



## **PRESS RELEASE**

### **Meeting highlights from the Committee for Medicinal Products for Human Use, 21-24 April 2008**

#### **Positive opinions**

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions, including two for 'informed consent' applications, recommending the granting of a marketing authorisation, for the following medicines:

- **Firazyr** (icatibant acetate), from Jerini AG, for the treatment of hereditary angioedema in adults with C1-esterase-inhibitor deficiency. Firazyr is the **47th orphan medicine** to receive a positive opinion. EMA review began on 15 August 2007 with an active review time of 204 days.
- **Janumet/Velmetia/Efficib** (sitagliptin / metformin hydrochloride)\*, from Merck Sharp & Dohme Ltd, for the treatment of type 2 diabetes mellitus. EMA review of Janumet and Velmetia began on 23 May 2007 with an active review time of 204 days. EMA review of Efficib began on 15 August 2007 with an active review time of 120 days.
- **Latixa** (ranolazine), from CV Therapeutics Europe Limited, for the treatment of stable angina pectoris. EMA review began on 27 December 2006 with an active review time of 177 days.
- **Relistor** (methylnaltrexone bromide), from Wyeth Europa Limited, for the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care. EMA review began on 23 May 2007 with an active review time of 204 days.
- **Tredaptive/Trevaclyn/Pelzont** (nicotinic acid/laropiprant), from Merck Sharp & Dohme Ltd, for the treatment of dyslipidaemia, particularly in patients with combined mixed dyslipidaemia and primary hypercholesterolaemia. EMA review of Tredaptive began on 20 July 2007 with an active review time of 202 days. EMA review of Trevaclyn and Pelzont began on 15 August 2007 with an active review time of 176 days.

#### **Revised positive opinion for Tyverb**

The CHMP adopted a revised positive opinion for **Tyverb** (lapatinib), from GlaxoSmithKline, following a previous positive opinion issued on December 2007. Following reports of hepatobiliary events associated with the use of Tyverb in ongoing clinical trials, the European Commission stopped its decision-making process and requested that the CHMP re-assess its recommendation to grant a conditional marketing authorisation for this medicine.

Having reviewed the new data, the CHMP concluded that the benefit-risk-balance for the use of Tyverb in the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2) and who have received prior therapy including anthracyclines, taxanes and trastuzumab is positive and recommended the granting of a marketing authorisation. The Committee recommended that the product information should be amended to add special warnings about the risk of hepatotoxicity.

#### **Positive opinion for 'informed consent' applications**

The CHMP adopted positive opinions for **Clopidogrel Winthrop** (clopidogrel hydrogen sulphate), from Sanofi Pharma Bristol Myers Squibb SNC, and **Clopidogrel BMS** (clopidogrel hydrogen sulphate), from Bristol-Myers Squibb Pharma EEIG, for which 'informed consent' applications were submitted, intended for the prevention of atherothrombotic events in adults. This type of application requires that reference is made to an authorised medicinal product and that the marketing authorisation

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\* corr The International Nonproprietary Name has been corrected.

holder of this reference product has given consent to the use of the dossier in the application procedure.

### **Extensions of indication**

The CHMP gave positive opinions for applications for extension of indication, adding new treatment options for the following previously approved medicines:

- **Abilify** (aripiprazole), from Otsuka Pharmaceutical Europe Ltd, to extend the indication for Abilify 7.5 mg/ml solution for injection for the rapid control of agitation and disturbed behaviours in patients with manic episodes in bipolar I disorder, when oral therapy is not appropriate. Abilify 7.5 mg/ml solution for injection is currently indicated for the rapid control of agitation and disturbed behaviours in patients with schizophrenia.
- **Apidra** (insulin glulisine), from Sanofi-Aventis Deutschland GmbH, to extend the indication to the paediatric population of six years or above. Apidra is currently authorised in the treatment of adult patients with diabetes mellitus.
- **Azopt** (brinzolamide), from Alcon Laboratories, to extend the indications to include adjunctive therapy with prostaglandin analogues. Azopt is currently indicated to decrease elevated intraocular pressure in ocular hypertension and open-angle glaucoma.
- **Mimpara** and **Parareg** (cinacalcet), from Amgen Europe B.V., to extend the indication to reduction of hypercalcaemia in patients with primary hyperparathyroidism for whom parathyroidectomy (surgery to remove parathyroid glands) would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines) but in whom parathyroidectomy is not clinically appropriate or is contraindicated. Mimpara and Parareg are currently indicated for the treatment of secondary hyperparathyroidism in patients with chronic renal disease and for reduction of hypercalcaemia in patients with parathyroid carcinoma.
- **Neupro** (rotigotine), from SchwarzPharma Ltd, to extend the indication to include the symptomatic treatment of moderate to severe restless legs syndrome. Neupro is currently indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease.
- **Reyataz** (atazanavir sulphate), from Bristol Myers Squibb Pharma EEIG, to extend the indication to include adult patients who have not used antiretroviral treatment before. Reyataz is currently indicated for the treatment of HIV-1 infected adults, who previously received antiretroviral treatment.

*Summaries of opinions for all mentioned products, including their full indication, can be found [here](#).*

### **Referral procedures concluded**

The CHMP finalised a referral procedure under Article 29 of Directive 2001/83/EC for **Oracea** (doxycycline), from FGK Representative Service GmbH, intended to reduce inflammatory lesions in patients with rosacea. The CHMP concluded that the benefits of Oracea in the present indication outweigh the risk of potential harmful effects related to the development of resistance and therefore recommended the granting of a marketing authorisation, subject to certain changes in the product information and post-marketing obligations. The procedure was initiated by the United Kingdom due to efficacy and safety concerns in the proposed indication, in particular the potential induction of bacterial resistance by Oracea in its intended use.

Referral procedures under Article 29 of Directive 2001/83/EC are initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure.

The CHMP finalised a number of referral procedures under Article 30 of Directive 2001/83/EC recommending the harmonisation of the product information across the European Union for the following medicines approved at the level of the Member States:

- **Cozaar** 25 mg, 50 mg, 100 mg film-coated tablets, (losartan potassium), from Merck Sharp & Dohme Inc, used as antihypertensive. The procedure was initiated by the European Commission.
- **Cozaar Comp** 50mg/12.5mg and 100mg/25mg film-coated tablets, (losartan potassium and hydrochlorothiazide), from Merck Sharp & Dohme Inc, used as antihypertensive. The procedure was initiated by the European Commission.

- **Lamictal and associated names** (lamotrigine), from GlaxoSmithKline Research & Development Limited, used as anticonvulsant. The procedure was initiated by the marketing authorisation holder.
- **Singulair** 4mg chewable tablets and 4mg oral granules (montelukast sodium), from Merck Sharp & Dohme Inc, used as bronchodilator. The procedure was initiated by the marketing authorisation holder.

### **Referral procedure started**

A harmonisation referral under Article 30 of the Directive 83/2001/EC as amended was started for **Diovan** (valsartan) Novartis, in the therapeutic group of antihypertensives, at the request of the European Commission.

Article 30 referrals are initiated with a view to harmonising product information for medicinal products authorised at Member State level.

The Committee started a review of issues related to the administration and supply of medicinal products containing or derived from **heparin** under Article 5(3) of Regulation (EC) No 726/2004, following detection of a contaminant in a limited number of batches in some Member States of the European Union. The initiation of the procedure was requested by Germany.

A more detailed CHMP meeting report will be published shortly.

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