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

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PRESS RELEASE
Committee for Orphan Medicinal Products
February 2006 Meeting

The sixty-fifth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 7 February 2006.

The Committee welcomed Dr. Julia Dunne, the UK alternate member to the CHMP, as an observer.

COMP Opinions

The Committee adopted 1 positive opinion on orphan medicinal product designation during this meeting:

- Human monoclonal antibody against HLA-DR, from GPC Biotech AG, for treatment of **multiple myeloma** (review time: 86 days).

One oral explanation took place during the meeting. The COMP noted that one application for orphan medicinal product designation was withdrawn by the sponsor during the evaluation phase of the procedure.

Overview of orphan designation procedures

The European Commission granted four positive decisions on orphan designation[1] since the last COMP meeting on 10-11 January 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Applications submitted	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
9	10	2	-	-	4

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.

[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.

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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 7-8 March 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.eu.int/

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Orphan Medicinal Product Designations received since the January 2006 COMP Meeting

Active substance	*E. Coli* heat-shock protein 70 with bovine retinal S-antigen
Sponsor	Biotech Tools SA
Orphan Indication	Treatment of autoimmune uveitis
Opinion receipt date	19/12/2005
Date of Commission Decision	24/01/2006

Active substance	Lentiviral vector containing the human Wiskott Aldrich syndrome protein gene
Sponsor	Généthon
Orphan Indication	Treatment of Wiskott-Aldrich syndrome
Opinion receipt date	19/12/2005
Date of Commission Decision	24/01/2006

Active substance	Purified inactivated Japanese encephalitis SA14-4-2 virus vaccine
Sponsor	Intercell AG
Orphan Indication	Prevention of Japanese encephalitis
Opinion receipt date	19/12/2005
Date of Commission Decision	24/01/2006

Active substance	Vandetanib
Sponsor	AstraZeneca UK Limited
Orphan Indication	Treatment of medullary thyroid carcinoma
Opinion receipt date	19/12/2005
Date of Commission Decision	24/01/2006

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 10-11 January 2006 -

Active substance	***Sponsor/applicant***	***EU Designation Number & Date of Orphan Designation***	***Designated Orphan Indication***
Dasatinib (Sprycel)	Bristol-Meyers Squibb Pharma EEIG	EU/3/05/338 23/12/2005	Treatment of acute lymphoblastic leukaemia
Dasatinib (Sprycel)	Bristol-Meyers Squibb Pharma EEIG	EU/3/05/339 23/12/2005	Treatment of chronic myeloid leukaemia