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**Press release**

# Committee on Advanced Therapies (CAT) celebrates its first birthday

The European Medicines Agency's Committee on Advanced Therapies (CAT) is celebrating the first year of its operations. One year on from its inauguration in January 2009, the Committee has taken important steps towards implementing and further developing the regulatory framework for advanced therapy medicinal products (ATMPs).

The Committee deals with ATMPs for human use that are based on gene therapy, somatic cell therapy or tissue engineering. They offer groundbreaking new treatment opportunities for diseases and injuries of the human body.

Since the establishment of the CAT, a multidisciplinary committee made up of some of the best available experts in the field, the Agency has received marketing authorisation applications for three ATMPs. For one of these medicines, ChondroCelect, the CAT proposed a positive opinion to the Agency's Committee for Medicinal Products for Human Use (CHMP); for another medicine, Cerepro, the CAT adopted a negative draft opinion. The third medicine, Contusugene ladenovec Gendux, was withdrawn by the applicant prior to the adoption of a final opinion by the CHMP.

The new classification procedure, introduced by the legislation on ATMPs, has received a great deal of interest from companies developing ATMPs. This procedure gives companies the opportunity to check whether the product they are developing can be considered an ATMP and can therefore benefit from the new regulatory pathway for these types of medicine. The procedure is optional, and takes place in advance of applying for a marketing authorisation. The CAT has received a total of 22 requests for classification in 2009, 12 of which have been finalised.

One request for certification of quality and non-clinical data from small and medium-sized enterprises (SMEs) developing ATMPs has been received. This is another new procedure introduced by the legislation on ATMPs and is aimed at providing an incentive to SMEs to conduct necessary studies to further develop their product.'

CAT experts were also busy contributing to scientific advice requests and paediatric investigation plans, reflecting the interest of pharmaceutical companies in the development of ATMPs. In addition to these

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activities the Committee prepared a large number of procedural and scientific guidelines for public consultation, helping applicants in preparing their applications.

2010 will be a busy year for the CAT with the numbers of requests submitted to the Committee expected to increase, as companies developing ATMPs become more familiar with the regulatory pathways available to them.

## Notes

1. More information about the CAT is available: http://www.ema.europa.eu/htms/general/contacts/CAT/CAT.html
2. More information about ATMPs are available on the Agency's website: http://www.ema.europa.eu/htms/human/advanced_therapies/intro.htm
3. A question-and-answer document with more information on the regulation of ATMPs is available: http://www.ema.europa.eu/pdfs/human/cat/Q&A_1432709en.pdf
4. ChondroCelect received a positive opinion by the CHMP in June 2009, and the subsequent marketing authorisation in October 2009. More information is available in the European Public Assessment Report (EPAR): http://www.ema.europa.eu/humandocs/Humans/EPAR/chondrocelect/chondrocelect.htm
5. Cerepro received a negative opinion by the CHMP in December 2009. More information about this opinion is available in a question-and-answer document: http://www.ema.europa.eu/pdfs/human/opinion/Cerepro_Q&A_828428en.pdf
6. The marketing authorisation application for Contusugene ladenovec Gendux was withdrawn in June 2009, prior to the adoption of an opinion by the CHMP. More information about the state of the scientific assessment of the CHMP is available: http://www.ema.europa.eu/humandocs/Humans/EPAR/contusugeneladenovecgendux/contusugeneladenovecgenduxW.htm
7. Regular monthly reports from CAT are available: http://www.ema.europa.eu/pressoffice/cat.htm
8. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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