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

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PRESS RELEASE

13th Meeting of the Committee for Orphan Medicinal Products

The Committee for Orphan Medicinal Products (COMP) held its thirteenth meeting on 22-23 May 2001.

The Committee welcomed Dr. Alex Nicholson, replacing Dr. Rashmi Shah as UK representative to the COMP.

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

- Multiple myeloma
- Graft versus host disease
- Invasive infections due to Vancomycin Resistant Enterococci (VRE) in colonised patients deemed at risk of infection
- Chronic pain requiring intraspinal analgesia
- Homocystinuria
- Emphysema secondary to congenital alpha-1-antitrypsin deficiency.

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

Four oral explanations took place during the meeting. The COMP noted that four applications for orphan medicinal product designation were withdrawn by the sponsors. Three decisions on orphan designation were granted by the European Commission[1] since the last COMP meeting on 9-10 April 2001 (see Annex I).

The status of orphan designation procedures, as of 23 May 2001, is summarised in the table below:

Intent to file notified	*Applications submitted*	*Applications withdrawn*	*Positive COMP Opinions*	*Negative COMP Opinions*	*Designations granted by Commission*
60	96	15	49	3	37

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

The next COMP meeting will be held on 11-12 June 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)

Medicinal products designated as Orphan Medicinal Products since 11 April 2001

Active substance	Humanised anti-HM1.24 monoclonal antibody
Sponsor	Chugai Pharma Europe Ltd
Orphan Indication	Treatment of multiple myeloma
Opinion receipt date	26 March 2001
Date of Commission Decision	10 May 2001

Active substance	Levodopa and Carbidopa (Gastroenteral use)
Sponsor	NeoPharma Production AB
Orphan Indication	Treatment of advanced idiopathic Parkinson's disease with severe motor fluctuations and not responding to oral treatment
Opinion receipt date	26 March 2001
Date of Commission Decision	10 May 2001

Active substance	Recombinant human C1-inhibitor
Sponsor	Pharming N.V.
Orphan Indication	Treatment of angioedema caused by C1 inhibitor deficiency
Opinion receipt date	26 March 2001
Date of Commission Decision	11 May 2001