 2002.

--ENDS--

For media enquiries only please contact:

Martin Harvey Allchurch

EMEA press officer, Tel. (44-20) 74 18 84 27, E-mail: [martin.harvey-allchurch@emea.eu.int](mailto:martin.harvey-allchurch@emea.eu.int)

Public