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

23 May 2002
COMP/1051/02

PRESS RELEASE

24th Meeting of the Committee for Orphan Medicinal Products

The twenty-fourth meeting of the Committee for Orphan Medicinal Products (COMP) was held on 22 May 2002.

Dr. Harrie Seeverens (COMP Member representing the Netherlands) and Dr. Sonja van Weely (Scientific Secretariat of Dutch Steering Committee for Orphan Drugs), informed the Committee about the Dutch rare disease initiatives. The Committee congratulated the Dutch representatives on the establishment of the national Steering Committee which has been set up to stimulate the development of orphan drugs, to improve the situation of patients with a rare disease, and to strengthen the transfer of information on rare diseases.

One positive opinion on the designation of orphan medicinal products, was adopted by the Committee during this meeting, for the following condition:

- Cystic fibrosis

Four oral explanations took place during the meeting, one in the framework of an appeal procedure. Following review of the grounds for appeal and the oral explanation of the sponsor, the COMP considered that the negative opinion it adopted in December 2001 should not be revised and a final negative opinion on orphan designation was issued.

Five applications for orphan medicinal product designation were withdrawn by sponsors. The European Commission granted three decisions on orphan designation[1] since the last COMP meeting on 29-30 April 2002, see Annex I. The status of orphan designation procedures, as of 22 May 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Intent to file notified	*Applications submitted*	*Applications withdrawn*	*Positive COMP Opinions*	*Negative COMP Opinions*	*Designations granted by Commission*
46	178	50	105	2[2]	101

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 a one day meeting to be held on 20 June 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/

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 Of the five negative opinions adopted to date: two applications have been subsequently withdrawn, two have resulted in final negative opinions and one has resulted in a final positive opinion following appeal.

3 Summarised COMP Opinions are available on the EMEA web-site (http://www.emea.eu.int/)

Medicinal products Designated as Orphan Medicinal Products
In April 2002

Active substance	Bryostatin-1
Sponsor	GPC Biotech AG,
Orphan Indication	Treatment of oesophageal cancer
Opinion receipt date	28/3/02
Date of Commission Decision	30/4/02

Active substance	Recombinant human alpha-1-antitrypsin
Sponsor	Baxter AG,
Orphan Indication	Treatment of emphysema secondary to congenital alpha-1-antitrypsin deficiency
Opinion receipt date	28/3/02
Date of Commission Decision	30/4/02

Active substance	Pseudomonas exotoxin (domains II/III)-Interleukin 13 chimeric protein
Sponsor	PPD Global Ltd,
Orphan Indication	Treatment of glioma
Opinion receipt date	28/3/02
Date of Commission Decision	30/4/02