25 March 2010
EMA/CAT/178413/2010

Monthly Report

Committee for Advanced Therapies (CAT)
March 2010 meeting

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 14th meeting on 11th-12th March 2010.

CENTRALISED PROCEDURE

Withdrawals

The European Medicines Agency has been formally notified by Ark Therapeutics Ltd of its decision to withdraw its application for a centralised marketing authorisation for the advanced therapy medicinal product Cerepro (sitimagene ceradenovec). The product was intended for the treatment of patients with high-grade operable glioma, an indication for which it was designated as an orphan medicinal product in February 2002.

Cerepro was the third advanced therapy product to be assessed by the CAT in 2009. Following the conclusions drawn by the CAT, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion for Cerepro in December 2009. The company had requested a re-examination of that opinion which the CAT started on 18 February 2010 and it was stopped due to the withdrawal from the applicant. A separate press release with more information is available at: http://www.ema.europa.eu/humandocs/PDFs/EPAR/cerepro/15185410en.pdf

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

A question-and-answer document is published at:
http://www.ema.europa.eu/pdfs/human/opinion/Cerepro_Q&A_828428en.pdf

Scientific recommendation on advanced therapy classification

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

The following medicine was classified as gene therapy medicinal products:

- Product consisting of a lentiviral vector expressing the truncated form of human tyrosine hydroxylase (TH), human aromatic L-amino-acid decarboxylase (AADC), human GTP-cyclohydrolase 1 (CH1), formulated as a frozen injectable suspension, intended for the treatment of Parkinson's disease.

The following medicine was classified as somatic cell therapy product:

- Product consisting of allogeneic T cells encoding an exogenous TK gene intended as adjunct treatment in haematopoietic stem cell transplantation.

The following medicine was classified as an ATMP:

- Product consisting of allogeneic human dermal fibroblasts, intended for the treatment of Dystrophic epidermolysis bullosa.

Based on the information submitted by the applicant, the CAT concluded that until the mechanism of action can be fully clarified, this product fulfils both the definitions of tissue engineered product and somatic cell therapy product. Therefore, according to Article 2(4) of Regulation (EC) No 1394/2007, this product will be considered a tissue engineered product for the time being.

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

General scientific issues

The Committee adopted the following document:

- Reflection paper on stem cell-based medicinal products (EMA/CAT/CPWP/571134/2009)

This reflection paper covers specific quality, non-clinical and clinical aspects related to stem cells based medicinal products. The document will be published in due course at:

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

The Committee addressed during the meeting topics related to:

Reflection paper on requirements for chondrocyte-containing products for cartilage repair of the knee (EMEA/CAT/CPWP/288934/2009): this document was revised further to comments received during the public consultation and it is expected to be adopted by CAT in the near future.

Organisational matters

The Committee discussed during the meeting topics related to:

- Proposal for a CAT Work programme 2010-2015;
- Cooperation with the European Directorate for the Quality of Medicines (EDQM) and appointment of mutual observes to meetings;
- Preparation of the second informal meeting of the CAT to be held under the Spanish presidency of the European Union.

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	1	2

Scientific recommendation on advanced therapy classification			
	2009	**2010**	**Total**
Submitted	22	4	26
Adopted	12	13	25

Contribution to scientific advice procedures			
	2009	**2010**	**Total**
Submitted*	17	7	24

* 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 MARCH 2010 CAT MEETING

The 15th meeting of the CAT will be held at the EMEA on 15th-16th April 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