European Medicines Agency
Press office

London, 30 June 2009
Doc. Ref. EMEA/CAT/405761/2009

PRESS RELEASE
Committee for Advanced Therapies adopts first classification recommendation for an advanced therapy medicinal product

The European Medicines Agency's (EMEA) Committee for Advanced Therapies (CAT) has adopted its first scientific recommendation on classification of an advanced therapy medicinal product.

Advanced therapy medicinal products are medicines 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.

Because advanced therapy medicinal products are very complex and science in this field is developing rapidly, there are often questions whether or not a product can be classified as an advanced therapy medicinal product, often because these products are at the border between medicinal products and other products such as medical devices.

The new legislation on advanced therapy medicinal products (Regulation (EC) No 1394/2007) has introduced a classification procedure that gives the opportunity for companies developing innovative new treatments to check whether the product they are developing can be considered an advanced therapy medicinal product, and can therefore benefit from the regulatory pathway for these types of medicine. The procedure is optional, and takes place in advance of applying for a marketing authorisation.

All requests for classification are assessed and considered by the CAT, the Agency's scientific committee for advanced therapies, which brings together scientific expertise in advanced therapies from across the European Union.

The first medicinal product to be classified by the CAT as an advanced therapy medicinal product is a somatic cell therapy medicinal product intended for the treatment of chronic venous leg ulcers. It is composed of substantially modified human allogeneic fibroblasts and keratinocytes administered in conjunction with fibrin as structural component.

The Committee delivered its scientific recommendation, after consultation with the European Commission and within the 60-day deadline, on 19 June 2009.

-- ENDS --

Notes:

1. Further information on the procedure for ATMP classification is available here: http://www.emea.europa.eu/htms/human/advanced_therapies/atmp_classification.htm
2. A summary of opinion for the classification is available here: http://www.emea.europa.eu/htms/human/advanced_therapies/recommendations.htm
3. More information on the work of the EMEA in the area of advanced therapies is available here: http://www.emea.europa.eu/htms/human/advanced_therapies/intro.htm
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu