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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 18-21 September 2006

Initial marketing authorisation applications

The Committee for Medicinal Products for Human Use (CHMP) gave two positive opinions on initial marketing authorisation applications for new treatment options for patients suffering from diabetes or from cancer:

- **Byetta** (exenatide), from Eli Lilly and Company Limited, received a positive opinion for the treatment of patients with type-2 diabetes. EMEA review began on 23 November 2005 with an active review time of 208 days.
- **Sprycel** (dasatinib), from BMS pharma EEIG, received a positive opinion for the treatment of chronic myeloid leukaemia in patients with resistance or intolerance to prior therapy including imatinib mesylate, and acute lymphoblastic leukaemia in patients with resistance or intolerance to prior therapy. Sprycel is the **31st orphan medicinal product*** to receive a positive opinion from the Committee. EMEA review began on 1 February 2006 with an active review time of 177 days.

Scientific opinion for medicinal products for use outside the European Union

The Committee adopted a positive opinion for **Aluvia** (lopinavir/ritonavir), from Abbott Laboratories Limited (UK). Aluvia is intended for the treatment of HIV-1-infected adults and children above the age of two years, in combination with other antiretroviral agents. The opinion was adopted in accordance with Article 58 of Regulation (EC) No 726/2004, which allows the CHMP, in the context of cooperation with the World Health Organization (WHO), to adopt scientific opinions for medicinal products intended exclusively for markets outside the European Union. Aluvia is the third medicinal product to receive a positive opinion under Article 58.

Extension of indication

The Committee gave positive opinions for applications for extensions of indication, adding new treatment options for previously approved medicines in the area of cancer, diabetes, infectious and cardiovascular diseases:

- **Taxotere** (docetaxel), from Aventis Pharma S.A., received a positive opinion to include the use of Taxotere in combination with cisplatin and 5-fluorouracil for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck. Taxotere was first granted marketing authorisation in the European Union on 27 November 1995 and is authorised for the treatment of breast cancer, non-small-cell lung cancer, prostate cancer and gastric adenocarcinoma.
- **Actos** (pioglitazone), from Takeda Europe R&D Centre Ltd., received a positive opinion to add triple oral combination therapy with metformin and sulphonylurea. Actos was first granted a marketing authorization in the European Union on 13 October 2000 and is authorised as monotherapy or as dual oral therapy with other medicinal products for the treatment of type-2 diabetes.
- **Noxafil** (posaconazole) and **Posaconazole SP** (posaconazole), from Schering Plough Europe, received a positive opinion to include prophylaxis of invasive fungal infections in high-risk patients and to add treatment of oropharyngeal candidiasis in adults. Noxafil and Posaconazole SP were first granted marketing authorisation in the European Union on 25 October 2005 and are currently authorised for several invasive fungal infections in adults.
- **Tracleer** (bosentan), from Actelion Registration Ltd, received a positive opinion to extend the indication to pulmonary arterial hypertension patients associated with congenital systemic-to-

* Correction of the number of orphan medicinal products

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pulmonary shunts and Eisenmenger's physiology.Tracleer was first granted marketing authorisation in the European Union on 15 May 2002 and is currently indicated fortreatment of pulmonary arterial hypertension (PAH) in selected patient populations with grade-III functional status.

New contraindications
The Committee recommended to add a contraindication for **Ketek** (telithromycin) and **Levviax** (telithromycin), from Aventis Pharma S.A., saying that in patients with severely impaired renal and/or hepatic functions the two medicinal products should not be administered concomitantly with strong CYP3A4 inhibitors, such as protease inhibitors or ketoconazole. Ketek and Levviax were first granted marketing authorisation on 9 July 2001 and are currently authorised for a number of respiratory-tract infections.

Summaries of opinions for all products mentioned above are available and can be found here.

Referral procedures concluded

The Committee concluded a referral procedure for **Glucomed** (glucosamine hydrochloride) and associated names, from Navamedic ASA, recommending the granting of a marketing authorisation for the relief of symptoms in mild to moderate osteoarthritis of the knee. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended) because of disagreement regarding the benefit-risk profile in this indication among the Member States during the mutual recognition procedure.

The Committee concluded a referral procedure for **Agopton** (lansoprazole) and associated names, from Takeda Pharma GmbH, with a recommendation to harmonise the product information, in particular therapeutic indications and posology, across the EU. The procedure was initiated by Germany under Article 30 of the Community code on human medicinal products (Directive 2001/83/EC as amended), which is triggered in order to harmonise differences between nationally authorised product information across the EU.

Referral procedures started
The European Commission asked the Committee to look at the risk-benefit profile of **veralipride**-containing medicinal products. This follows concerns regarding psychiatric and neurological reactions reported with veralipride. The procedure was initiated under Article 31 of Directive 2001/83/EC as amended. Veralipride is indicated for the treatment of hot flushes and psycho-functional symptoms such as anxiety, depression or irritability of confirmed menopause.

The Committee started a referral procedure for a generic medicinal product called **Simvastatine** (simvastatine) from Neo Pharma Ltd because of concerns over the reliability of a bioequivalence study used to demonstrate comparability with the originator product. The procedure was initiated by the Netherlands under Article 36 of the Community code on human medicinal products (Directive 2001/83/EC as amended).
Article 36 procedures are initiated where a Member State considers that there are public health issues relating to a product that may require regulatory action.

A more detailed CHMP meeting report will be published shortly.

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