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

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PRESS RELEASE
Committee for Orphan Medicinal Products
December 2006 Meeting

The seventy-fourth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 5-6 December 2006.

COMP Opinions

The Committee adopted 6 positive opinions on orphan medicinal product designation during this meeting:

- Complement factor H, from Laboratoire français du Fractionnement et des Biotechnologies (LFB), **for treatment of atypical haemolytic uraemic syndrome (aHUS) associated with an inherited abnormality of the complement system** (review time: day 55)
- Fenretinide, from Cancer Research UK, **for treatment of soft tissue sarcomas** (review time: day 55)
- Fenretinide, from Cancer Research UK, **for treatment of malignant bone tumours** (review time: day 55)
- Forodesine hydrochloride, from Napp Pharmaceuticals Research Limited, **for treatment of cutaneous T cell lymphoma** (review time: day 87)
- Recombinant modified vaccinia Ankara expressing human 5T4, from **Oxford Biomedica (UK) Ltd, for treatment renal cell carcinoma** (review time: day 55)
- Thiotepa, from Adienne S.r.l, **for conditioning treatment prior to haematopoietic progenitor cell transplantation** (review time: day 87)

Two oral explanations on orphan medicinal product designation took place during the meeting.

Prior to this meeting, the Committee adopted one positive opinion via written procedure on 16 November 2006:

- Tazarotene, from Orfagen, **for treatment of congenital ichthyoses** (review time: day 67)

Withdrawals of Orphan Medicinal Product Applications

The COMP noted that one application for orphan medicinal product designation were withdrawn by the sponsors during evaluation phase of the procedure.

Overview of orphan designation procedures

The European Commission granted twelve positive decisions on orphan designation[1] since the last COMP meeting on 8-9 November 2006 (see Annex 1).

[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)

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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Applications submitted	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
98	81	18	-	2	76

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 9-10 January 2007.

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.

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

Orphan Medicinal Product Designations received since the November 2006 COMP Meeting

Active substance	Antisense oligonucleotide 5'-d[P-Thio] (CCCTG CTCCC CCCTG GCTCC)-3'
Sponsor	CanReg (Europe) Limited
Orphan Indication	Treatment of acute myeloid leukaemia
Opinion receipt date	17 October 2006
Date of Commission Decision	3 November 2006

Active substance	Budesonide (oral use)
Sponsor	Dr Falk Pharma GmbH
Orphan Indication	Treatment of Graft-versus-Host Disease
Opinion receipt date	17 October 2006
Date of Commission Decision	3 November 2006

Active substance	Catumaxomab
Sponsor	Fresenius Biotech GmbH
Orphan Indication	Treatment of gastric cancer
Opinion receipt date	17 October 2006
Date of Commission Decision	3 November 2006

Active substance	Ciclosporin (implant)
Sponsor	Dr. Manfred Zoltobrocki
Orphan Indication	Prevention of rejection for corneal transplant
Opinion receipt date	17 October 2006
Date of Commission Decision	3 November 2006

Active substance	Doxorubicin hydrochloride (liposomal)
Sponsor	GP-Pharm S.A.
Orphan Indication	Treatment of soft tissue sarcoma
Opinion receipt date	25 September 2006
Date of Commission Decision	27 October 2006

Active substance	Heparin-binding epidermal growth factor-like growth factor (HB-EGF), amino acids 74-148
Sponsor	Dr Michael Moore
Orphan Indication	Prevention of necrotizing enterocolitis
Opinion receipt date	25 September 2006
Date of Commission Decision	31 October 2006

Active substance	Human cytomegalovirus immunoglobulin
Sponsor	Biotest Pharma GmbH
Orphan Indication	Prevention of congenital cytomegalovirus infection following primary cytomegalovirus infection
Opinion receipt date	25 September 2006
Date of Commission Decision	31 October 2006

Active substance	Iodine (^{131}I) anti-tenascin monoclonal antibody 81C6
Sponsor	BCG (Europe) Ltd
Orphan Indication	Treatment of glioma
Opinion receipt date	17 October 2006
Date of Commission Decision	30 October 2006

Active substance	L-asparaginase encapsulated in erythrocytes
Sponsor	Erytech Pharma S.A.
Orphan Indication	Treatment of acute lymphoblastic leukemia
Opinion receipt date	25 September 2006
Date of Commission Decision	27 October 2006

Active substance	Paclitaxel (liposomal)
Sponsor	MediGene AG
Orphan Indication	Treatment of pancreatic cancer
Opinion receipt date	17 October 2006
Date of Commission Decision	31 October 2006

Active substance	Recombinant fusion protein consisting of the extracellular portion of CD95 fused to the Fc part of a human IgG1 molecule
Sponsor	Apogenix GmbH
Orphan Indication	Prevention of Graft-versus-Host disease
Opinion receipt date	25 September 2006
Date of Commission Decision	31 October 2006

Active substance	Temsirolimus
Sponsor	Wyeth Europa Limited
Orphan Indication	Treatment of mantle cell lymphoma
Opinion receipt date	17 October 2006
Date of Commission Decision	6 November 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 8-9 November 2006-

Active substance	***Sponsor/applicant***	***EU Designation Number & Date of Orphan Designation***	***Designated Orphan Indication***
beclomethasone 17, 21-dipropionate (Orbec)	Voisin Consulting S.A.R.L.	EU/3/02/093 13/03/2002	Treatment of intestinal graft-versus-host disease
Muramyl Tripeptide Phosphatidyl Ethanolamine (Mepact)	Immunodesigned Molecules SA	EU/3/04/206 21/06/2004	Treatment of osteosarcoma