European Medicines Agency
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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 16-19 July 2007

Positive opinions
The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) adopted 5 positive opinions, one of which related to a generic medicinal product, recommending the granting of a marketing authorisation for the following medicinal products:

- **Celsentri** (maraviroc), from Pfizer Limited, for use, in combination with other antiretroviral medicinal products, in treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable. EMEA review began on 27 December 2006 with an active review time of 169 days.
- **Ecalta** (anidulafungin), from Pfizer Limited, for the treatment of invasive candidiasis in adult non-neutropenic patients. EMEA review began on 27 September 2006 with an active review time of 210 days.
- **Galvus** (vildagliptin), from Novartis Pharma AG, for the treatment of type 2 diabetes mellitus as dual oral therapy in combination with metformin, sulphonylurea or thiazolidinedione. EMEA review began on 16 August 2006 with an active review time of 203 days.
- **Yondelis** (ecteinascidin), from PharmaMar S.A., for the treatment of advanced soft tissue sarcoma. Yondelis is the **42nd orphan medicinal product** to receive a positive opinion. EMEA review began on 16 August 2006 with an active review time of 210 days.

Positive opinion for the first generic medicine for human use
The CHMP adopted the first positive opinion for a generic medicine for human use. The product concerned, **Zalasta** (olanzapine), from Krka d.d. Novo Mesto, is intended for the treatment of schizophrenia and moderate to severe manic episode. The reference product for Zalasta is Zyprexa, from Eli Lilly Nederland B.V., which is already authorised in the EU, in the applied indications. EMEA review began on 25 October 2006 with an active review time of 177 days. A separate press release is available on the EMEA website.

Negative opinion
The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Natalizumab** (natalizumab), from Elan Pharma. Natalizumab was intended to be used to treat moderate to severe active Crohn's disease in patients who had an inadequate response to or could not take conventional treatments for the disease and who have evidence of active inflammation. It was to be used alone or in combination with other medicines for Crohn's disease. EMEA review began on 18 October 2004 with an active review time of 204 days.
A separate question-and-answer document explaining the grounds for the negative opinion for Natalizumab is available on the EMEA website.

Re-examination procedure concluded
Following the re-examination of the negative opinion adopted on 26 April 2007, the CHMP confirmed its previous position and adopted a final negative opinion for **Genasense** (oblimersen), from Genta Development Ltd, intended for the treatment of advanced or metastatic melanoma.
A separate question-and-answer document with more information about the re-examination procedure is available.

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

- **Aclasta** (zoledronic acid), from Novartis Europharm Ltd, to extend the indication to include the treatment of osteoporosis in post-menopausal women at increased risk of fracture. Aclasta is currently indicated for the treatment of Paget's disease of the bone.
- **Aranesp and Nespo** (darbepoetin alfa), from Amgen Europe B.V. and Dompé Biotec S.p.A, to remove a restriction of the use of Aranesp and Nespo, to also allow treatment of anaemia in children younger than 11 years of age with chronic renal failure. Aranesp and Nespo are currently indicated for treatment of anaemia associated with chronic renal failure and symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.
- **Avastin** (bevacizumab), from Roche Registration Ltd, to extend the indication to include first-line treatment, in combination with platinum-based chemotherapy, of patients with unresectable, advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology. Avastin is currently indicated in combination with intravenous 5-fluorouracil/folinic acid or intravenous 5-fluorouracil/folinic acid/irinotecan for first-line treatment of patients with metastatic carcinoma of the colon or rectum and in combination with paclitaxel for first-line treatment of patients with metastatic breast cancer.
- **Cubicin** (daptomycin), from Novartis Europharm LTD, to extend the indication to include treatment of right-sided infective endocarditis (RIE) due to *Staphylococcus aureus* and *Staphylococcus aureus* bacteraemia (SAB) when associated with RIE or with cSSTI. Cubicin is currently authorised for treatment of complicated skin and soft-tissue infections in adults.
- **Glustin** (pioglitazone), from Takeda Global R&D Centre (Europe) Ltd, to include the use of pioglitazone as triple oral therapy in combination with metformin and a sulphonylurea, in patients with insufficient glycaemic control despite dual oral therapy. Additionally, the Committee recommended the inclusion of the combination therapy with insulin in type-2 diabetes mellitus patients with insufficient glycaemic control on insulin for whom metformin is inappropriate because of contraindications or intolerance.
- **Telzir** (fosamprenavir), from Glaxo Group, to include treatment against HIV infection of adolescents and children aged 6 years or older. Telzir is currently indicated in combination with low dose ritonavir for the treatment of HIV-1 infected adults in combination with other antiretroviral medicinal products.

New contraindication for Acomplia (rimonabant)
Following an assessment of the information on psychiatric adverse events with Acomplia (rimonabant), from sanofi-aventis, the CHMP recommended the addition of a contraindication that the medicine must no longer be used in patients with ongoing major depression, and/or with ongoing treatment with antidepressants, because of the risk of psychiatric side-effects. A separate press release and a question-and-answer document are available.

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

Referral procedures concluded
The CHMP finalised referral procedures under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended), initiated because of disagreement among the Member States in the context of the mutual recognition procedure related to serious risk public health grounds, for:

- **Xeomin** (clostridium botulinum type A neurotoxin complex), from Merz Pharmaceuticals GmbH, is indicated for the symptomatic management of blepharospam and cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adults. This procedure was initiated because of disagreement between Member States regarding the proposed posology and the need for data in repeated administration and on immunogenicity. The CHMP recommended the granting of the marketing authorisation for Xeomin.

- Fentanyl-containing transdermal patches from Ratiopharm GmbH (**Fentanyl-ratiopharm 25/50/75/100 µg/h Matrixpflaster** and **Fentanyl-ratiopharm 25/50/75/100 µg/h TTS**), indicated for the management of severe chronic pain. This procedure was initiated because of disagreement between Member States regarding the scope of the proposed indication, the contraindications and the demonstration of bioequivalence with the reference medicinal product. The CHMP concluded that the benefits of Fentanyl-ratiopharm and associated names outweigh the risks and that the marketing authorisation should be granted.

Referral procedures started
The CHMP started referral procedures under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended) for **Pulairmax** (budenoside), from IVAX Pharmaceuticals UK, intended for the treatment of persistent bronchial asthma. The procedure was initiated because of concerns over bioequivalence with the reference medicinal product.

The CHMP began a harmonisation referral procedure under Article 30 of the Community code on human medicinal products for **Ciflox** and **Uniflox** (ciprofloxacin), from Bayer Pharma SA, intended for the treatment of various bacterial infections. Article 30 referrals are initiated with a view to harmonising product information for medicinal products authorised at Member State level.

The CHMP started a referral under Article 31 of the Community code on human medicinal products for **methylphenidate-containing products** intended for the treatment of attention deficit hyperactivity disorder and narcolepsy, because of safety concerns related to cardiovascular events and cerebrovascular disorders. The procedure was initiated at the request of the European Commission.

Four additional Committee Members
Four new co-opted Committee Members
The CHMP appointed four new co-opted members to join the Committee adding specific areas of complementary expertise in the fields of quality (non biologicals), quality and safety (biological) with expertise in Advanced Therapies (Gene, Cell and Tissue Therapies) and pharmacovigilance with expertise in epidemiology and risk management. The four members are:

- Jean-Louis Robert (Luxembourg)
- Christian Schneider (Germany)
- Sol Ruiz (Spain)
- Ingemar Persson (Sweden)

Under the CHMP Rules of Procedure, the Committee may appoint up to five co-opted members with a three year mandate to provide additional expertise as necessary. These new members have been co-opted following the expiry of the mandate of the previous co-opted members appointed in 2004.

A more detailed CHMP meeting report will be published shortly.

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