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EMA/COMP/313/03

PRESS RELEASE

32nd Meeting of the Committee for Orphan Medicinal Products

The thirty-second meeting of the Committee for Orphan Medicinal Products (COMP) took place on 6-7 February 2003.

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

- Systemic sclerosis
- Tricyclic antidepressants poisoning
- *Pseudomonas aeruginosa* infections in patients with cystic fibrosis

One oral explanation took place during the meeting. The COMP noted that sponsor withdrew one application for orphan medicinal product designation.

The European Commission granted three decisions on orphan designation¹ since the last COMP meeting on 9-10 January 2003, see Annex I. The status of orphan designation procedures, as of 7 February 2003, is summarised in the table below:

<i>Intent to file notified</i>	<i>Applications submitted</i>	<i>Applications withdrawn</i>	<i>Positive COMP Opinions</i>	<i>Negative COMP Opinions</i>	<i>Designations granted by Commission</i>
64	241	67	140	4 ²	129

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions³, 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 18-19 March 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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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opinions, one has resulted in a final positive opinion following appeal, and two applications have been subsequently withdrawn.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 January 2003 COMP Meeting**

Active substance	G17(9) gastrin-diphtheria toxoid conjugate
Sponsor	Orion Clinical Services Limited
Orphan Indication	Treatment of pancreatic cancer
Opinion receipt date	20/12/2002
Date of Commission Decision	24/01/2003

Active substance	G17(9) gastrin-diphtheria toxoid conjugate
Sponsor	Orion Clinical Services Limited
Orphan Indication	Treatment of gastric cancer
Opinion receipt date	23/12/2002
Date of Commission Decision	28/01/2003

Active substance	Carboxypeptidase G2
Sponsor	Enact Pharma PLC
Orphan Indication	Adjunctive treatment in patients at risk of methotrexate toxicity
Opinion receipt date	23/12/2002
Date of Commission Decision	03/02/2003