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

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PRESS RELEASE
Committee for Orphan Medicinal Products
November 2003 Meeting

The fortieth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 5-6 November 2003. The Committee welcomed Prof George Shorten as the new Irish COMP Member, who will replace Dr Brendan Buckley.

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

- Aneurysmal subarachnoid haemorraghe
- Pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension
- Multiple myeloma
- Iron overload requiring iron chelation therapy
- Soft tissue sarcoma
- Hereditary factor XIII deficiency

Of these six opinions, four were adopted on day 60 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. Two oral explanations took place during the meeting. The COMP noted that sponsors withdrew two applications for orphan medicinal product designation. A sponsor withdrew one appeal procedure before grounds were submitted. Another appeal procedure is still ongoing.

The European Commission granted seven decisions on orphan designation[1] since the last COMP meeting on 9-10 October 2003. The status of orphan designation procedures, from January 2003 until 7 November 2003, is summarised below:

Intent to file notified	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
95	76	51	33	1	1	45

Overview of orphan designation procedures

Year	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Final negative COMP Opinions*	*Designations granted by Commission*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

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)

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The next COMP meeting will be held from 4 to 5 December 2003.

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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[2] Summarised COMP Opinions are available on the EMEA web-site.

Medicinal products Designated as Orphan Medicinal Products since the October 2003 COMP Meeting

Active substance	Trabectedin
Sponsor	Pharma Mar SA Sociedad Unipersonal
Orphan Indication	Treatment of Ovarian cancer
Opinion receipt date	17/09/2003
Date of Commission Decision	17/10/2003

Active substance	Eculizumab
Sponsor	QuadraMed
Orphan Indication	Treatment of paroxysmal nocturnal haemoglobinemia
Opinion receipt date	17/09/2003
Date of Commission Decision	17/10/2003

Active substance	H-Tyrosine-Glycine-Phenylalanine-Glycine-Glycine-OH
Sponsor	Abiogen Pharma S.p.A.
Orphan Indication	Treatment of chronic idiopathic myelofibrosis
Opinion receipt date	17/09/2003
Date of Commission Decision	20/10/2003

Active substance	Herpes simplex 1 virus-thymidine kinase and truncated low affinity nerve growth factor receptor transfected donor lymphocytes (INN)
Sponsor	MolMed S.p.A.
Orphan Indication	Adjunctive treatment in hematopoietic cell transplantation
Opinion receipt date	17/09/2003
Date of Commission Decision	20/10/2003

Active substance	Human immunoglobulin
Sponsor	Orfagen
Orphan Indication	Treatment of Dermatomyositis
Opinion receipt date	17/09/2003
Date of Commission Decision	20/10/2003

Active substance	Human immunoglobulin
Sponsor	Orfagen
Orphan Indication	Treatment of Polymyositis
Opinion receipt date	17/09/2003
Date of Commission Decision	24/10/2003

Active substance	Trientine dihydrochloride
Sponsor	Univar Limited
Orphan Indication	Treatment of Wilson' s disease
Opinion receipt date	17/09/2003
Date of Commission Decision	24/10/2003