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
October 2003 Meeting

The thirty-ninth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 9-10 October 2003. The Committee welcomed Dr. Peter Arlett from the Pharmaceuticals Unit of Directorate-General Enterprise at the European Commission, who replaces Dr. Julia Dunne. The Committee warmly thanked Dr. Dunne for her contribution and collaboration.

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

- Glioma
- Chronic Lymphocytic Leukaemia
- Mantle Cell Lymphoma
- Pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension

Of these four opinions, three 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. Three oral explanations took place during the meeting. The COMP noted that sponsors withdrew four applications for orphan medicinal product designation. Two sponsors submitted a letter of intention to appeal following the negative opinions adopted in July 2003. Detailed grounds for appeal must be submitted within 90 days of receipt of the opinion.

The European Commission granted six decisions[1] on orphan designation since the last COMP meeting on 29-30 July 2003. The status of orphan designation procedures, from January 2003 until 10 October 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Intent to file notified	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
96	70	45	30	2	0	38

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Year	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Final negative COMP Opinions*	*Designations granted by Commission*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 5 to 7 November 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 September 2003 COMP Meeting

Active substance	Antisense Oligonucleotide (TATCCGGAGGGCTCGCCATGCTGCT)
Sponsor	Gene Signal SAS
Orphan Indication	Treatment of retinopathy of prematurity
Opinion receipt date	07/08/2003
Date of Commission Decision	02/10/2003

Active substance	Antisense Oligonucleotide (TATCCGGAGGGCTCGCCATGCTGCT)
Sponsor	Gene Signal SAS
Orphan Indication	Treatment of neovascular glaucoma
Opinion receipt date	07/08/2003
Date of Commission Decision	02/10/2003

Active substance	Yttrium (^{90}Y) antiferritin polyclonal antibodies
Sponsor	Monoclonal Antibodies Therapeutics (MAT)
Orphan Indication	Treatment of Hodgkin lymphoma
Opinion receipt date	07/08/2003
Date of Commission Decision	02/10/2003

Active substance	5,6,7,8-Tetrahydrobiopterin
Sponsor	Prof. Dr. Adelbert A. Roscher
Orphan Indication	Treatment of hyperphenylalaninemia
Opinion receipt date	07/08/2003
Date of Commission Decision	02/10/2003

Active substance	α-1-acid glycoprotein
Sponsor	Bio Products Laboratory
Orphan Indication	Treatment of cocaine poisoning
Opinion receipt date	07/08/2003
Date of Commission Decision	02/10/2003

Active substance	Nolatrexed
Sponsor	Scirex Ltd.
Orphan Indication	Treatment of hepatocellular carcinoma
Opinion receipt date	11/08/2003
Date of Commission Decision	02/10/2003