European Medicines Agency
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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 26-29 May 2009

Initial evaluation
The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions, recommending the granting of a marketing authorisation, for the following medicines:

- **Afinitor** (everolimus), from Novartis Europharm Ltd., intended for the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy. The review began on 23 July 2008, with an active review time of 206 days. Afinitor is the **55th orphan medicine** to receive a positive opinion from the CHMP.
- **Mozobil** (plerixafor), from Genzyme Europe B.V., intended for use in combination with granulocyte-colony stimulating factor (G-CSF) to enhance the mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly. The review began on 25 June 2008, with an active review time of 207 days. Mozobil is the **56th orphan medicine** to receive a positive opinion from the CHMP.
- **Samsca** (tolvaptan), from Otsuka Pharmaceutical Europe Ltd, intended for the treatment of hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH). The review began on 27 February 2008, with an active review time of 207 days.

Generic medicines
The Committee adopted six positive opinions recommending a marketing authorisation for generic medicines of Plavix (clopidogrel, as hydrogen sulphate), the reference medicine already authorised in the European Union. The medicines concerned are:

- **Clopidogrel 1A Pharma** (clopidogrel, as besilate)**, Clopidogrel ratiopharm GmbH** (clopidogrel, as besilate)**, Clopidogrel Acino** (clopidogrel, as besilate) **and Clopidogrel Hexal** (clopidogrel, as besilate), all from Acino Pharma GmbH,
- **Clopidogrel Teva** (clopidogrel, as hydrogen sulphate), from Teva Pharma B.V.,
- **Grepid** (clopidogrel, as besilate), from Pharmathen S.A..

The Committee also adopted a positive opinion for **Topotecan Actavis** (topotecan), from Actavis Group PTC ehf. The reference medicine for this generic product is Hycamtin.

Re-examination procedures
Following re-examination of its negative opinion adopted in January 2009, the Committee adopted a final positive opinion under exceptional circumstances, subject to certain specific obligations to be reviewed annually, for **Vedrop** (tocofersolan), from Orphan Europe S.A.R.L., intended for the treatment of vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis.

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

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Extension of indication – positive opinions
The Committee gave positive opinions for applications for the extension of indication, adding a new treatment option, for the following medicines:

- **Alimta (**pemetrexed), from Eli Lilly Nederland B.V., to extend the indication to include monotherapy maintenance treatment of locally advanced or metastatic non-small cell lung cancer in patients whose disease has not progressed immediately following platinum-based chemotherapy. Alimta is already authorised in this indication as monotherapy for second-line treatment after prior chemotherapy, and as first line treatment in combination with cisplatin. It is also authorised as combination therapy for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.
- **Pandemrix (**H5N1) (split virion, inactivated, adjuvanted), **PrePandrix** (H5N1) (split virion, inactivated, adjuvanted), and **Prepandemic influenza vaccine** (H5N1) (split virion, inactivated, adjuvanted), all from GlaxoSmithKlineBiologicals S.A., to extend the use of these vaccines to include subjects aged 61 years and older based on clinical trial data. Pandemrix is a mock-up pandemic influenza vaccine, intended for the prevention of influenza during an officially declared pandemic influenza situation, once the pandemic viral strain has been included. Prepandrix and Prepandemic influenza vaccine are pre-pandemic vaccines intended to trigger an immune response against the H5N1 strain of the influenza virus before or during an officially declared influenza pandemic.
- **Revatio (**sildenafil), from Pfizer Limited, to extend the indication to include the treatment of patients with pulmonary arterial hypertension (PAH) classified as WHO functional class II. Revatio is currently authorised for the treatment of PAH classified as WHO functional class III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease.

Summaries of opinion for all mentioned medicines, including their full indication, can be found here.

Lifting of supply and treatment restrictions for Neupro
The Committee recommended that the supply and treatment restrictions for Neupro (rotigotine transdermal patch), from Schwarz Pharma Ltd, be lifted. Once this recommendation is endorsed by the European Commission, the ban on prescribing Neupro to patients not yet taking the medicine will be reversed. Doctors in the European Union will then be able to prescribe Neupro to all patients in accordance with the approved product information and prescriptions will no longer be limited to one month.

A separate press release with more detailed information is available here.

Follow-up recommendations on use of antiviral medicines in the event of an influenza A/H1N1 pandemic

The Committee has adopted a set of follow-up recommendations to its guidance on the use of Tamiflu (oseltamivir) in children under one year of age and the use of Tamiflu and Relenza (zanamivir) in pregnant and breastfeeding women in the case of a declared influenza A/H1N1 published on 8 May 2009.

The detailed follow-up recommendations are available here.

Referral procedures concluded
The CHMP concluded a referral procedure under Article 29 of Directive 2001/83/EC, as amended. This type of procedure is initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure or the decentralised procedure. The medicine concerned is

- **Loratadine Sandoz 10 and associated names** (loratadine), 10 mg tablets from Sandoz BV, intended for symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria. The procedure was initiated because of concerns by some Member States over bioequivalence of the medicine with the innovator product. The CHMP concluded that bioequivalence had not been adequately demonstrated. The CHMP recommended the refusal of the granting of the Marketing Authorisation in the Concerned Member States and the suspension of the Marketing Authorisation for Loratadine Sandoz 10 in the Member States where the product is currently authorised.

A separate question-and-answer documents with more information about the abovementioned procedurs is available here.

Referral procedure started

The CHMP started a referral for **modafinil-containing medicines**, on the request of the United Kingdom, because of safety concerns relating to skin and hypersensitivity reactions and psychiatric disorders. Modafinil-containing medicines are wakefulness promoting stimulants authorised for the symptomatic relief of excessive sleepiness associated with narcolepsy and in some Member States also for use in obstructive sleep apnoea/hypopnoea syndrome and/or moderate to sever chronic shift work sleep disorder. The referral was initiated under Article 31 of Directive 2001/83/EC, as amended.

A more detailed CHMP meeting report will be published shortly.

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Media enquiries only to:
Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu