

CO.DON AG: European Commission grants indefinite renewal of EU-wide marketing authorization for the pharmaceutical product Spherox

Teltow / Leipzig, 05 Mai 2022 – The European Commission grants the indefinite renewal of the EU-wide marketing authorization for the pharmaceutical product Spherox without additional obligations. In addition, Spherox will be removed from the list of medicinal products with additional monitoring measures, in which every medicinal product of the category ATMP (advanced therapy medicinal products) is included after approval.

By granting the marketing authorization, the European Commission is following the recommendation made in February by the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA).

The Committee for Human Medicinal Products is a scientific committee of the EMA that assesses the quality, efficacy and safety of medicines for which pharmaceutical companies have applied for marketing authorization.

Tilmann Bur, CO.DON AG's CEO: "This important decision secures the long-term use of our drug for the regenerative treatment of cartilage damage of the knee joint throughout the EU and is an essential basis for further business development and expansion in the addressed markets."

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 AG received central EU marketing authorisation for this product, followed by the marketing authorization for Switzerland in March 2019. At the Leipzig site, CO.DON has built one of the largest facilities for the production of human cells on an industrial scale for in-house and contract manufacturing. The shares in CO.DON AG are listed on the Frankfurt Stock Exchange (ISIN: DE000A3E5C08). Executive Board: Tilmann Bur.

Further information is available from www.codon.de.

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