

News from the EMA

Activities of the COMP

Results from the May meeting 2011 of the COMP

The COMP met on 4-5 May 2011 and adopted the following **ten positive opinions on orphan medicinal product designation**:

- **Fresolimumab** for treatment of focal segmental glomerulosclerosis, Genzyme Europe BV.
- **Pegylated recombinant *Erwinia chrysanthemi* L-asparaginase** for treatment of acute lymphoblastic leukaemia, Alize Pharma II.
- **Peretinoin** for treatment of hepatocellular carcinoma, Kowa Pharmaceutical Europe Co. Ltd.
- **Acadesine** for treatment of multiple myeloma, Advancell - Advanced In Vitro Cell Technologies S.A.
- **Low molecular weight dextran sulfate** for treatment for mobilisation of progenitor cells prior to stem cell transplantation, TikoMed AB.
- **Methyl *O*-4-*O*-[2-[2-[2-[2-[*N*-[(1*R*)-1-[[4-(aminoiminomethyl)phenyl]methyl]-2-oxo-2-(1-piperidinyl)ethyl]-*N*2-[(4-methoxy-2,3,6-trimethylphenyl)sulfonyl]-L- α -asparaginy]-4-aminobutanoyl-*N*6-[5-[(3*aS*,4*S*,6*aR*)-hexahydro-2-oxo-1*H*-thieno[3,4-*d*]imidazol-4-yl]-1-oxopentyl]-L-lysyl]amino]ethoxy]ethoxy]ethyl]-2,3-di-*O*-methyl-6-*O*-sulfo- α -D-glucopyranosyl-(1 \square 4)-*O*-2,3-di-*O*-methyl- β -D-glucopyranuronosyl-(1 \square 4)-*O*-2,3,6-tri-*O*-sulfo- α -D-glucopyranosyl-(1 \square 4)-*O*-2,3-di-*O*-methyl- α -L-idopyranuronosyl-(1 \square 4)-3-*O*-methyl- α -D-glucopyranoside 2,6-bis(hydrogen sulfate) octasodium salt** for prevention of ischaemia/reperfusion injury associated with solid organ transplantation, Endotis Pharma.
- **Mixture of seven synthetic fragments consisting of p21 RAS peptides** for treatment of pancreatic cancer, Targovax AS.
- ***N*-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide dihydrochloride salt** for treatment of post-essential thrombocythaemia myelofibrosis, Cres Pharmaceuticals Limited.
- ***N*-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide dihydrochloride salt** for treatment of post-polycythaemia vera myelofibrosis, Cres Pharmaceuticals Limited.
- ***N*-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide, dihydrochloride salt** for treatment of primary myelofibrosis, Cres Pharmaceuticals Limited.

Three oral hearings took place.

The COMP adopted five lists of questions and three opinions that the following products should be kept in the orphan registry of the European Commission:

- **Carbaglu (Carglumic acid)** for treatment of isovaleric acidaemia, Orphan Europe S.A.R.L.
- **Carbaglu (Carglumic acid)** for treatment of methylmalonic acidaemia, Orphan Europe S.A.R.L.
- **Carbaglu (Carglumic acid)** for treatment of propionic acidaemia, Orphan Europe S.A.R.L.

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

- **Axitinib (INLYTA)** for treatment of renal cell carcinoma; Pfizer.

The status of orphan designations/authorisations as of 5 May 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	37	43	0	18	28	1
2000-2010	1234	850	16	827	300	59
Total 2000-2011	1271	893	16	845	328	60

Next COMP meeting: 6-9 June 2011

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for:

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