News from the EMA

Activities of the COMP

Results from the February meeting 2011 of the COMP

The COMP met on 8-9 February 2011 and adopted the following **13 positive opinions on orphan medicinal product designation**:

- **[N-((2S,3R,3aS,3'R,4a'R,6S,6a'R,6b'S,7aR,12a'S,12b'S,Z)-3,6,11',12b'-tetramethyl-2',3a,3',4,4',4a',5,5',6,6',6a',6b',7,7a,7',8',10',12',12a',12b'-icosahydro-1'*H*,3*H*-spiro[furo[3,2-b]pyridine-2,9'-naphtho[2,1-a]azulene]-3'-yl)methanesulfonamide hydrochloride]** for treatment of chondrosarcoma, Voisin Consulting S.A.R.L.
- **Apomorphine hydrochloride** for treatment of moderate and severe traumatic brain injury; Dr Elkan Raphael Gamzu.
- **Human anthrax monoclonal antibody** for post-exposure prophylaxis of inhalation anthrax disease; Emergent Sales and Marketing Germany GmbH.
- **Lisuride hydrogenmaleate** for treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension; Sinoxa Pharma UG.
- **S-Nitrosoglutathione** for treatment of pre-eclampsia; Salupont Consulting Ltd.
- **9-*cis*-Retinyl acetate** for treatment of Leber's congenital amaurosis; ORS Oxford Ltd.
- **9-*cis*-Retinyl acetate** for treatment of retinitis pigmentosa; ORS Oxford Ltd.
- **Adeno-associated viral vector containing the human *ARSB* gene** for treatment of mucopolysaccharidosis type VI (Maroteux-Lamy syndrome); Fondazione Telethon.
- **Adeno-associated viral vector containing the human *NADH dehydrogenase 4* gene** for treatment of Leber's hereditary optic neuropathy; Institut de la Vision.
- **Allogeneic bone marrow stem cells treated *ex vivo* with 16,16-dimethyl prostaglandin E2** for treatment of acute myeloid leukaemia; Fate Therapeutics LTD.
- **Allogeneic umbilical cord blood cells treated *ex vivo* with 16,16-dimethyl prostaglandin E2** for treatment of acute myeloid leukaemia; Fate Therapeutics LTD.
- **Lenalidomide** for treatment of diffuse large B-cell lymphoma; Celgene Europe Limited.
- **Recombinant fusion protein linking human coagulation factor VIIa with human albumin** for treatment of haemophilia B; CSL Behring GmbH.

The COMP adopted four lists of questions. Three oral hearings took place. Three applications for orphan medicinal product designation were withdrawn.

The COMP adopted one 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:

- **Esbriet (pirfinedone)** for treatment of idiopathic pulmonary fibrosis; Intermune Europe Limited.

The status of orphan designations/authorisations as of 9 February 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	9	23	0		4	0
2010	174	123	2	128	51	4
2000-2009	1060	727	14	699	249	57
Total 2000-2011	1243	873	16	827	304	61

Next COMP meeting: 8-9 March 2011

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu