

Press release

12 January 2015

co.don AG reaches key milestone for EU-wide approval

Successful patient recruitment for Phase III clinical trial

Teltow. co.don AG has been able to complete the patient recruitment phase of the Phase III clinical trials successfully, in preparation for EU-wide marketing authorisation.

The aim of the clinical study is to compare the effectiveness and safety of matrix-associated autologous chondrocyte implants (ACI-M) with co.don condrosphere® against microfracture treatment and to present these data to the European Medicines Agency in London.

In December 2013 co.don AG received national approval for the pharmaceutical product co.don condrosphere® from the Paul Ehrlich Institute, the German medicines agency.

Dr Andreas Baltrusch, CEO of the company: "EU-wide marketing authorisation for the 28 countries currently in the EU will open up a completely new market positioning and a massive increase in the potential market." The Executive Board estimates the addressable market volume following approval at approximately € 1.2 billion p.a..

A total of twelve leading clinics (trial centres) throughout Germany and in Poland were involved in the trials, including four university clinics. The trial is a pivotal, multi-centric, prospective and randomised open-label trial in accordance with the internationally accepted standard Good Clinical Practice (GCP) (Trial no. cod 16 HS 13). Results are expected and will be published in the near future.

co.don condrosphere® is used for the regenerative treatment of articular cartilage defects, principally in the knee, but increasingly also in the hip and ankle joints. The three-dimensional chondrocyte implants are cultivated by co.don® AG in special laboratories exclusively from the patient's own cells. More than 6,000 patients have been treated with co.don® AG's patented procedure to date.



About co.don® AG:

The biopharmaceutical company is one of the leading specialists worldwide in cell cultivation for the regenerative treatment of articular cartilage defects and spinal disc defects. In many cases the use of the company's patented pharmaceutical product can avert the need for joint and spinal disc replacement surgery. Orthopaedic, accident and neuro-surgeons are increasingly applying these regenerative therapy methods. The shares in co.don® AG are listed on the Frankfurt Stock Exchange (ISIN: DE000A1K0227). The company's Executive Board is made up of Dr Andreas Baltrusch (CEO) and Ms Vilma Methner (COO, CSO).

Further information is available from: <u>www.ihre-zellzuechter.de</u> oder <u>www.codon.de</u>

More information about the clinical trials: https://clinicaltrials.gov/

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