News from the EMA

Activities of the COMP

Results from the January meeting 2011 of the COMP

The COMP met on 11-12 January 2011 and adopted the following **ten positive opinions on orphan medicinal product designation**:

- **Darinaparsin** for treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/disseminated), Ziopharm Oncology Limited.
- **Glufosfamide** for treatment of pancreatic cancer, Theradex (Europe) Ltd.
- **(S)-{8-fluoro-2-2[4-(3-methoxyphenyl)-1-piperazinyl]-3-[2-methoxy-5-(trifluoromethyl)-phenyl]-3,4-dihydro-4-quinazolinyl}acetic acid** for prevention of cytomegalovirus (CMV) disease in patients with impaired cell mediated immunity deemed at risk, AiCuris GmbH & Co. KG.
- **Human anthrax monoclonal antibody** for treatment of inhalation anthrax disease, Emergent Sales and Marketing Germany GmbH.
- **Ombrabulin** for treatment of soft tissue sarcoma, Sanofi Aventis.
- **R-baclofen** for treatment of fragile X syndrome, Lakeside Regulatory Consulting Services Ltd.
- **Recombinant fusion protein linking human coagulation factor VIIa with human albumin** for treatment of haemophilia A, CSL Behring GmbH.
- **Recombinant thymidine phosphorylase encapsulated in autologous erythrocytes** for treatment of mitochondrial neurogastrointestinal encephalomyopathy (MNGIE) due to thymidine phosphorylase deficiency, St George's University of London.
- **Synthetic double-stranded siRNA oligonucleotide directed against transthyretin mRNA** for treatment of familial amyloid polyneuropathy, Voisin Consulting SARL.
- **Vorinostat** for treatment of multiple myeloma, Merck Sharp & Dohme Limited.

The European Commission granted 15 final orphan designations.

The COMP adopted five lists of questions. Three oral hearings took place and one application for orphan medicinal product designation was withdrawn.

The COMP adopted 1 opinion recommending to the European Commission that the following orphan medicinal product which will be approved within the next weeks be kept in the Community registry of orphan medicinal products since it still fulfilled the designation criteria for an orphan medicinal product:

- **Orphacol (Cholic acid)** for treatment of inborn errors of primary bile acid synthesis, Laboratoires CTRS.

The status of orphan designations/authorisations as of 12 January 2011 is given in the following table:

Year	Applica-tions submitted	Positive COMP Opinions	Final negative COMP Opinions	Designations granted by Commission	Applications withdrawn	EU marketing authorisa-tions since 2000
2011	1	10	0		1	0
2010	174	123	2	128	51	4
2000-2009	1060	727	14	699	249	57
Total 2000-2010	1235	860	16	827	301	61*

*The figure for EU marketing authorisations had to be reduced from 63 to 61 since the orphan product Thelin (Sitaxentan) was withdrawn by Pfizer from the market and Ruconest has no orphan designation.

Next COMP meeting: 8-9 February 2011

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu