EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2013
EMA/54023/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

MACI

Matrix applied characterised autologous cultured chondrocytes

On 25 April 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for MACI, an implant intended for the repair of symptomatic, full-thickness cartilage defects of the knee in adult patients. The applicant for this medicinal product is Genzyme Europe B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

MACI is an advanced therapy medicinal product (ATMP). It is to be available as an implantation matrix consisting of characterised autologous cultured chondrocytes on a collagen membrane (500,000 to 1,000,000 cells per cm^2), to be trimmed and implanted into the cartilage defect of the damaged knee. The product's ATC code is M09AX02.

MACI has been investigated in a randomised, open-label parallel-group trial in which MACI was compared with microfracture surgery in 144 adult patients with knee cartilage defects (grade III and IV of the Modified Outerbridge Scale) ranging between 3 and 20 cm^2 in surface area. At week 104, MACI was superior to microfracture in improving pain and knee function, with significantly more MACI-treated patients responding to treatment than microfracture patients (63 of 72 [87.50%] vs. 49 of 72 [68.06%], P= 0.016). Response to treatment was defined as an improvement of the Knee Injury and Osteoarthritis Outcome Score (KOOS) of at least 10 points for both pain and knee function.

With regard to safety, MACI has been causally linked to symptomatic graft hypertrophy and graft delamination. Patients may also have peri-operative complications related to surgical intervention. A pharmacovigilance plan for MACI will be implemented as part of the marketing authorisation.

The CHMP, on the basis of quality, safety and efficacy data submitted, considered the benefit-to-risk balance for MACI to be positive and therefore recommended the granting of the marketing authorisation. The full recommended indication is: "the repair of symptomatic, full-thickness cartilage defects of the knee (grade III and IV of the Modified Outerbridge Scale) of 3-20 cm^2 in skeletally mature adult patients.".

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.