27 June 2013
EMA/CAT/323934/2013
Patient Health Protection

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

June 2013 meeting

The Committee for Advanced Therapies (CAT) held its 50th CAT meeting on 25th – 26th June 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.

Centralised Procedure: Evaluation of Provenge concluded

CAT adopted by majority a positive draft opinion on the marketing authorisation application for Provenge. Provenge (Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF (Sipuleucel-T)) from Dendreon UK Limited is a somatic cell therapy medicinal product indicated for treatment of asymptomatic or minimally symptomatic metastatic (non-visceral) castrate resistant prostate cancer in male adults in whom chemotherapy is not yet clinically indicated.

On basis of the draft CAT opinion, CHMP adopted by majority a positive opinion recommending the granting of a marketing authorisation for Provenge.

More information on the Provenge approval can be found here: EMA Press release

Scientific recommendation on advanced therapy product classification

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

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

- Autologous expanded adipose tissue derived mesenchymal stem cells combined with beta-tricalciumphospate for the treatment of bone defects.

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

European Medicines Agency - ATMP classification

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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[ii]	1[ii]	2	5 Corresponding to 4 ATMPs
Negative draft Opinion	1[i]	0	1[ii]	0	0	2 Corresponding to 0 ATMPs*
Withdrawals	1	1[i]	0	0	2	4
Ongoing MAAs						2

i Same product (Cerepro)
ii Same product (Glybera)
* MAAs subsequently withdrawn or re-examined.

Scientific recommendation on advanced therapy classification						
	2009	**2010**	**2011**	**2012**	**2013**	**Total**
Submitted	22	19	12	17	12	87
Adopted	12	27	12	14	14	81

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	11	137

* 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 June 2013 CAT meeting

The 51st meeting of the CAT will be held at the Agency on 18th – 19st July 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)

Tony Humphreys
Head of Regulatory, Procedural and Committee Support Sector
Tel.: (+44-20) 7418 8583
Fax: (+44-20) 7523 7051
AdvancedTherapies@ema.europa.eu