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

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PRESS RELEASE
Committee for Orphan Medicinal Products
November 2006 Meeting

The seventy-third meeting of the Committee for Orphan Medicinal Products (COMP) took place on 8-9 November 2006.

COMP Opinions

The Committee adopted 2 positive opinions on orphan medicinal product designation during this meeting:

- Paclitaxel (micellar), from Oasmia Pharmaceutical AB, **for treatment of ovarian cancer** (review time: day 88)
- Forodesine hydrochloride, from Napp Pharmaceuticals Research Limited, **for treatment of acute lymphoblastic leukaemia,** (review time: day 60)

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

The Committee adopted 1 negative opinion on significant benefit review at the time of Marketing Authorisation during this meeting. The sponsor may submit grounds for appeal within 90 days of receipt of the opinion.

Withdrawals of Orphan Medicinal Product Applications

The COMP noted that three applications for orphan medicinal product designation were withdrawn by the sponsors during evaluation phase of the procedure.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 five positive decisions on orphan designation[1] since the last COMP meeting on 3-4 October 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Applications submitted	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
90	74	17	-	2	64

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

[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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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.

Procedural Announcement-submission of product information in Maltese

On 1st May 2007 the derogation regarding the status of the Maltese language as part of a Commission decision issued in the context of the orphan designation procedure will come to an end.
As Maltese will be required for orphan designation procedure, which will receive a COMP opinion as of February/March 2007, and in an effort to anticipate any possible delays in the decision-making process, we would strongly advise companies with planned regulatory activity in the first quarter of 2007 to initiate the translation process for their products in Maltese as soon as possible.

Date of next COMP meeting

The next COMP meeting will be held on 5-6 December 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.

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

Orphan Medicinal Product Designations received since the October 2006 COMP Meeting

Active substance	5-(2,6-Difluoro-phenoxy)-3(R,S)-{2(S)-[2(S)-(3-methoxycarbonyl-2(S)-{3-methyl-2(S)-[(quinoline-2-carbonyl)-amino]-butyrylamino}-propionylamino)-3-methyl-butyrylamino]-propionylamino}-4-oxo-pentanoic acid methyl ester
Sponsor	Theraptosis
Orphan Indication	Treatment of neonatal brain injury
Opinion receipt date	25 September 2006
Date of Commission Decision	23 October 2006

Active substance	Adenoviral vector containing human p53 gene
Sponsor	Gendux AB
Orphan Indication	Treatment of Li Fraumeni Syndrome
Opinion receipt date	25 September 2006
Date of Commission Decision	23 October 2006

Active substance	Arimoclomol
Sponsor	Wainwright Associates Ltd
Orphan Indication	Treatment of amyotrophic lateral sclerosis
Opinion receipt date	25 September 2006
Date of Commission Decision	26 October 2006

Active substance	Genetically modified allogeneic (human) tumour cells for the expression of IL-7, GM-CSF, CD80 and CD154, in fixed combination with a DNA-based double stem loop immunomodulator (dSLIM)
Sponsor	MOLOGEN AG
Orphan Indication	Treatment of renal cell carcinoma
Opinion receipt date	25 September 2006
Date of Commission Decision	23 October 2006

Active substance	Human Interleukin-2 (glycosylated tetrasaccharide, glycosylated trisaccharide and non-glycosylated) (inhalation use)
Sponsor	Immunservice GmbH
Orphan Indication	Treatment of renal cell carcinoma
Opinion receipt date	17 October 2006
Date of Commission Decision	27 October 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 3-4 October *2006 -*

Active substance	***Sponsor/applicant***	***EU Designation Number & Date of Orphan Designation***	***Designated Orphan Indication***
Eculizumab (Soliris)	Alexion Europe SAS	EU/3/03/166 17/10/2003	Treatment of paroxysmal nocturnal haemoglobinemia
Histamine dihydrochloride (Ceplene)	EpiCept GmbH	EU/3/05/272 11/04/2005	Treatment of acute myeloid leukaemia
Nilotinib (Tasigna)	Novartis Europharm Limited - UK	EU/3/06/375 22/05/2006	Treatment of chronic myeloid leukaemia
Temsirolimus (Torisel)	Wyeth Europa Limited - United Kingdom	EU/3/06/365 06/04/2006	Treatment of renal cell carcinoma