European Medicines Agency

London, 27th October 2009
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COMMITTEE FOR ADVANCED THERAPIES (CAT)
OCTOBER 2009 MEETING
MONTHLY REPORT

The CAT Monthly Report includes statistical data for the current year on CAT scientific recommendation on 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 9th meeting on 15th-16th October 2009.

Scientific recommendation on advanced therapy classification

The CAT adopted four scientific recommendations on the following classification of advanced therapy medicinal products (ATMPs).

The following medicine was classified as tissue engineered medicinal product;

- Product consisting of a suspension of expanded autologous skeletal muscle derived cells (myoblasts), intended for regeneration of the external urethral sphincter muscle (rhabdosphincter) in patients suffering from various levels of stress urinary incontinence.

The following medicines were classified as somatic cell therapy medicinal product;

- Product consisting of a combination of lysates of tumour cells (autologous and allogenic) and living cells of a glioblastoma cell line, intended for the treatment of glioblastoma.

- Product consisting of haploidentical donor T lymphocytes genetically modified to express HSV-Tk gene, intended as adjunctive treatment post bone marrow transplantation in high risk acute leukaemia patients.

- Product consisting of autologous tolerogenic dendritic cells derived from peripheral blood monocytes, intended for the treatment of rheumatoid arthritis.

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

Further information on the ATMP classification procedure can be found at:
http://www.emea.europa.eu/htms/human/advanced_therapies/atmp_classification.htm

Certification of quality and non-clinical data for SMEs[1] developing ATMPs

The Committee appointed the CAT-coordinator for the first application on certification of quality data of an ATMP developed by an SME. The certification system has been designed as an incentive for SMEs to develop ATMPs. Although the certification procedure is a stand-alone evaluation procedure,

[1] small and medium-sized enterprises

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it aims at facilitating the evaluation of any future application for clinical trial authorisation or a marketing authorisation application (MAA), provided that these applications are based on the same data.
This procedure is expected to start in November 2009 and the CAT is expected to deliver an opinion in 90 days (active time).
Further information on the ATMP classification procedure can be found at:
http://www.emea.europa.eu/htms/human/advanced_therapies/certification.htm

Organisational matters

The Committee addressed during the meeting topics related to:

- Rules for extension of timelines for clock-stops during the evaluation of MAA for ATMPs;
- Coordination with Paediatric Committee (PDCO) and process for providing input to Paediatric Investigation Plans (PIPs) for ATMPs;
- Outcome of the first informal meeting of the CAT held on the 1-2 October 2009 in Stockholm under the Swedish presidency of the European Union: very positive feedback on the coordination with CHMP, COMP and PDCO;
- Comments on the draft EMEA transparency policy;
- EMEA's roadmap to 2015.

General scientific issues

The Committee discussed:

- ICH Considerations on Oncolytic Viruses (EMEA/CHMP/GTWP/607698/2008): a version following regional public consultations was adopted by ICH Steering Committee in September 2009 and it is available on the ICH website at http://www.ich.org/LOB/media/MEDIA4929.pdf;
- Reflection paper on stem cell containing products, developed by CPWP;
- The Committee held a teleconference call with colleagues at the US-FDA Office of Cellular Tissues and Gene Therapies (OCTGT) on topics of common interest.
- The Committee welcomed Dr. Thomas Montag-Lessing from the Paul Ehrlich Institute, Germany, who gave a lecture on alternative, rapid methods for sterility testing and, additionally, for alternative pyrogen testing of ATMPs.

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	**Total**
Submitted	3	3
Ongoing	1	1
Positive draft Opinion	1	1
Negative draft Opinion	0	0
Withdrawals	1	1

Scientific recommendation on advanced therapy classification		
	2009	**Total**
Submitted	12	12
Ongoing	5	5
Adopted	7	7

Contribution to scientific advice procedures		
	2009	**Total**
Submitted*	12	12

* Comments from CAT submitted to SAWP

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

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

* Comments from CAT submitted to PDCO

UPCOMING MEETINGS FOLLOWING THE OCTOBER 2009 CAT MEETING

- The 10th meeting of the CAT will be held at the EMEA on 12th-13th November 2009.

NOTE:

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

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