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PRESS RELEASE

23rd Meeting of the Committee for Orphan Medicinal Products

The twenty-third meeting of the Committee for Orphan Medicinal Products (COMP) was held on 29-30 April 2002.

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

- Acute intermittent porphyria
- Adrenal cortical carcinoma
- Visceral leishmaniasis

Three oral explanations took place during the meeting. The COMP noted that 2 applications for orphan medicinal product designation were withdrawn by sponsors.

The status of orphan designation procedures, as of 30 April 2002, 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Applications withdrawn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>
45	178	45	104	1 ¹	98

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions², which the Agency routinely publishes following adoption of the respective decisions on orphan designation by the European Commission.

The Committee adopted a final version of its guideline (COMP/189/01) on the format and content of the annual report on the state of development of an orphan medicinal product, which has been updated to incorporate comments received during the consultation period. The final version of the guideline is available on the EMEA web-site.

The next COMP meeting will be held on 22-23 May 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 Of the five negative opinions adopted to date, one appeal is ongoing. Two applications have been subsequently withdrawn, one has resulted in a final negative decision and one has resulted in a final positive opinion following appeal.

² Summarised COMP Opinions are available on the EMEA web-site (<http://www.emea.eu.int/>)
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