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

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PRESS RELEASE

28th Meeting of the Committee for Orphan Medicinal Products

The twenty-eighth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 8-9 October 2002.

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

- Glioma (*2 x opinions*)
- Graft versus host disease
- Low flow priapism
- Cystic fibrosis

One oral explanation took place during the meeting. The COMP noted that two applications for orphan medicinal product designation were withdrawn by sponsors.

The European Commission granted one decision on orphan designation[1] since the last COMP meeting on 11-12 September 2002, see Annex I. The status of orphan designation procedures, as of 9 October 2002, is summarised in the table below:

Intent to file notified	*Applications submitted*	*Applications withdrawn*	*Positive COMP Opinions*	*Negative COMP Opinions*	*Designations granted by Commission*
52	212	60	123	3[2]	115

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 Committee discussed and endorsed a revised version of the Commission guideline (ENTR/6283/00)[4] on the format and content of applications for designation as orphan medicinal products. Section D.3 of the guideline, titled "Justification of significant benefit", has been updated and now notes that the COMP may take into account the potential availability of a medicinal product to patients when assessing whether it will be of 'significant benefit'. In preparing an application for orphan medicinal product designation, sponsors are requested to follow this guideline.

The next COMP meeting will be held on 14-15 November 2002.

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 six negative opinions adopted to date: 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 (http://www.emea.eu.int/)

4 ENTR/6283/00 is available on the EMEA and Commission (http://pharmacos.eudra.org/F2/) web-sites

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

Active substance	Doxorubicin carbon/iron magnetically targeted microparticles
Sponsor	Interface International Consultancy Limited
Orphan Indication	Treatment of hepatocellular carcinoma.
Opinion receipt date	24/07/2002
Date of Commission Decision	11/09/2002