PRESS RELEASE

CO.DON AG: GMP inspection of the higher federal authority and the Saxony state directorate at the Leipzig site successfully completed

Teltow / Leipzig, 07 June 2021 – Last week, the inspection of the new production plant at the Leipzig site was carried out by the higher federal authority, the Paul Ehrlich Institute (PEI), and the Saxony state authority. The content of the inspection was the implementation of the GMP guidelines imposed by the health authorities. GMP - "Good Manufacturing Practice" is an internationally binding standard to ensure the highest safety and quality requirements in the pharmaceutical sector. In addition to ensuring consistent product quality, compliance with this standard also ensures fulfilment of the binding requirements stipulated by the health authorities for marketing.

The result of the successfully completed two-day inspection revealed neither critical nor serious deficiencies, but only a few other observations, which, however, have no influence on the timing of the start of production.

At the end of April 2021, the European Medicines Agency (EMA) had granted CO.DON AG approval for its new manufacturing facility in Leipzig.

Thus, after an intensive implementation and validation phase lasting almost one and a half years, all key regulatory milestones have been achieved on time and on budget, enabling the company to start routine production for Spherox at the Leipzig site in the third quarter of the current financial year and thus supply the European markets.

Tilmann Bur, CO.DON AG board member: "We can be justifiably proud of the positive inspection result. We have made great efforts and worked hard to achieve this goal. On behalf of the Executive Board, I would like to thank the entire CO.DON team at both sites, because it was the joint performance across all sites that made this excellent inspection result possible."

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 16,000 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: DE000A1K0227). Executive Board: Tilmann Bur, Dr Achim Simons.

Further information is available from www.codon.de.

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