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

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PRESS RELEASE

31st Meeting of the Committee for Orphan Medicinal Products

The thirty first meeting of the Committee for Orphan Medicinal Products (COMP) took place on 9-10 January 2003.

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

- Primary apnea of premature newborns
- Angioedema
- Systemic amyloidosis
- Myelodysplastic syndrome
- Follicular lymphoma *(2 x opinions)*

Two oral explanations took place during the meeting. The COMP noted that five applications for orphan medicinal product designation were withdrawn by sponsors.

The European Commission granted five decisions on orphan designation[1] since the last COMP meeting on 12-13 December 2002, see Annex I. The status of orphan designation procedures, as of 10 January 2003, is summarised in the table below:

Intent to file notified	*Applications submitted*	*Applications withdrawn*	*Positive COMP Opinions*	*Negative COMP Opinions*	*Designations granted by Commission*
53	234	66	137	4[2]	126

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions[3], 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 6-7 February 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/

For further information, please contact:

Martin Harvey, EMEA press officer
Tel. (+44-20) 74 18 84 27,
E-mail: martin.harvey@emea.eu.int

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 Of the seven negative opinions adopted to date: one is subject to appeal, three have resulted in final negative opinions, one has resulted in a final positive opinion following appeal, and two applications have been subsequently withdrawn.

3 Summarised COMP Opinions are available on the EMEA web-site.

Medicinal products Designated as Orphan Medicinal Products since the December 2002 COMP Meeting

Active substance	5-aminolevulinic acid hydrochloride
Sponsor	Medac Gesellschaft für klinische Spezialpräparate mbH
Orphan Indication	Intra-operative photodynamic diagnosis of residual glioma
Opinion receipt date	16/10/2002
Date of Commission Decision	13/11/2002

Active substance	Monoclonal antibody to human interleukin-6
Sponsor	OPI Orphan Pharma International
Orphan Indication	Treatment of post-transplant lymphoproliferative disorders
Opinion receipt date	20/11/2002
Date of Commission Decision	18/12/2002

Active substance	Recombinant inhibitor of human plasma kallikrein
Sponsor	Dyax s.a.
Orphan Indication	Treatment of angioedema
Opinion receipt date	20/11/2002
Date of Commission Decision	18/12/2002

Active substance	Cholic acid
Sponsor	Agence générale des équipements et produits de santé - Etablissement pharmaceutique des hôpitaux de Paris (AGEPS-EPHP)
Orphan Indication	Treatment of inborn errors in primary bile acid synthesis
Opinion receipt date	20/11/2002
Date of Commission Decision	18/12/2002

Active substance	3,4 diaminopyridine phosphate
Sponsor	AGEPS-EPHP Agence Générale des Équipements et Produits de Santé - France
Orphan Indication	Treatment of Lambert-Eaton myasthenic syndrome
Opinion receipt date	20/11/2002
Date of Commission Decision	18/12/2002