

## News from the EMA

### Activities of the COMP

#### Results from the April meeting 2012 of the COMP

The COMP met on 11-12 April 2012 and adopted the following **eight positive opinions on orphan medicinal product designation**:

- **Adenovirus-associated vector containing human *Fas-c* gene** for treatment of glioma, Gregory Fryer Associates Ltd.
- **N-hydroxy-4-(3-methyl-2-(S)-phenyl-butyrylamino) benzamide** for treatment of meningioma, Sirius Regulatory Consulting Limited.
- **N-hydroxy-4-(3-methyl-2-(S)-phenyl-butyrylamino) benzamide** for treatment of schwannoma, Sirius Regulatory Consulting Limited.
- **1-(4-{4-amino-7-[1-(2-hydroxyethyl)-1H-pyrazol-4-yl]thieno [3,2-c]pyridin-3-yl}phenyl)-3-(3-fluorophenyl)urea** for treatment of ovarian cancer, Abbott Laboratories.
- **Autologous CD34+ cells transfected with lentiviral vector containing the Wiskott-Aldrich syndrome protein gene** for treatment of Wiskott-Aldrich syndrome, Fondazione Telethon.
- **Autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human *ABCD1* cDNA** for treatment of adrenoleukodystrophy, bluebird bio France.
- **Levoglutamide** for treatment of sickle cell disease, Emmaus Medical Europe Limited.
- **Polyinosine-polycytidylic acid coupled with the polycationic polyethyleneimine** for treatment of pancreatic cancer, Bioncotech Therapeutics S.L.

Since the March meeting 2012 the European Commission granted **eleven final designations as orphan medicinal product**.

The COMP adopted **eight lists of questions** on initial applications.

**Four oral hearings** took place.

For the following orphan medicinal products EU marketing authorisations have been granted:

- Mercaptopurine oral suspension from Nova Laboratories for treatment of acute lymphoblastic leukaemia (ALL) of adults, adolescents and children on 9 March 2012
- Bronchitol (Mannitol) inhalation powder hard capsules from Pharmaxis for treatment of cystic fibrosis in adults as an add on therapy to the best standard of care on 13 April 2012.

The status of orphan designations/authorisations as of 12 April 2012 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submitted	Positive COMP Opinions	Final negative COMP Opinions	Designations granted by Commission	Applications withdrawn	EU marketing authorisations since 2000
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2012	49	44	0	40	11	2
2000-2011	1400	961	18	934	345	61
Total 2000-2012	1449	1005	18	975	356	63

Next COMP meeting: 10-11 May 2012

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for:

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