

News from the EMA

Activities of the COMP

Results from the April meeting 2011 of the COMP

The COMP met on 6-7 April 2011 and adopted the following **four positive opinions on orphan medicinal product designation**:

- **Adeno-associated viral vector serotype 9 containing the human sulfamidase gene** for treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome), Laboratorios del Dr. Esteve, S.A.
- **Allogeneic T cells encoding an exogenous thymidine kinase gene** for treatment of acute lymphoblastic leukaemia, LTK Farma.
- **Chimeric monoclonal antibody against GD2** for treatment of neuroblastoma, United Therapeutics Europe Ltd.
- **Genetically modified human adenovirus encoding human PH20 hyaluronidase** for treatment of pancreatic cancer, VCN Biosciences S.L.

The COMP adopted three lists of questions. Two oral hearings took place. One application for orphan medicinal product designation was withdrawn.

For the following orphan medicinal products applications for centralised approvals have been made:

- **Eculizumab (Soliris)** for treatment of atypical haemolytic uremic syndrome; Alexion Europe
- **[gly2]-recombinant human glucagon-like peptide (Revestive)** for treatment of short bowel syndrome; Nycomed.

For the orphan medicinal product Celecoxib (Onsenal) authorised for the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis on 17 October 2003 the marketing authorisation was withdrawn by the European Commission on 28 March 2011 due to the decision of the marketing authorisation holder Pfizer to voluntarily withdraw this marketing authorisation; therefore the number of marketing authorisations for orphan products in the following table had to be reduced to 60.

The status of orphan designations/authorisations as of 7 April 2011 is given in the following table:

Year	Applications submitted	Positive COMP Opinions	Final negative COMP Opinions	Designations granted by Commission	Applications withdrawn	EU wide marketing authorisations since 2000
2011	36	33	0	18	10	0
2000-2010	1234	850	16	827	300	60
Total 2000-2011	1270	883	16	845	310	60

Next COMP meeting: 4-5 May 2011

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu