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

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PRESS RELEASE
36th Meeting of the Committee for Orphan Medicinal Products

The thirty-sixth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 12-13 June 2003.

The members of the Committee elected the Vice-Chairman for the new mandate (2003-2006) in accordance with the internal rules of procedure of the COMP. Mr. Y. Le Cam (Patient Representative nominated by the European Commission) was re-elected as Vice-Chairman, following a successful mandate from 2000 to 2003.

Two observers from Accession Countries attended the June Meeting.

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

- Cutaneous T cell lymphoma
- Adrenal insufficiency
- Cystic fibrosis (2 opinions)
- Acute lymphoblastic leukaemia
- Glioma
- Sickle cell syndrome
- Ovarian cancer
- Metachromatic leukodystrophy
- Primary growth hormone insensitivity syndrome (Laron syndrome)

Of these ten opinions, seven were adopted on day 42 of the procedure, well before the 90-day deadline the Committee has to give an opinion following receipt of a valid application.

Three oral explanations took place during the meeting. The COMP noted that sponsors withdrew two applications for orphan medicinal product designation. Three decisions were granted by the European Commission on orphan designation[1] since the last COMP meeting on 7-8 May 2003, see Annex I. The status of orphan designation procedures, from January 2003 until 13 June 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Intent to file notified	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Appeals ongoing*	*Final negative COMP Opinions*	*Designations granted by Commission*
66	36	28	15	3	0	16

Overview of orphan designation procedures

[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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Year	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Final negative COMP Opinions*	*Designations granted by Commission*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.

The next COMP meeting will be held on 29-30 July 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 May 2003 COMP Meeting

Active substance	Liarozole
Sponsor	Barrier Therapeutics NV
Orphan Indication	Treatment of congenital ichthyoses
Opinion receipt date	28/04/2003
Date of Commission Decision	10/06/2003

Active substance	Rubitecan
Sponsor	Eurogen Pharmaceuticals Limited
Orphan Indication	Treatment of pancreatic cancer
Opinion receipt date	28/04/2003
Date of Commission Decision	10/06/2003

Active substance	5-10-Methylene-tetrahydrofolate
Sponsor	Biofol AB
Orphan Indication	Treatment of pancreatic cancer in combination with 5-fluorouracil
Opinion receipt date	15/04/2003
Date of Commission Decision	11/06/2003