EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2013
EMA/CAT/453488/2013
Patient Health Protection

CAT monthly report of application procedures, guidelines and related documents on advanced therapies

July 2013 meeting

The Committee for Advanced Therapies (CAT) held its 51st CAT meeting on 18th – 19th July 2013.

The CAT Monthly Report includes statistical data on CAT scientific recommendations on Advanced Therapy Medicinal Product (ATMP) classification, certifications, initial evaluations, CAT contributions to Scientific Advice and Paediatric Investigation Plans, as well as variations, line extensions, renewals.

Scientific recommendation on advanced therapy product classification

Further to consultation with the European Commission, the CAT finalised six scientific recommendations on the following classification of advanced therapy medicinal product (ATMP).

The following product was classified as a Tissue engineered product, combined ATMP:

- Human dermal fibroblasts cultured on bioresorbable polyglactin mesh intended for the treatment of wounds and ulcers.

The following products were classified as Tissue engineered products:

- Autologous cultured bone-marrow derived mesenchymal stem cells intended for the treatment of chronic myocardial ischemia with left ventricular dysfunction;
- Autologous cultured bone-marrow derived mesenchymal stem cells, pretreated by melatonin, intended for the treatment of chronic myocardial ischemia with left ventricular dysfunction.

The following product was classified as a somatic cell therapy medicinal product:

- Autologous dendritic cells activated with autologous oncolysate intended for the treatment of glioma.

The following products were classified as not an ATMP:

- Concentrate of autologous, uncultured, custom prepared bone marrow aspirate intended for the treatment of avascular necrosis, e.g. of the femur head.

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- Replication-defective Simian adenoviral vector encoding expressing the Non-structural region of hepatitis C virus (HCV) in which a mutation has been introduced. The product is intended for treatment of HCV and HCV-induced hepatocellular carcinoma.

Further information on the ATMP classification procedure can be found at:

European Medicines Agency - ATMP classification

Overview of product-related activities

The Committee discussed ongoing evaluation procedures for ATMPs and other related procedures as summarised in the following tables:

Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Submitted MAAs	3	1	2	3	1	10
Positive draft Opinion	1	0	1[i]	1[i]	2	5 Corresponding to 4 ATMPs
Withdrawals	1	1	0	0	2	4
Ongoing MAAs						2

[i] Same product (Glybera)

Scientific recommendation on advanced therapy classification						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Submitted	22	19	12	17	12	87
Adopted	12	27	12	14	20	87

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Submitted	1	0	0	1	1	3
Adopted	0	1	0	1	0	2

Scientific advice procedures on ATMPs						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Discussed*	25	30	36	31	18	140

* Most scientific advices for ATMPs are discussed by the CAT at 2 time points during the SA procedure

Paediatric Investigation Plans (PIP) for ATMPs						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Discussed*	4	7	6	9	4	31

* PIPs for ATMPs are discussed by the CAT once or twice during the procedure

Upcoming meetings following the July 2013 CAT meeting

The 52nd meeting of the CAT will be held at the Agency on 12th – 13th September 2013.

NOTE:

1. This Monthly Report and other documents can be found on the internet at the following location: European Medicines Agency - Committee meeting reports - CAT: Committee meeting reports
2. Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at: European Medicines Agency - CAT - Committee for Advanced Therapies (CAT)

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