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Press Office

Press release

European Medicines Agency recommends approval of combined advanced-therapy product

MACI is intended for the repair of cartilage defects; it is the first combined tissue-engineered medicine authorised across the EU

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisation for MACI (matrix-induced autologous chondrocyte implantation), an advanced-therapy medicinal product (ATMP), for the repair of symptomatic, full-thickness cartilage defects of the knee of 3-20 cm^2 in skeletally mature adult patients.

Cartilage has a poor ability to repair itself when injured. Injuries to the smooth cartilage surface of the knee joint increase rubbing and friction in the knee and predispose the knee to further cartilage wear and erosion, which can eventually lead to osteoarthritis if untreated.

A number of surgical procedures aiming to repair cartilage have been developed to treat patients with articular cartilage defect of the knee. One of them is autologous chondrocyte implantation (ACI), a therapy based on tissue engineering which was first described in 1994. It uses chondrocytes, or cartilage cells, which are derived from the patient's own cartilage, grown outside the patient's body and then transplanted into the patient's lesions after several weeks. The benefit of ACI over other restoration techniques is that larger lesions can be treated.

MACI is a third-generation ACI product. Contrary to the previous generations, MACI uses a scaffold formed of porcine collagen on which autologous chondrocytes are seeded. At implantation, the scaffold is trimmed to the size and shape of the cartilage defect. The cells/collagen structure is held in place in the lesion with fibrin glue.

Being an ATMP, MACI was evaluated by the Agency's Committee for Advanced Therapies (CAT), which gave a positive opinion for the approval of MACI at its April 2013 meeting. The CHMP has now confirmed the CAT's opinion. Since the introduction of the European Union (EU) regulation on advanced therapies in 2007, the centralised procedure has become compulsory for ATMPs, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. MACI was already authorised in certain EU countries before the regulation came into force, but in order to comply with the European legislation on ATMPs it had to be evaluated through the centralised procedure. MACI has now become the first combined tissue-engineering product recommended for approval across the EU.

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The CHMP opinion on MACI will now be sent to the European Commission for adoption of a marketing-authorisation decision.

The applicant for MACI is Genzyme.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Prior to the regulation on advanced therapies and during the ATMP transitional period, MACI was available in the following European countries in accordance with national legislations: Austria, Belgium, Denmark, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain and the United Kingdom. As such, MACI has been available in some European markets since 1998.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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