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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 15-18 October 2007

Positive opinions

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) adopted 7 positive opinions, including 2 for biosimilar medicinal products and 1 for a generic medicinal product, recommending the granting of a marketing authorisation for the following medicinal products:

- **Abraxane** (5 mg/ml nanoparticle albumen bound paclitaxel), from Abraxis BioScience Limited, for the treatment as monotherapy of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard anthracycline-containing therapy is not indicated. EMEA review began on 27 September 2006 with an active review time of 202 days.
- **Atripla** [efavirenz/emtricitabine/tenofovir disoproxil (as fumarate)], from Bristol-Myers Squibb Gilead Sciences and Merck Sharp & Dohme Limited, for treatment of human immunodeficiency virus-1 (HIV-1) infection in adults. EMEA review began on 25 October 2006 with an active review time of 202 days.
- **Avamys** (fluticasone furoate), from Glaxo Group Ltd, for the treatment of the symptoms of allergic rhinitis. EMEA review began on 16 August 2006 with an active review time of 202 days.
- **Nevanac** (nepafenac), from Alcon Laboratories (UK) Limited, for the prevention and treatment of postoperative pain and inflammation associated with cataract surgery. EMEA review began on 24 January 2007 with an active review time of 205 days.

Positive opinion for similar biological medicinal products

The CHMP adopted positive opinions for the biosimilar medicinal product **Silapo** [epoetin zeta (rhEPO)], from Stada Arzneimittel AG, and **Retacrit** [epoetin zeta (rhEPO)], from Hospira Enterprises B.V., intended for the treatment of anaemia associated with chronic kidney disease and in oncology patients to treat anaemia and reduce blood-transfusion requirements, and to increase the yield of autologous blood in a pre-donation programme. Both medicinal products have been shown to be similar to Eprex/Erypo, the reference medicinal product already authorised in the EU in the applied indications. EMEA review began on 19 July 2006 for Silapo and 20 May 2007 for Retacrit with an active review time of 202 and 85 days respectively.

Positive opinion for a generic medicinal product

The CHMP adopted a positive opinion for **Olanzapine Teva** (olanzapine), from Teva Pharma BV, for the treatment of schizophrenia and moderate to severe manic episode. The reference product for Olanzapine Teva is Zyprexa, from Eli Lilly Nederland B.V., which is already authorised in the EU, in the applied indications. EMEA review began on 27 December 2006 with an active review time of 177 days.

Extensions of indication

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

- **Ariclaim** (duloxetine), from Eli Lilly Nederland B.V., to extend the indication to include diabetic peripheral neuropathic pain in adults. Ariclaim is currently authorised for women for the treatment of moderate to severe stress urinary incontinence.

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- **MabCampath** (alemtuzumab), from Genzyme B.V., to extend the indication to first line treatment of B-cell chronic lymphocytic leukaemia (B-CLL) in patients for whom fludarabine combination chemotherapy is not appropriate. MabCampath was initially authorised for the second-line treatment of patients with chronic lymphocytic leukaemia (CLL) who have been treated with alkylating agents.
- **Remicade** (infliximab), from Centocor B.V., to update the psoriatic arthritis indication with improvement of physical function and reduction of the rate of progression of peripheral joint damage. Remicade is currently indicated for the treatment of rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.
- **Taxotere** (docetaxel), from Aventis Pharma S.A., and **Docetaxel Winthrop** (docetaxel), from Aventis Pharma S.A., to change the indication for head and neck cancer from induction treatment in combination with cisplatin and 5-fluorouracil of inoperable locally advanced squamous cell carcinoma to induction treatment in combination with cisplatin and 5-fluorouracil of locally advanced squamous cell carcinoma. Taxotere and Docetaxel Winthrop are currently indicated for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer.

Negative opinion for extension of indication
The CHMP adopted a negative opinion for an extension of indication of **Zavesca** (miglustat), from Actelion Ltd. The indication applied for related to the treatment of neurological manifestations in patients with Niemann-Pick type C disease, an inherited neurodegenerative disease of childhood and adolescence. Zavesca is an orphan medicinal product. It is currently approved for the oral treatment of mild to moderate type 1 Gaucher disease. A separate question-and-answer document explaining the grounds for the negative opinion for the extension of indication is available on the EMEA website.

Summaries of opinions for all mentioned products, including their full indication, can be found here.

Re-assessment of the benefits and risks of rosiglitazone and pioglitazone concluded
Finalising a review of rosiglitazone and pioglitazone, the CHMP confirmed that the benefits of these medicines continue to outweigh the risks. In addition, the Committee recommended to modify the product information for **Avandia** (rosiglitazone), from GlaxoSmithKline, to reflect the conclusions of the review. A separate press release and a question-and-answer document with more information are available, together with the summary of opinion.

Referral procedures concluded
The CHMP recommended the revocation of the marketing authorisation for a number of generic medicinal products containing **cetirizine dihydrochloride** because the bioequivalence with the reference medicinal product could not be established. The procedures were initiated by the Netherlands under Article 36 of Directive 2001/83/EC as amended for the following products and associated trade names: Cetirizine dihydrochloride-APEX 10mg, Cetirizine dihydrochloride Copyfarm 10mg, Cetirizine dihydrochloride Dermapharm 10mg and Cetirizine dihydrochloride Nordic Drugs 10 mg film-coated tablets.

Further to a CHMP review conducted in 2006, the concerned national marketing authorisations were suspended by the European Commission because of concerns regarding good clinical and laboratory practices (GCP/GLP) compliance that impacted on the quality and reliability of bioequivalence studies supporting the marketing authorisations. Due to GCP concerns still identified in a further study, the CHMP recommended the revocation of the marketing authorisations for these generic medicinal products.

Referral procedures started
The CHMP started a referral procedure for **Rapinyl 50, 100, 200, 300, 400, 600 and 800 microgram** (fentanyl citrate), from ProStrakan Ltd, intended for the treatment of pain. The referral procedure was initiated under Article 29(4) of 2001/83/EC because of a disagreement among some Member States whether additional data demonstrating efficacy and safety of Rapinyl in the management of breakthrough pain is required. Referral procedures under Article 29(4) are normally initiated because

of disagreement between Member States on applications for medicinal products based on potential serious risk to public health.

At the request of the European Commission, the CHMP started a harmonisation referral under Article 30 of the Directive 83/2001/EC as amended for **Zyrtec/Reactine** (cetirizine), from UCB, because the product information for these medicines in the EU Member States shows clinically important differences in the approved indications and posology, as well as in further sections of the summary of product characteristics, in particular with regard to the paediatric population. Article 30 referrals are normally initiated with a view to harmonising product information for medicinal products authorised at Member State level.

Review procedures under Article 107
The CHMP finalised a procedure under Article 107, initiated as a result of the evaluation of pharmacovigilance data, for cough medicines containing clobutinol, following the suspension of the marketing authorisation for these medicines in Germany, due to concerns regarding side-effects affecting the heart. The CHMP concluded that the benefits of these medicines do not outweigh their risks and therefore recommended that the marketing authorisations for clobutinol-containing medicines be withdrawn throughout the EU.
A separate press release and a question-and-answer document with more information are available.

A more detailed CHMP meeting report will be published shortly.

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