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Regenerative cartilage therapy targets EU launch

co.don AG, a fully integrated biopharmaceutical company, is a leading specialist in autologous cell cultivation (i.e., using the patient's own cells) for the regenerative treatment of articular cartilage defects and spinal disc defects. Left untreated, cartilage defects can often result in damage requiring joint replacement surgery. "With our regenerative therapy options our aim is to postpone joint replacement, or ideally to avoid it altogether, and so to maintain patients' quality of life and everyday mobility," said Dirk Hessel, CEO of co.don AG.

Based in Teltow and Berlin, co.don AG currently markets its regenerative therapy methods in Germany, where uptake is increasing among orthopedic surgeons, trauma surgeons and neurosurgeons. The company's lead product, co.don chondrosphere, has been used for more than 10 years in over 150 clinics to treat more than 10,000 patients. The statutory health insurance companies in Germany have reimbursed treatment costs for knee and hip joints since 2007 and for vertebral joints since 2008.

Autologous chondrocyte implant

co.don chondrosphere is an autologous chondrocyte (cartilage cell) implant that is cultured outside the body via a patented pharmaceutical process taking around 5–7 weeks. A dedicated clean-room production plant with proprietary Integrated Isolator Technology has been developed for the manufacturing process and quality control. A small piece of undamaged cartilage from the patient's joint and the patient's serum are used to engineer cell aggregates (spheroids) consisting of matrix-associated chondrocytes *in vitro*. The cells form the matrix without the need for scaffolds, and the process does not involve antibiotics, fungistatic agents, growth factors or genetic modification. The risks of rejection, inflammation and infection are therefore very low.

A minimally invasive arthroscopic procedure is carried out to insert the cultured chondrospheres into the damaged cartilage, where they adhere naturally and form new cartilage tissue that combines with the existing healthy cartilage. Normal functionality may return to the joint after rehabilitation.

co.don chondrosphere has already been approved for use in Germany by the Paul-Ehrlich-Institut in accordance with Section 4b of the German Medicinal Products Act. Phase 2 and 3 clinical trials are ongoing in preparation for submission to the European Medicines Agency, and EU marketing authorization is anticipated by the end of 2017.

The aim of the phase 3 trial is to compare the safety and effectiveness of co.don chondrosphere with that of microfracture procedures for the treatment of cartilage defects in knee joints. In a phase 2 trial, outcomes were measured using the KOOS (knee injury and osteoarthritis outcome score), which reflects the patient's assessment of pain and mobility, and the MOCART (magnetic resonance observation of cartilage repair tissue) score, which measures clinical success. 3-year follow-up of phase 2 postoperative data indicated a substantial improvement in patient well-being.

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