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

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PRESS RELEASE

29th Meeting of the Committee for Orphan Medicinal Products

The twenty-ninth meeting of the Committee for Orphan Medicinal Products (COMP) took place on 14-15 November 2002.

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

- Inborn errors of primary bile acid synthesis
- Angioedema
- Lambert-Eaton myasthenic syndrome
- Post-transplant lymphoproliferative disorders

One oral explanation took place during the meeting. The COMP noted that one application for orphan medicinal product designation was withdrawn by sponsors.

The European Commission granted six decisions on orphan designation[1] since the last COMP meeting on 8-9 October 2002, see Annex I. The status of orphan designation procedures, as of 15 November 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Intent to file notified	*Applications submitted*	*Applications withdrawn*	*Positive COMP Opinions*	*Negative COMP Opinions*	*Designations granted by Commission*
57	220	61	127	3[2]	121

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 held on 12-13 December 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 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opinions, one has resulted in a final positive opinion following appeal, and two applications have been subsequently withdrawn.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/)

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

Active substance	Autologous Renal Cell Tumor Vaccine
Sponsor	Liponova GmbH
Orphan Indication	Treatment of renal cell carcinoma
Opinion receipt date	12/09/2002
Date of Commission Decision	21/10/2002

Active substance	Boswellia serrata resin dry extract
Sponsor	Pharmasan GmbH
Orphan Indication	Treatment of peritumoral edema derived form brain tumour
Opinion receipt date	12/09/2002
Date of Commission Decision	21/10/2002

Active substance	Iodine 131 radiolabeled anti-nucleohistone H1 chimeric biotinylated monoclonal antibody
Sponsor	Interface International Consultancy Ltd
Orphan Indication	Treatment of glioma
Opinion receipt date	09/10/2002
Date of Commission Decision	13/11/2002

Active substance	Duramycin
Sponsor	Gerd Döring
Orphan Indication	Treatment of cystic fibrosis
Opinion receipt date	09/11/2002
Date of Commission Decision	13/11/2002

Active substance	Etilefrin
Sponsor	Laboratoires SERB
Orphan Indication	Treatment of low flow priapism
Opinion receipt date	16/10/2002
Date of Commission Decision	13/11/2002

Active substance	anti-CD 147 murine monoclonal IgM
Sponsor	SangStat UK Limited
Orphan Indication	Treatment of Graft versus Host Disease
Opinion receipt date	09/10/2002
Date of Commission Decision	14/11/2002