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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
25-28 July 2005

Initial marketing authorisations

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

- **Aptivus** (tipranavir), from Boehringer Ingelheim International GmbH, for the treatment of Human Immunodeficiency Virus (HIV-1) infection in highly pre-treated adult patients with virus that is resistant to multiple protease inhibitors. EMEA review began on 15 November 2004 with an active review time of 204 days.
- **Kepivance** (palifermin), from Amgen Europe B.V., for the prevention and treatment of oral mucositis in patients with haematological (blood and blood-forming tissues) cancers undergoing myoablative therapy, which suppresses bone marrow activity. EMEA review began on 19 July 2004 with an active review time of 217 days.
- **Noxafil** (posaconazole) and **Posaconazole SP** (posaconazole), from SP Europe, for the treatment of certain invasive fungal infections in patients whose disease did not respond to certain commonly used antifungal agents or who were intolerant of these other agents. EMEA review began on 19 July 2004 with an active review time of 219 days.
- **Procoralan** (ivabradine) and **Corlentor** (ivabradine), from Les Laboratoires Servier, for the treatment of chronic stable angina pectoris. EMEA review began on 17 May 2004 with an active review time of 211 days.
- **Revatio** (sidenafil citrate), from Pfizer Limited, for the treatment of pulmonary arterial hypertension. EMEA review began on 20 December 2004 with an active review time of 177 days. **Revatio is the twenty-second orphan medicinal product to receive a positive CHMP opinion**.
- **Xolair** (omalizumab), from Novartis Europharm Ltd., for the treatment of severe persistent allergic asthma. EMEA review began on 19 July 2004 with an active review time of 214 days.

Extensions of indications and other recommendations

The Committee adopted opinions for the extension of indications of products that are already authorised on the European Union.

- **Keppra** (levetiracetam), UCB S.A., to extend the indication of adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation to children from 4 years of age with epilepsy. Keppra was first authorised in the European Union on 29 September 2000.
- **Remicade** (infliximab), Centocor B.V., to extend its indication to include treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systematic therapy including cyclosporine, methotrexate or PUVA. Remicade was first authorised in the European Union on 13 August 1999.

The Committee recommended a new contraindication for **Forsteo** (teriparatide) to exclude patients with skeletal malignancies or bone metastases from treatment.

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Summaries of opinion for initial marketing authorisation applications, extensions of indication and other recommendations are available and can be found here.

The Committee finalised an arbitration procedure for **Coversyl** 2 and 4 mg (perindopril tert-butylamine salt) and associated trade names from Les Laboratoires Servier, recommending the extension of the indication to include the reduction of risk of cardiac events in patients with stable coronary artery disease with a history of myocardial infarction and/or revascularisation. Coversyl is authorised in a number of EU Member States and is currently indicated for the treatment of hypertension and symptomatic heart failure. The referral was made by the Netherlands under Article 6(12) of Commission Regulation (EC) No 1084/2003.

A more detailed CHMP meeting report will be published shortly.

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