



**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**  
**SUMMARY OF POSITIVE OPINION\***  
**for**  
**CHONDROCELECT**

Common name: *characterised viable autologous cartilage-forming cells expanded ex vivo expressing specific marker proteins*

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP), in agreement with the draft positive opinion adopted by the Committee for Advanced Therapies (CAT), adopted a positive opinion,\*\* recommending to grant a marketing authorisation for the medicinal product ChondroCelect, 10000 cells/ $\mu$ l, implantation suspension intended for treatment of repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society [ICRS] grade III or IV) in adults. Concomitant asymptomatic cartilage lesions (ICRS grade I or II) might be present. The applicant for this medicinal product is *TIGENIX NV*. ChondroCelect is an advanced therapy medicinal product, and in particular it is a tissue engineered product.

The active substance of ChondroCelect is characterised viable autologous cartilage-forming cells expanded ex vivo expressing specific marker proteins, a cell-based medicinal product. The chondrocytes are taken from a small biopsy of healthy cartilage from the patient, grown outside the body, and then re-implanted during surgery with the aim to repair cartilage defects by the formation of durable cartilage.

The benefits of the autologous chondrocyte implantation (ACI) technique using ChondroCelect are the repair of single symptomatic cartilage defects of the femoral condyle and the restoration of functional cartilage with the aim to reduce the risk of developing knee osteoarthritis on the long term.

The most common side effects are arthralgia, cartilage hypertrophy, joint crepitation and joint swelling.

A risk management system was required as part of marketing authorisation for ChondroCelect. The risk management system includes educational programme, controlled distribution system, and conduct of further studies to obtain more information about safety and efficacy of the product.

The approved indication is: 'Repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society [ICRS] grade III or IV) in adults. Concomitant asymptomatic cartilage lesions (ICRS grade I or II) might be present. Demonstration of efficacy is based on a randomised controlled trial evaluating the efficacy of ChondroCelect in patients with lesions between 1-5cm<sup>2</sup>'. ChondroCelect must be administered by an appropriately qualified surgeon and is restricted to hospital use only.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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\* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

\*\* Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for ChondroCelect and therefore recommends the granting of the marketing authorisation.