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COMP/140/01

PRESS RELEASE

12th Meeting of the Committee for Orphan Medicinal Products

The Committee for Orphan Medicinal Products (COMP) held its twelfth meeting on 9-10 April 2001.

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

- Emphysema secondary to congenital alpha-1-antitrypsin deficiency
- Methanol poisoning
- Ovarian cancer
- Scarring in glaucoma filtration surgical procedures
- Severe Combined Immunodeficiency (SCID) X1 Disease
- Soft tissue sarcoma

These opinions, will now be forwarded to the European Commission for the decision making process.

One oral explanation took place during the meeting and two applications for orphan medicinal product designation were withdrawn by the sponsors. Eight decisions on orphan designation were granted by the European Commission¹ in March 2001, see Annex I.

The status of orphan designation procedures, as of 10 April 2001, is summarised in the table below:

<i>Year</i>	<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Applications withdrawn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>
2000	31	72	3	26	-	14
2001	17	14	8	17	3	20
<i>Total</i>	<i>48</i>	<i>86</i>	<i>11</i>	<i>43</i>	<i>3</i>	<i>34</i>

The Committee appointed co-ordinators and experts for a number of upcoming applications.

The 1st EMEA Workshop with the Pharmaceutical Industry on Orphan Medicinal Products was held on 11 April 2001. Members of the COMP, the European Commission and the EMEA met with fifty representatives of the pharmaceutical industry. The European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Association for Bioindustries (EuropaBio), the Emerging Biopharmaceutical Enterprises (EBE) and sponsors of products which have been subject of positive opinions were represented. The Committee's achievements to date were discussed as well as proposals for improving transparency. A Press Release from this Workshop (COMP/141/01) will be published on the EMEA's website.

The next COMP meeting will be held on 22-23 May 2001.

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/register/orphreg.htm>)
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**Medicinal products Designated as Orphan Medicinal Products
in March 2001**

Active substance	Ibuprofen
Sponsor	Orphan Europe
Orphan Indication	Prevention of patent ductus arteriosus in premature neonates of less than 34 weeks of gestational age
Opinion receipt date	19/1/01
Date of Commission Decision	5/3/01

Active substance	Inolimomab
Sponsor	OPi Orphan Pharma international
Orphan Indication	Treatment of Graft versus Host Disease
Opinion receipt date	18/1/01
Date of Commission Decision	5/3/01

Active substance	Ribavirin
Sponsor	ICN Pharmaceuticals Ltd.
Orphan Indication	Treatment of adenovirus infection in immunocompromised patients
Opinion receipt date	18/1/01
Date of Commission Decision	8/3/01

Active substance	8-cyclopentyl-1,3-dipropylxanthine
Sponsor	SciClone Pharmaceuticals Italy S.r.l
Orphan Indication	Treatment of cystic fibrosis
Opinion receipt date	13/2/01
Date of Commission Decision	29/3/01

Active substance	Arsenic trioxide
Sponsor	Cell Therapeutics (UK) Ltd.
Orphan Indication	Treatment of myelodysplastic syndromes
Opinion receipt date	13/2/01
Date of Commission Decision	29/3/01

Active substance	Arsenic trioxide
Sponsor	Cell Therapeutics (UK) Ltd.
Orphan Indication	Treatment of multiple myeloma
Opinion receipt date	13/2/01
Date of Commission Decision	29/3/01

Active substance	Ranpirnase
Sponsor	Dr. Erika Morgenstern
Orphan Indication	Treatment of malignant mesothelioma
Opinion receipt date	13/2/01
Date of Commission Decision	29/3/01

Active substance	Gusperimus trihydrochloride
Sponsor	Euro Nippon Kayaku GmbH
Orphan Indication	Treatment of Wegener's Granulomatosis
Opinion receipt date	13/2/01
Date of Commission Decision	29/3/01