

CO.DON AG: Results of the Phase III clinical trial

Berlin / Teltow / Leipzig, 9.11.20 – The five-year follow-up confirms the two-year final analysis of the multicentric, prospective, randomised, controlled Phase III trial co.wisi (cod16 HS13) with autologous chondrocyte implants for the effectiveness and safety of the method.

Compared with the results of the alternative therapy, better clinical results were observed continuously in the areas of “Activities in daily life” (24-60 months after treatment), “Sport and leisure” (36-60 months after treatment) and “Quality of life in relation to the affected knee” (60 months after treatment). The primary aim of the study – to demonstrate that autologous chondrocyte implants are not inferior to the comparative therapy of microfracturing – was achieved by means of clinical scores and imaging (MRT).

A total of 102 patients with defined locations and sizes of cartilage defect in the knee joint were randomised in 11 centres. The present evaluation is based on data from what is known as the KOOS score, a clinical scoring system that provides a statistical framework for patients’ own estimates of any restrictions in their lives due to knee cartilage defects. Medical imaging technology (MRT) also showed an improvement in patients who had been treated with autologous chondrocyte implants.

Dr Christian Kaps, Vice President Scientific Affairs: “We are very pleased that the primary aim of the trial was confirmed after the five-year follow-up period, because it further strengthens the clinical evidence for our EU-authorized therapy product. I would like to take this opportunity to thank all the participants in the study centres who have collected the data so carefully over this long period and are a vital part of this success.”

CO.DON AG develops, produces and distributes autologous cell therapies for the minimally invasive repair of cartilage defects. The product being marketed is a cell therapy product for the minimally invasive treatment of cartilage damage in the knee joint that uses only the patient's own cartilage cells ("autologous chondrocytes"). CO.DON's method is currently used in over 200 clinics in Germany and more than 15,000 patients have already been treated. In July 2017 CO.DON received EU-wide marketing authorisation for its product, with approval for Switzerland following in March 2019. At its site in Leipzig CO.DON has built one of the largest plants for the industrial-scale production and contract manufacturing of human cells. The shares in CO.DON AG are listed on the Frankfurt Stock Exchange (ISIN: DE000A1K0227). Executive Board: Tilmann Bur.

Further information is available from www.codon.de.

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