London, 26 January 2010
EMA/CAT/38910/2010

Committee for Advanced Therapies (CAT)
January 2010 meeting
Monthly Report

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

In addition, the report includes a summary table of the draft opinions issued by the CAT in the current year and a list of adopted guidelines and other public documents.

The Committee for Advanced Therapies (CAT) held its 12th meeting on 14th-15th January 2010.

The CAT celebrated the first year of its operations since its inauguration in January 2009. Highlights of CAT activities in its first year are available at:
http://www.ema.europa.eu/pdfs/human/cat/2568410en.pdf

Centralised procedure

Re-examination procedures started (new applications) under Article 9(2) of Regulation (EC) No. 726/2004

The Agency has been formally requested by Ark Therapeutics Ltd [Applicant for Cerepro [adenovirus-mediated Herpes Simplex Virus-thymidine kinase gene (Adv.HSV-tk)] to re-examine the negative opinion adopted during the meeting of the Committee for Medicinal Products for Human Use (CHMP) on 14th–17th December 2009, recommending that an initial marketing authorisation for this product was refused.

The applicant did not agree with the adopted opinion. The CAT will be responsible for preparation of the draft opinion on this re-examination procedure according to Article 8(1) of Regulation (EC) No. 1394/2007 which will then be transmitted to the CHMP for final adoption.

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
An agency of the European Union

Cerepro is intended for use in conjunction with ganciclovir sodium for the treatment of patients with operable high grade glioma.

Scientific recommendation on advanced therapy classification

Further to the end of public consultation and experience gained with the CAT scientific recommendations on ATMP classifications, the CAT amended the following document:

- Procedural Advice on Scientific Recommendation on Advanced Therapy Classification (EMA/CAT/99623/2009).

The timelines for the ATMP classification procedure have been revised shortening the pre-submission activities to 15 calendar days. Moreover, the CAT recommendation will be adopted at Day 30, pending consultation with European Commission. This will allow, when no comments have been received from the Commission, to conclude the procedure already at Day 40.

This procedural advice document will be available in due course on the EMEA web site at:

http://www.ema.europa.eu/htms/human/advanced_therapies/atmp_classification.htm

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

The following medicine was classified as a gene therapy medicinal product:

- Product consisting of an adenovirus encoding vascular endothelial growth factor C (VEGF-C), intended for the treatment of secondary lymphoedema associated with the treatment of breast cancer.

The following medicines were classified as somatic cell therapy medicinal products:

- Product consisting of allogeneic natural killer cells activated with a lysate from a cell line which is established from a patient with acute monoblastic leukaemia, intended for the treatment of acute myeloid leukaemia.
- Autologous cell therapy product, intended for the treatment of Crohn's disease.

The following medicines were classified as tissue engineered products:

- Product consisting of allogeneic cultured corneal epithelial cell sheet in amniotic membrane scaffold, intended for the treatment of ocular diseases.
- Product consisting of autologous cultured chondrocytes integrated in a scaffold, intended for repair of symptomatic cartilage defects in joints such as the knee and ankle. This product was classified as a combined ATMP.

The following medicine was classified as an ATMP:

- Centrifuged autologous bone marrow containing hematopoietic and mesenchymal stem cells, intended for the treatment of incomplete and complete chronic traumatic spinal cord injury.

Based on the information submitted by the applicant, the CAT could at this point in time not classify this product in one of the ATMP subclasses (in this case somatic cell therapy medicinal products or tissue engineered product).

The CAT delivered its scientific recommendations after consultation with the European Commission within 60 days (active review time) after receipt of the final requests.

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

http://www.ema.europa.eu/htms/human/advanced_therapies/atmp_classification.htm

The CAT adopted another four scientific recommendations pending consultation with European Commission. Information on these scientific recommendations will be included in the February monthly report.

Organisational matters

The Committee was informed about the topic related to:

- Reflection paper on the further involvement of patients and consumers in the Agency's activities (EMA/10723/2009);

General scientific issues

The Committee noted the publication of the following documents:

- Draft 'Question and Answers' document on gene therapy, developed by GTWP;
- Draft 'Concept Paper on the Revision of the Note for Guidance on the Quality, Pre-clinical and Clinical Aspects of Gene Transfer Medicinal Products', developed by GTWP (public consultation ending on 31st March 2010);

These documents are available at:

http://www.ema.europa.eu/htms/human/humanguidelines/multidiscipline.htm#gene

- Draft 'Concept paper on the development of a guideline on the application of the risk-based approach according to Annex I Part IV of Dir. 2001/83/EC applied to ATMPs', developed by CPWP/GTWP (public consultation ending on 31st March 2010).

This document will be published soon at:
http://www.ema.europa.eu/htms/human/humanguidelines/multidiscipline.htm#cellthera py

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 MAA for ATMP			
	2009	**2010**	**Total**
Submitted	3	1	4
Positive draft Opinion	1	0	1
Negative draft Opinion	1	0	1
Withdrawals	1	0	1

Scientific recommendation on advanced therapy classification			
	2009	**2010**	**Total**
Submitted	22	3	25
Adopted	12	6	18

Contribution to scientific advice procedures			
	2009	**2010**	**Total**
Submitted*	17	3	20

* Comments from CAT submitted to SAWP

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

Contribution to Paediatric Investigation Plans (PIP) for ATMPs			
	2009	**2010**	**Total**
Submitted*	3	0	3

* Comments from CAT submitted to PDCO

UPCOMING MEETINGS FOLLOWING THE JANUARY 2010 CAT MEETING

The 13th meeting of the CAT will be held at the EMEA on 11th-12th February 2010.

NOTE:

1. This Monthly Report and other documents can be found on the internet at the following location: http://www.ema.europa.eu
2. Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at: http://www.ema.europa.eu/htms/human/advanced_therapies/intro.htm and http://www.ema.europa.eu/htms/general/contacts/CAT/CAT.html

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