The European Agency for the Evaluation of Medicinal Products
Pre-authorisation Evaluation of Medicines for Human Use

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EMEA/COMP/66/04

PRESS RELEASE
Committee for Orphan Medicinal Products
February 2004 Meeting

The forty-third meeting of the Committee for Orphan Medicinal Products (COMP) took place on 4-5 February 2004.

Dr. Markku Toivonen, Chairman of the Scientific Advice Working Group (SAWG), was invited to the meeting to discuss protocol assistance and proposals for optimising the procedure and improving future collaboration.

Six positive opinions on the designation of orphan medicinal products were adopted by the Committee during this meeting, for the following conditions:

- Congenital venous malformations
- Congenital lymphatic malformations
- Friedreich's ataxia
- Lipoprotein lipase deficiency
- Myelodysplastic syndromes
- Ovarian cancer

Of these six opinions, five were adopted on day 48 of the procedure, well before the 90-day deadline for the Committee's opinion following receipt of a valid application.

No negative opinions on orphan medicinal product designation were adopted. One oral explanation took place during the meeting. The COMP noted that one application for orphan medicinal product designation was withdrawn by a sponsor.

The European Commission granted two decisions on orphan designation[1] since the last COMP meeting on 13-14 January 2004 (see Annex 1).

The status of orphan designation procedures, to date for 2004, is summarised below:

Applications submitted	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
11	9	2	-	-	3

An overview of orphan designation procedures for 2000-2003 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.

The Committee endorsed a 'Note for Sponsors of Orphan Medicinal Products regarding Enlargement of the European Union (EMEA/COMP/66/04)', which has been published on the EMEA web-site.

The next COMP meeting will be held on 16-17 March 2004.

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[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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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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Medicinal products Designated as Orphan Medicinal Products since the January 2004 COMP Meeting

Active substance	Tacrolimus hydrate
Sponsor	Sucampo Pharma Europe Limited
Orphan Indication	Treatment of vernal keratoconjunctivitis
Opinion receipt date	12/12/2003
Date of Commission Decision	14/1/2004

Active substance	Cilengitide
Sponsor	Merck KGaA
Orphan Indication	Treatment of glioma
Opinion receipt date	12/12/2003
Date of Commission Decision	14/1/2004

Overview of Procedures for Orphan Medicinal Product Designation for 2000-2003

Year	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Final negative COMP Opinions*	*Designations granted by Commission*
2003	87	54	35	1	55
2002	80	43	24	3	49
2001	83	64	25	1	64
2000	72	26	3	0	14