



European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends first marketing authorisation for an advanced therapy medicinal product

The European Medicines Agency has recommended the first marketing authorisation for an advanced therapy medicinal product, following a positive opinion from the Agency's Committee for Advanced Therapies (CAT) and the Committee for Medicinal Products for Human Use (CHMP).

ChondroCelect, from TiGenix NV, is a cell-based medicine that is used to repair defects in the cartilage of the femoral condyle (the end of the thighbone) in the knee. It consists of chondrocytes (cartilage-forming cells) that are taken from a healthy region of the patient's cartilage, grown outside the body, and then re-implanted during surgery.

ChondroCelect is the first product to benefit from the new legal and regulatory framework for advanced therapy medicinal products (Regulation (EC) No 1394/2007). This framework is designed to ensure the free movement of advanced medicines within the European Union (EU), to facilitate their access to the EU market, and to foster the competitiveness of European pharmaceutical companies in the field, while guaranteeing the highest level of health protection for patients.

The CAT, a multidisciplinary committee bringing together some of the best available experts in gene therapy, somatic cell therapy and tissue engineering, assessed the scientific data provided to support the marketing authorisation application for ChondroCelect. In line with the procedure set out by the Regulation on advanced therapy medicinal products, the CAT prepared a draft opinion, which was forwarded to the CHMP. On the basis of this opinion, the CHMP adopted its recommendation that ChondroCelect be granted marketing authorisation on 25 June 2009.

As part of the application, the CAT and the CHMP have required the company to submit a risk management plan with a series of measures, including further studies to ensure that the medicine's efficacy and safety are followed up in a robust manner once it is on the market.

The scientific recommendation will now be forwarded to the European Commission for the adoption of a legally binding marketing authorisation decision.

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Notes:

1. A summary of opinion for ChondroCelect with the full indication is available here: http://www.emea.europa.eu/pdfs/human/opinion/ChondroCelect_38336609en.pdf
2. The European Public Assessment Report (EPAR) for ChondroCelect with detailed information on the scientific assessment of the medicine will be published once the European Commission has adopted a marketing authorisation decision.
3. More information about the Agency's work in the field of advanced therapy medicinal products can be found here: http://www.emea.europa.eu/htms/human/advanced_therapies/intro.htm
4. A question-and-answer document on the regulation of advanced therapy medicinal products is available here: http://www.emea.europa.eu/pdfs/human/cat/Q&A_1432709en.pdf
5. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.emea.europa.eu

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