European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

4 October 2006
EMEA/COMP/383989/2006

PRESS RELEASE
Committee for Orphan Medicinal Products
October 2006 Meeting

The seventy-second meeting of the Committee for Orphan Medicinal Products (COMP) took place on 3-4 October 2006.

COMP Opinions

The Committee adopted 9 positive opinions on orphan medicinal product designation during this meeting:

- 4,7,10,13,16,19-Docosahexaenoic acid, from Mr. Jose Manuel Cela Lopez, **for treatment of retinitis pigmentosa,** (review time: day 52)
- Budesonide (oral use), from Dr Falk Pharma GmbH, **for treatment of Graft-versus-Host disease** (review time: day 52)
- Catumaxomab, from Fresenius Biotech GmbH, **for treatment of gastric cancer** (review time: day 87)
- Ciclosporin (implant), from Dr. Manfred Zoltobrocki, **for prevention of rejection for corneal transplant,** (review time: day 52)
- Antisense oligonucleotide 5'-d[P-Thio} (CCCTG CTCCC CCCTG GCTCC)-3', from CanReg(Europe) Limited, **for treatment of acute myeloid leukaemia** (review time: day 52)
- Human interleukin-2 (glycosylated tetrasaccharide, glycosylated trisaccharide and non-glycosylated) (inhalation use), from Immunoservice GmbH, **for treatment of renal cell carcinoma,** (review time: day 87)
- Iodine (^{131}I) anti-tenascin monoclonal antibody 81C6, from BCG (Europe) Ltd, **for treatment of glioma** (review time: day 52)
- Paclitaxel (liposomal), from MediGene AG, **for treatment of pancreatic cancer** (review time: day 52)
- Temsirolimus, from Wyeth Europa Limited, **for treatment of mantle cell lymphoma** (review time: day 52)

Withdrawals of Orphan Medicinal Product Applications

The COMP noted that one application for orphan medicinal product designation was withdrawn by the sponsor during evaluation phase of the procedure.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Overview of orphan designation procedures

The European Commission granted four positive decisions on orphan designation[1] since the last COMP meeting on 5-6 September 2006 (see Annex 1).

The status of orphan designation procedures, to date for 2006, is summarised below:

Applications submitted	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
85	72	14	-	2	59

An overview of orphan designation procedures for 2000-2005 is provided in Annex 2.

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions[2], which the Agency routinely publishes following adoption of the respective decisions on orphan designation by the European Commission.

Applications for Marketing Authorisation for Orphan Medicinal Products

Details of those designated orphan medicinal products that have been the subject of a centralised application for marketing authorisation since the last COMP meeting are provided in Annex 3.

Date of next COMP meeting

The next COMP meeting will be held on 8-9 November 2006.

NOTE: This Press Release, together with other information about the work of the EMEA, may be found on the internet at the following location: http://www.emea.europa.eu.

For further information, please contact:
Martin Harvey Allchurch, EMEA press officer
Tel. (+44-20) 74 18 84 27, E-mail: press@emea.europa.eu.

1 Details of all orphan designations granted to date by the European Commission are entered in the Community Register of Orphan Medicinal Products (http://pharmacos.eudra.org/F2/register/index.htm)

2 These documents are available on the EMEA web-site.

Orphan Medicinal Product Designations received since the October 2006 COMP Meeting

Active substance	4-amino-(6R,S)-5,6,7,8-tetrahydro-L-biopterin dihydrochloride
Sponsor	vasopharm BIOTECH GbH
Orphan Indication	Treatment of moderate and severe traumatic brain injury
Opinion receipt date	28 July 2006
Date of Commission Decision	28 August 2006

Active substance	Amphotericin B (for inhalation use)
Sponsor	Nektar Therapeutics UK Ltd
Orphan Indication	Prevention of pulmonary fungal infections in patients deemed at risk
Opinion receipt date	28 July 2006
Date of Commission Decision	28 August 2006

Active substance	Autologous tumor-derived immunoglobulin idiotype coupled to keyhole limpet haemocyanin
Sponsor	Analytica International GmH
Orphan Indication	Treatment of follicular lymphoma
Opinion receipt date	28 July 2006
Date of Commission Decision	28 August 2006

Active substance	Opebacan
Sponsor	XOMA Ireland Ltd
Orphan Indication	Treatment of meningococcal disease
Opinion receipt date	28 July 2006
Date of Commission Decision	28 August 2006

Overview of Procedures for Orphan Medicinal Product Designation for 2000-2005

Year	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Final negative COMP Opinions*	*Designations granted by Commission*
2005	118	88	30	0	88
2004	108	75	22	4	72
2003	87	54	41	1	55
2002	80	43	30	3	49
2001	83	64	27	1	64
2000	72	26	6	0	14

Overview of Designated Orphan Medicinal Products that have been the subject of a Centralised Application for Marketing Authorisation

- update since the last COMP meeting on 5-6 September 2006 -

Active substance	***Sponsor/applicant***	***EU Designation Number & Date of Orphan Designation***	***Designated Orphan Indication***
1,3-Propanedisulfonic acid, disodium salt (Kiacta)	Neurochem Luxco II SARL	EU/3/01/051 31/07/2001	Treatment of systemic secondary amyloidosis
Fluocinolone acetonide (prolonged-release intravitreal implant) (Retisert 590 microgram intravitreal implant)	Bausch and Lomb (UK) Ltd	EU/3/05/261 07/03/2005	Treatment of non-nfectious uveitis affecting the posterior segment of the eye
Mecasermin (Increlex)	Tercica Europe Limited - Ireland	EU/3/06/373 22/05/2006	Treatment of primary insulin-like growth factor-1 deficiency due to molecular or genetic defects