PRESS RELEASE

CO.DON AG: 5-year results confirm safety and effectiveness of matrix-associated autologous chondrocyte transplantation with spheroids

Teltow / Leipzig, 25 January 2022 – The Orthopaedic Journal of Sports Medicine, published by the American Orthopaedic Society for Sports Medicine, AOSSM, one of the world's leading associations for sports medicine, has published the 5-year results of the Phase II clinical trial with the advanced pharmaceutical product from CO.DON AG, which holds central marketing authorisation for the EU.

The Phase II clinical trial examined the effectiveness and safety of various dosages of the matrix-associated autologous chondrocyte transplantation with spheroids (Spherox) in medium to large defects (4 to 10 cm^2) in various locations of the knee joint. The publication reported on 73 male and female patients aged from 18 to 50, who were treated with the autologous chondrocyte spheroid implants (Spherox) and divided at random into three dosage groups: 24 were in the low-dose group (3 - 7 spheroids/cm^2 defect), 25 medium-dose group (10 - 30 spheroids/cm^2 defect) and 24 in the high-dose group (40 - 70 spheroids/cm^2 defect). The trial results clearly show a positive effectiveness and safety profile for the autologous chondrocyte transplantation with spheroids for defect sizes of up to 10 cm^2, and the continued effectiveness of all the tested dosages for 5 years, until the end of the trial period. Evidence of effectiveness is based on the analysis of various scores assigned by the patients, the clinicians and imaging methods. For the patients it was essentially the KOOS total score and the KOOS subscores (KOOS - Knee Injury and Osteoarthritis Outcome Score), supported by the International Knee Documentation Committee score and the modified Lysholm score. Compared with the starting values, the results obtained during the follow-up period show a clear benefit from the treatment on the basis of clinically relevant findings. In addition, the MOCART score derived from MRI images (MRI - magnetic resonance imaging) shows a structural repair of the cartilage defects after treatment over the entire five-year follow-up period.

One important new aspect of this publication, compared with earlier reports, is that the different locations and sizes of the treated cartilage defects were also compared. All the localisations and defect sizes show a comparable clinical improvement. No differences were found in the clinical results between the different dosage groups.

The study is available to the public at https://journals.sagepub.com/doi/10.1177/23259671211053380.

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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 17,000 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: DE000A3E5C08). Executive Board: Tilmann Bur, Dr Achim Simons.

Further information is available from *www.codon.de.*

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