

## News from the EMA

### Activities of the COMP

#### Results from the March meeting 2011 of the COMP

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

- **Human dermal fibroblasts cultured on a bioresorbable polyglactin mesh** for treatment of epidermolysis bullosa; TMC Pharma Services Ltd.
- **Human embryonic stem-cell-derived retinal pigment epithelial cells** for treatment of Stargardt's disease; TMC Pharma Services Ltd.
- **Metronidazole** for treatment of pouchitis; FORMAC Pharmaceuticals N.V.
- **S-farnesylthiosalicylic acid** for treatment of pancreatic cancer; TMC Pharma Services Ltd.
- **Sulfonated monophosphorylated mannose oligosaccharide** for treatment of hepatocellular carcinoma; S-Cubed Limited.
- **Viral vector containing DNA encoding the human SMN protein** for treatment of 5q spinal muscular atrophy; the University of Sheffield.

The COMP adopted one list of questions. Four oral hearings took place. Four applications for orphan medicinal product designation were withdrawn.

For the following orphan medicinal product an application for centralised approval has been made:

- **Romidepsin (TBC)** for treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/disseminated); Celgene Europe.

The status of orphan designations/authorisations as of 9 March 2011 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submitted	Positive COMP Opinions	Final negative COMP Opinions	Designations granted by Commission	Applications withdrawn	EU marketing authorisations since 2000
2011	20	29	0	18	9	0
2000-2010	1234	850	16	827	300	61
Total 2000-2011	1254	879	16	845	309	61

Next COMP meeting: 6-7 April 2011

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for:

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