



20 September 2002

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PRESS RELEASE

27th Meeting of the Committee for Orphan Medicinal Products

The twenty-seventh meeting of the Committee for Orphan Medicinal Products (COMP) took place on 11-12 September 2002.

On 1 August 2002 the Committee adopted a positive opinion via written procedure for the following condition:

- Uremic pruritus

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

- Renal cell carcinoma
- Oedema derived from brain tumours
- Post-transplantation lymphoproliferative disorders

One negative opinion on orphan medicinal product designation was adopted. This opinion will be forwarded to the sponsor, who may submit detailed grounds for appeal within 90 days of receipt of the opinion.

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 The COMP noted that four applications for orphan medicinal product designation were withdrawn by sponsors.

The European Commission granted 9 decisions on orphan designation¹ since the last COMP meeting on 17-18 July 2002, see Annex I. The status of orphan designation procedures, as of 12 September 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Applications withdrawn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>
50	207	58	118	3 ²	114

Further information on designated orphan medicinal products is publicly available in the form of summarised COMP Opinions³, which the Agency routinely publishes following adoption of the respective decisions on orphan designation by the European Commission.

Dr. Rembert Elbers was elected to represent the COMP at the EMEA Scientific Advice Review Group, in replacement of Prof. Hans-Georg Eichler who resigned from the Committee in July 2002.

The next COMP meeting will be held on 8-9 October 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: one has been adopted at this meeting and may be subject to appeal, two 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 July 2002 COMP Meeting**

Active substance	Purified bromelain
Sponsor	Prof. Keith Judkins
Orphan Indication	Treatment of partial deep dermal and full thickness burns
Opinion receipt date	03/07/2002
Date of Commission Decision	30/07/2002

Active substance	Thymalfasin
Sponsor	SciClone Pharmaceuticals Italy S.r.l
Orphan Indication	Treatment of hepatocellular carcinoma
Opinion receipt date	03/07/2002
Date of Commission Decision	30/07/2002

Active substance	Myristoylated-peptidyl-recombinant SCR1-3 of human complement receptor type I
Sponsor	Adprotech Limited
Orphan Indication	Prevention of post transplantation graft dysfunction
Opinion receipt date	03/07/2002
Date of Commission Decision	30/07/2002

Active substance	Oregovomab
Sponsor	Dorian Regulatory Affairs
Orphan Indication	Treatment of ovarian cancer
Opinion receipt date	03/07/2002
Date of Commission Decision	30/07/2002

Active substance	Antisense NF-K β p65 Oligonucleotide
Sponsor	InDex Pharmaceuticals AB
Orphan Indication	Treatment of active ulcerative colitis
Opinion receipt date	03/07/2002
Date of Commission Decision	30/07/2002

Active substance	Myristoylated-peptidyl-recombinant Human CD59
Sponsor	Adprotech Limited
Orphan Indication	Treatment of paroxysmal nocturnal haemoglobinuria
Opinion receipt date	24/07/2002
Date of Commission Decision	11/09/2002

Active substance	Mitotane
Sponsor	Etablissement Pharmaceutique des Hôpitaux de Paris (AGEPS-EPHP)
Orphan Indication	Treatment of adrenal cortical carcinoma
Opinion receipt date	24/07/2002
Date of Commission Decision	11/09/2002

Active substance	Benzoic acid, sodium salt
Sponsor	Ethicare GmbH
Orphan Indication	Treatment of non-ketotic hyperglycinaemia
Opinion receipt date	24/07/2002
Date of Commission Decision	11/09/2002

Active substance	(-)-17-(cyclopropylmethyl)-3,14 β -dihydroxy-4,5 α -epoxy-6 β -[N-methyl-trans-3-(3-furyl) acrylamido] morphinan hydrochloride (intravenous use)
Sponsor	Toray Europe Limited
Orphan Indication	Treatment of uremic pruritus
Opinion receipt date	05/08/2002
Date of Commission Decision	11/09/2002