European Medicines Agency
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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
22-23 June 2004

The Committee adopted 6 positive opinions on initial marketing authorisation applications for:

- **Angiox** (bivalirudin), from The Medicines Company UK Ltd, for use as an anticoagulant in patients undergoing percutaneous coronary intervention. EMEA review began on 18 August 2003, with an active review time of 176 days.
- **Alimta** (pemetrexed), from Eli Lilly Nederland B.V., for the treatment of malignant pleural mesothelioma and non-small cell lung cancer. EMEA review began on 18 August 2003, with an active review time of 197 days.
- **Protelos** and **Osseor** (strontium ranelate), from Les Laboratoires Servier, for the treatment of postmenopausal osteoporosis to reduce the risk of vertebral and hip fractures. EMEA review began on 21 July 2003, with an active review time of 194 days.
- **Raptiva** (efalizumab), from Serono Europe Ltd, for the treatment of moderate to severe chronic plaque psoriasis. EMEA review began on 24 February 2003, with an active review time of 185 days.
- **Wilzin** (zinc acetate dihydrate), from Orphan Europe SARL, for the treatment of Wilson's disease. EMEA review began on 24 March 2003 with an active review time of 195 days. Wilzin was designated an orphan medicinal product on 31 July 2001 and is the **eighteenth orphan medicinal product** to receive a positive CHMP opinion.

Summaries of these opinions, including the full indications for each product, are available on the EMEA web site: http://www.emea.eu.int

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

- **Mabthera** (rituximab), Roche Registration Ltd, to extend its use in combination with CVP (cyclophosphamide, vincristine and prednisolone) chemotherapy for the treatment of previously untreated patients with indolent non-Hodgkin's Lymphoma. Mabthera was first authorised in the European Union on 2 June 1998.
- **Prevenar** (pneumococcal conjugate vaccine), Wyeth-Lederle Vaccines SA, to extend the age range of vaccination from 2 years to up to 5 years of age. Prevenar was first authorised in the European Union on 2 February 2001.

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 CHMP meeting report will be published shortly.

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