News from the EMEA

Activities of the COMP

Results from the November meeting 2010 of the COMP

The COMP met on 9-10 November 2010 and adopted the following **12 positive opinions on orphan medicinal product designation**:

- Deferiprone for treatment of sickle cell disease, Apotex Europe B.V.
- Nimorazole for treatment of squamous cell carcinoma of the head and neck in patients undergoing radiotherapy, Azanta A/S.
- Paquinimod for treatment of systemic sclerosis, Active Biotech Research AB.
- Recombinant human histone H1.3 and recombinant human N-bis-met-histone H1.3 for treatment of acute lymphoblastic leukaemia, SymbioTec GmbH.
- Tasimelteon for treatment of non-24-hour sleep-wake disorder in blind people with no light perception, Vanda Pharmaceuticals Limited.
- Autologous tumour-derived immunoglobulin idiotype coupled to keyhole limpet hemocyanin for treatment of mantle cell lymphoma, Analytica International Inc.
- Doxorubicin hydrochloride (in heat-sensitive liposomes) for treatment of hepatocellular carcinoma, Biological Consulting Europe Ltd.
- Human plasmin for treatment of acute peripheral arterial occlusion, Talecris Biotherapeutics GmbH.
- Maytansinoid-conjugated humanized monoclonal antibody against CD56 for treatment of multiple myeloma, ImmunoGen Europe Limited.
- Plitidepsin for treatment of primary myelofibrosis, Pharma Mar SA Sociedad Unipersonal.
- Plitidepsin for treatment of post-polycythaemia vera myelofibrosis, Pharma Mar SA Sociedad Unipersonal.
- Plitidepsin for treatment of post-essential thrombocythaemia myelofibrosis, Pharma Mar SA Sociedad Unipersonal.

The European Commission granted 12 final orphan designations.

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 Four applications for orphan medicinal product designation were withdrawn.

For the following designated orphan product a marketing authorisation was granted:

- Ruconest (Conestat alfa) from Pharming Group for the treatment of hereditary angioedemas on 2 October 2010.

The status of orphan designations/authorisations as of 10 November 2010 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submitted	Positive COMP Opinions	Final negative COMP Opinions	Designations granted by Commission	Applications withdrawn	EU marketing authorisa-tions since 2000
2010	149	117	3	98	46	5
2000-2009	1060	727	14	699	249	58
Total 2000-2010	1209	844	17	797	295	63

Next COMP meeting: 7-8 December 2010

Exclusively reported by Dr. Siegfried Throm, German Association of Research-Based Pharmaceutical Companies (e-mail: s.throm@vfa.de)
for:
Guide to Drug Regulatory Affairs • **www.drugregulatoryaffairs.eu**