

News from the EMEA

Activities of the COMP

Results from the June meeting 2010 of the COMP

The COMP met on 1-3 June 2010 and adopted the following **20 positive opinions on orphan medicinal product designation**:

- **11-(2-pyrrolidin-1-yl-ethoxy)-14,19-dioxa-5,7,26-triaza-tetracyclo [19.3.1.12,6.18,12] heptacosa-1(25),2(26),3,5,8,10,12(27),16,21,23-decaene** for treatment of primary myelofibrosis, Voisin Consulting S.A.R.L.
- **11-(2-pyrrolidin-1-yl-ethoxy)-14,19-dioxa-5,7,26-triaza-tetracyclo [19.3.1.12,6.18,12] heptacosa-1(25),2(26),3,5,8,10,12(27),16,21,23-decaene** for treatment of post-polycythaemia vera myelofibrosis, Voisin Consulting S.A.R.L.
- **11-(2-pyrrolidin-1-yl-ethoxy)-14,19-dioxa-5,7,26-triaza-tetracyclo [19.3.1.12,6.18,12] heptacosa-1(25),2(26),3,5,8,10,12(27),16,21,23-decaene** for treatment of post-essential thrombocythaemia myelofibrosis, Voisin Consulting S.A.R.L.
- **Abarelix** for treatment of low-flow priapism, Speciality European Pharma Ltd.
- **Autologous dendritic cells pulsed with recombinant human-fusion protein (mucin 1 - glutathione S transferase) coupled to oxidised polymannose** for treatment of ovarian cancer, Prima Biomed Europe Ltd.
- **Eflornithine** for treatment of familial adenomatous polyposis, Cancer Prevention Pharma Ltd.
- **1-[2-(Benzo[1,2,5]thiadiazol-5-ylamino)-6-(2,6-dichloro-phenyl)-pyrido[2,3-*d*]pyrimidin-7-yl]-3-*tert*-butyl-urea** for treatment of acute myeloid leukaemia, Sanofi Aventis.
- **Adenovirus-associated viral vector serotype 10 carrying the human N-sulfoglycosamine sulphohydrolase and sulfatase modifying factor 1 cDNAs** for treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome), SANFILIPPO Therapeutics SAS.
- **Allogeneic human dermal fibroblasts** for treatment of epidermolysis bullosa, Intercytex Ltd.
- **Allogeneic T cells encoding an exogenous TK gene** for treatment of acute myeloid leukaemia, LTKFarma SAS.
- **Autologous bone marrow-derived mononuclear cell fraction for treatment of thromboangiitis obliterans (Buerger's disease)**, t2cure GmbH.
- **Cyclic pyranopterin monophosphate** for treatment of molybdenum cofactor deficiency type A, Orphatec Pharmaceuticals GmbH.
- **Cysteamine bitartrate (gastroresistant capsule)** for treatment of cystinosis, Raptor Pharmaceuticals Europe BV.
- **Forodesine** for treatment of chronic lymphocytic leukaemia, Mundipharma Research Limited.
- **Glutathione-pegylated liposomal doxorubicine hydrochloride** for treatment of glioma, to-BBB Technologies BV.
- **Heat-killed *Mycobacterium vaccae* (whole cell)** for treatment of tuberculosis, Immodulon Therapeutics Ltd.
- **Nafamostat mesylate** for treatment of cystic fibrosis, Mucokinetica Ltd.
- **Recombinant fusion protein consisting of human coagulation factor VIII attached to the Fc domain of human IgG1** for treatment of haemophilia A, Biogen Idec Limited.
- **Recombinant porcine VIII (B domain deleted)** for treatment of haemophilia A, Ipsen Biopharmaceuticals EU Limited.
- **Vorinostat** for treatment of malignant mesothelioma, Merck Sharp & Dohme Limited.

The European Commission granted no more final orphan designations. For the following product an application for marketing authorisation was made:

- Plenadren (hydrocortisone modified release tablet) from DuoCort Pharma AB, Sweden, for treatment of adrenal insufficiency.

Two applications for orphan medicinal product designation were withdrawn.

The COMP adopted nine lists of questions and one protocol assistance letter. Four oral hearings took place.

The status of orphan designations/authorisations as of 2 June 2010 is given in the following table:

Year	Applications submitted	Positive COMP Opinions	Final negative COMP Opinions	Designations granted by Commission	Applications withdrawn	EU marketing authorisations since 2000
2010	72	57	2	29	26	3
2000-2009	1060	727	14	699	269	57
Total 2000-2010	1132	776	16	728	295	60

Next COMP meeting: 7-8 July 2010

Exclusively reported by Dr. Siegfried Throm, German Association of Research-Based Pharmaceutical Companies (e-mail: s.throm@vfa.de)
for:

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