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

8 December 2003
EMEA/COMP/1603/03

PRESS RELEASE
Committee for Orphan Medicinal Products
December 2003 Meeting

The forty-first meeting of the Committee for Orphan Medicinal Products (COMP) took place on 4-5 December 2003.

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

- *Burkholderia cepacia* lung infection in cystic fibrosis
- Glioma
- Vernal keratoconjunctivitis

Of these three opinions, two were adopted on day 49 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 The COMP noted that one application for orphan medicinal product designation was withdrawn by a sponsor. One appeal procedure is ongoing.

The European Commission granted two decisions on orphan designation[1] since the last COMP meeting on 5-6 November 2003 (see Annex 1). An overview of orphan designation procedures to date, in this and previous years, is summarised below:

Year	*Applications submitted*	*Positive COMP Opinions*	*Applications withdrawn*	*Final negative COMP Opinions*	*Designations granted by Commission*
2003	87	54	34	1	47
2002	80	43	24	3	49
2001	83	64	25	1	64
2000	72	26	3	0	14

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.

A revised version of the document titled 'General Information for Sponsors of Orphan Medicinal Products' (EMEA/4795/00 Rev2)[2] was agreed by the Committee. This document has been updated to include information on sponsor's options in case of a negative outcome in an orphan designation procedure, appeals, and marketing authorisations under exceptional circumstances.

The next COMP meeting will be held next year on 13-14 January 2004.

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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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.

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

Active substance	Gimatecan
Sponsor	Sigma Tau Industrie Farmaceutiche Riunite S.p.A
Orphan Indication	Treatment of glioma
Opinion receipt date	21/10/2003
Date of Commission Decision	01/12/2003

Active substance	Recombinant antibody derivative against human CD19 and CD3
Sponsor	Micromet AG
Orphan Indication	Treatment of Mantle Cell Lymphoma
Opinion receipt date	21/10/2003
Date of Commission Decision	01/12/2003