European Medicines Agency
Press office

London, 27 April 2007
Doc. Ref. EMEA/186566/2007

PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 23-26 April 2007

First accelerated assessment concluded

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the granting of a marketing authorisation for the first medicinal product for human use that has been evaluated by the new accelerated assessment procedure.

Soliris (eculizumab), from Alexion Europe SAS, is intended to reduce haemolysis (destruction of red blood cells) in patients with paroxysmal nocturnal haemoglobinuria (PNH). This is a rare blood disorder, in which the red blood cells are weak and are destroyed more rapidly than normal, causing the urine to turn red or dark during an episode (or paroxysm) of haemolysis. Soliris is the **37th orphan medicinal** product to receive a positive CHMP opinion. EMEA review began on 25 October 2006 with an active review time of 147 days.

A separate press release is available here.

Other positive opinions

The CHMP adopted positive opinions for:

- **Circadin** (melatonin), from Neurim Pharmaceuticals EEC Ltd, intended for the short-term treatment of primary insomnia in patients aged 55 or older. EMEA review began on 26 October 2005 with an active review time of 209 days.
- **Invega** (paliperidone), from Janssen-Cilag International NV, intended for the treatment of schizophrenia in adults. EMEA review began on 24 May 2006 with an active review time of 202 days.
- **Optaflu** (influenza vaccine [surface antigen, inactivated, prepared in cell culture]), from Novartis Vaccine and Diagnostics GmbH & Co. KG, intended for prevention of seasonal influenza in adults. EMEA review began on 19 July 2006 with an active review time of 202 days.
- **Pergoveris** (follitropin alfa and lutropin alfa), from Serono Europe Ltd, intended for the stimulation of follicular development in women with severe luteinising hormone (LH) and follicle stimulating hormone (FSH) deficiency. EMEA review began on 29 March 2006 with an active review time of 208 days.
- **Siklos** (hydroxycarbamide), from Addmedica SAS, intended to prevent vaso-occlusive crisis, a painful complication of sickle cell syndrome in paediatric and adult patients. Siklos is the **38th orphan medicinal product** to receive a positive opinion. EMEA review began on 26 October 2005 with an active review time of 208 days.

Negative opinions

The CHMP adopted two negative opinions recommending the refusal of a marketing authorisation for:

- **Cerepro** (adenovirus-mediated *Herpes simplex* virus-thymidine kinase gene), from Ark Therapeutics Ltd. Cerepro is a designated orphan medicinal product intended for the treatment of patients with operable high-grade glioma.
- **Genasense** (oblimersen), from Genta Development Ltd, intended for the treatment of advanced or metastatic melanoma.

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Separate question-and-answer documents explaining the grounds for the negative opinions for Cerepro and for Genasense are available on the EMEA website.

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

- **Humira** and **Trudexa** (adalimumab), from Abbott Laboratories, to extend the indication to include treatment of adult patients with severe active Crohn's disease. Humira and Trudexa are currently authorised for treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.
- **Renagel** (sevelamer), from Genzyme B.V., to extend the indication to include the control of hyperphosphataemia in adult patients on peritoneal dialysis. Renagel is currently indicated for the control of hyperphosphatemia in adult patients on haemodialysis.
- **Pegintron** and **Viraferonpeg** (peginterferon alfa-2b), from Schering Plough Europe, to extend the indication of these medicines to include the treatment of adult patients with hepatitis C-infection who have not been treated previously and who have clinically stable HIV co-infection. It is recommended that peginterferon alfa-2b in this indication be used in combination with Rebetol. (see also 'New contraindications')
- **Rebetol** (ribavirin), from Schering Plough Europe, to extend the indication of the medicine to include the treatment of adult patients with hepatitis C-infection who have not been treated previously and who have clinically stable HIV co-infection. Rebetol must be used in combination with peginterferon alfa-2b in this indication. (see also 'New contraindications')

New contraindications
The CHMP also recommended the addition of a new contraindication for **Pegintron** and **Viraferonpeg (**peginterferon alfa-2b), from Schering Plough Europe, that treatment of hepatitis C should not be initiated in patients with hepatitis C and HIV co-infection who have cirrhosis and a Child-Pugh score of 6 or higher. As **Rebetol,** also from Schering Plough Europe, is used in combination with peginterferon alfa-2b to treat hepatitis C in patients with hepatitis C and HIV co-infection, this contraindication will also be mentioned in the product information of Rebetol.

Deletion of an indication
The CHMP recommended that the indication for **Visudyne** (verteporfin), from Novartis Europharm Ltd, in the treatment of occult subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) be deleted, following evaluation of new data showing that the efficacy was insufficient to maintain it.

Visudyne is still indicated to treat patients with:
- exudative (wet) AMD with predominantly classic subfoveal CNV,
- subfoveal CNV secondary to pathological myopia.

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

Referral procedures concluded

Concluding a referral procedure for **Cefuroximaxetil 125 omhulde tabletten 125 mg, Cefuroximaxetil 250 omhulde tabletten 250 mg, Cefuroximaxetil 500 omhulde tabletten 500 mg,** (cefuroxim [as axetil]), from Sandoz B.V., the Committee recommended that a marketing authorisation for the treatment of mild to moderately severe infections caused by micro-organisms susceptible to cefuroxime be granted, but that the medicines should not be used in the treatment of uncomplicated gonorrhoea.
The referral procedure was initiated under Article 29 of the Community Code on medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated because of disagreements between the EU Member States in the context of the mutual-recognition procedure.

Referral procedures started

The CHMP started a number of referral procedures under Article 29 of the Community Code on medicinal products for human use (Directive 2001/83/EC):

- **Xeomin** (Clostridium botulinum type A neurotoxin complex), from Merz Pharmaceuticals GmbH
- **Bicaluplex 150mg tablet** (Bicalutamide), from Ingers Industrial Solutions s.r.o.
- **Menitorix** (Hib/MenC conjugate vaccine), from GlaxoSmithKline Biologicals.

A more detailed CHMP meeting report will be published shortly.

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