



**COMMITTEE FOR ADVANCED THERAPIES (CAT)
JULY 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 seventh meeting on 16th-17th July 2009.

Initial applications for marketing authorisation

Withdrawals

The EMEA has been formally notified by Gendux Molecular Limited of its decision to withdraw its application for a centralised marketing authorisation for **Contusugene Ladenovec Gendux** (contusugene ladenovec). Contusugene Ladenovec Gendux was expected to be used for the treatment of recurrent or refractory squamous cell carcinoma of the head and neck. A separate question-and-answer document with more information on the withdrawal of this application can be found [here](#).

Organisational matters

The Committee addressed during the meeting topics related to:

- Discussion on future steps to establish cooperation with notified bodies for issues related to the assessment of combined advanced therapy medicinal products;
- Clarifications on fee reduction for ATMP marketing authorisation for hospitals and SMEs according to Article 19 of Regulation (EC) No 1394/2007;
- Discussion on the update of procedure for the appointment of Rapporteurs;
- Preparation of the first informal meeting of the CAT to be held under the Swedish presidency of the European Union;
- Draft EMEA transparency policy;
- Preparation of the first hearing with interested parties to CAT (see procedural announcement below)

PROCEDURAL ANNOUNCEMENT

First hearing with interested parties to the CAT

In June 2009 the Committee agreed on the establishment of a list of interested parties to CAT with a view to fostering an active dialogue with industries, developers, academia, patients and clinicians and to exchange scientific views and further develop the regulatory framework for the authorisation of ATMPs.

In order to establish such a list, a call for interest to become an interest party to the CAT was published at: http://www.emea.europa.eu/hums/human/advanced_therapies/interested_parties.htm

As a result of the call, the CAT will invite representatives of the eligible organisation to the first hearing to be held at the EMEA on 11th September 2009.

Organisations are reminded to submit their expression of interest by 31st July 2009.

General scientific issues

The Committee discussed:

- First draft of a reflection paper on requirements for chondrocyte-containing products developed by CPWP;
- Conduct of 'site visits' to be conducted by GLP inspectors in the context of ATMP certification procedures;

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	8	8
Ongoing	7	7
Adopted	1	1

Contribution to scientific advice procedures		
	2009	Total
Submitted*	10	10

* Comments from CAT submitted to SAWP

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

UPCOMING MEETINGS FOLLOWING THE JULY 2009 CAT MEETING

- The 8th meeting of the CAT will be held at the EMEA on 10th-11th September 2009. The 1st informal meeting of the CAT will be held on 1st-2nd October 2009 in Stockholm, Sweden.

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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