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

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EMEA/COMP/38/02

PRESS RELEASE

20th Meeting of the Committee for Orphan Medicinal Products

The twentieth meeting of the Committee for Orphan Medicinal Products (COMP) was held on 22-23 January 2002.

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

- Alkaptonuria
- Chronic iron overload requiring chelation therapy
- Glioma
- High-grade glioma
- Intestinal Graft-versus-Host Disease
- Juvenile myelomonocytic leukaemia
- Ovarian cancer
- Renal cell carcinoma (*3 x opinions*)

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

Five oral explanations took place during the meeting, one of which related to an appeal procedure. The COMP noted that four applications for orphan medicinal product designation were withdrawn by sponsors.

The status of orphan designation procedures, as of 23 January 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Intent to file notified	*Applications submitted*	*Applications withdrawn*	*Positive COMP Opinions*	*Negative COMP Opinions*	*Designations granted by Commission*
43	160	33	98	1[1]	78

The EMEA will initiate publication of summarised COMP Opinions on the EMEA web-site following adoption of the respective decisions on orphan designation by the European Commission[2]. The Committee agreed with the proposals for publication put forward by the COMP's Working Group with Interested Parties (COMP-WGIP), which includes representatives of patients' organisations and the pharmaceutical industry. The relevant sponsor will be given the opportunity to delete any information deemed to be commercially confidential from the draft 'public summary of opinion' prior to its publication. The release of the first public summary of opinions is expected in February following receipt of the corresponding Commission Decisions.

Feedback from the CPMP Scientific Advice Review Group (SciARG) meeting held on 14 January 2002 was presented to COMP by its members, Prof. Hans-Georg Eichler and Dr. Rashmi Shah, who were nominated by the Committee in December 2001 to represent COMP at SciARG for protocol assistance procedures.

1 Of the five negative opinions adopted to date, one appeal is ongoing. Three applications have been subsequently withdrawn and one has resulted in a final positive opinion following appeal.

2 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)

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The 1st EMEA Workshop for Health Professionals and Academia on Orphan Medicinal Products was held on 24 January 2002. Seventeen representatives of EU societies of health professionals, learned societies and national organisations funding research met with COMP members and EMEA staff. The Committee's achievements to date were discussed as well as proposals for future collaboration with health professionals and academia. A Press Release from this Workshop (COMP/34/02) will be published on the EMEA web-site.

The next COMP meeting will be a one-day meeting and will take place on 26 February 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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