European Medicines Agency
Directorate

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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
15-18 November 2004

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

- **Azilect** (rasagiline), from Teva Pharma GmbH, for the treatment of Parkinson's disease. EMEA review began on 27 October 2003 with an active review time of 208 days.
- **Orfadin** (nitisinone), from Swedish Orphan International AB, for the treatment of hereditary tyrosinemia type 1. EMEA review began on 21 July 2003 with an active review time of 197 days. Orfadin was designated an orphan medicinal product on 29 December 2000 and is the **nineteenth orphan medicinal product** to receive a positive CHMP opinion.
- **Prialt** (ziconotide), from Elan Pharma International Ltd, for the treatment of severe, chronic pain in patients who require intrathecal analgesia. EMEA review began on 26 May 2003 with an active review time of 196 days. Prialt was designated an orphan medicinal product on 9 July 2001 and is the **twentieth orphan medicinal product** to receive a positive CHMP opinion.
- **Truvada** (emtricitabine/tenofovir disoproxil) from Gilead Science International Limited, for use in antiretroviral combination therapy for the treatment of Human immunodeficiency virus (HIV-1) infection in adults. Truvada is a fixed dose combination of two antiretroviral agents (emtricitabine and tenofovir disoproxil) to be administered once a day. EMEA review began on 29 March 2004 with an active review time of 182 days.

More information about these products can be obtained in the summaries of opinions available on the EMEA web site: http://www.emea.eu.int

The Committee also adopted a number of extensions of indication for medicinal products that are already marketed in the European Union:

- **Advate** (octocog alfa), Baxter AG, to include children under the age of 6 in the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). Advate was first authorised in the European Union on 2 March 2004.
- **Avandia** (rosiglitazone), GlaxoSmithKline, to extend its use in the treatment of type 2 diabetes mellitus as a triple oral combination treatment, i.e. rosiglitazone in combination with metformin and a sulphonylurea. Avandia was first authorised in the European Union on 11 July 2000.
- **Taxotere** (docetaxel), Aventis, to extend its use in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer and in combination with Herceptin (trastuzumab) for the treatment of patients with metastatic breast cancer whose tumours overexpress HER2. Taxotere was first authorised in the European Union on 27 November 1995.

The Committee began a Community-wide referral procedure for **Crestor** (rosuvastatin) 5 mg from AstraZeneca following a referral made by the United Kingdom. The referral was initiated because of public health concerns relating to differing views on whether Crestor 5 mg should be the recommended starting dose for patients with predisposing factors to myopathy only, or for all patients. Crestor is licensed in a number of EU Member States in dosages ranging from 5 to 40 mg. The referral is made under Article 29(2) of the Community Code on medicines for human use.

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Guidance on the development of similar biological (biosimilar) medicinal products

A number of draft guidance documents on the development of biosimilar products were agreed by the Committee; these follow and complement the two existing EMEA guidelines adopted in 2003. The CHMP agreed on a draft overarching guideline on similar biological medicinal products, which describes the EMEA approach to the development and approval of these products. As part of this, the two existing guidelines will be revised to give more detailed guidance on the comparability and biosimilarity aspects of the quality, non-clinical and clinical development of biosimilar medicinal products. The draft overarching guideline will be published next week for a three-month public consultation period.

In addition the Committee agreed on 4 concept papers that will lead to guidelines on the development of biosimilar medicinal products in the following specific classes:

- recombinant human granulocyte-colony-stimulating factor containing products
- recombinant human insulin containing products
- recombinant human growth hormone containing products
- recombinant human erythropoietin containing products

These will also be published next week for a two-month public consultation period.

A more detailed CHMP meeting report will be published shortly.

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