DOUBLE BOND Pharmaceutical

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Clinical trial results indicate that Inofer markedly and significantly improved iron uptake, iron saturation and iron stores in patients with heart failure and iron deficiency

Double Bond Pharmaceutical International AB presents the results from a study evaluating Inofer – a medical product against iron deficiency – in patients with heart failure and iron deficiency without having anemia. Current knowledge recommends iron treatment to be given intravenously, as patients with heart failure have so far been regarded to have an insufficient uptake of oral iron treatment. In this pilot study, patients who received oral Inofer (iron succinate) had a markedly and significantly improved iron uptake, with improved iron saturation and iron stores.

Iron deficiency occurs in about 15% globally and in about 50% in patients with heart failure. The presence of iron deficiency leads to poor energy and impaired cardiac activity that may require hospitalization regardless of whether anemia is present or not. In many respects, the symptoms of iron deficiency are rather like those occurring in heart failure. Iron deficiency has a central role in oxygen supply and utilization of oxygen in the tissue. In addition, iron is essential for blood formation but also important for the energy process in the tissues such as cellular respiration, oxidative phosphorylation, nitric oxide generation and for the energy process in the citric acid cycle. This means that cells with high energy requirements, such as skeletal muscle and heart muscle, are particularly susceptible to iron deficiency.
About 250,000 people in Sweden have symptomatic heart failure and half of them may have iron deficiency at the same time. This combination of diagnoses leads to increased severity of symptoms and often to hospitalizations. Treatment with common iron tablets does not seem to work due to insufficient intestinal uptake or some other unknown factor. In order to treat iron deficiency in patients with heart failure, iron-containing drugs must currently be injected intravenously in a healthcare facility, which is resource-intensive.

In a 3-months study, Inofer (oral iron succinate) was evaluated for patients with heart failure and iron deficiency without having anemia. As earlier announced, a clinical trial of Inofer was approved by the Swedish Medical Products Agency and the National Ethical Committee June 20, 2018, and the study started on October 4 when the first patient received treatment with Inofer tablets. The study was conducted at the research unit, Skellefteå Hospital and was led by the consultant in cardiology Kurt Boman, senior professor at Umeå University and Med. Dr Mona Olofsson. In this study, 20 patients with heart failure and iron deficiency without having anemia were recruited to receive oral Inofer twice daily under a minimum of 3 months. The primary objective of this pilot study was to investigate iron uptake saturation and iron stores in these patients. A second aim was to explore iron uptake also after 6 weeks.

Double Bond Pharmaceutical International AB now presents results from the above cited clinical trial with Inofer. The data are now analysed, and results show that Inofer given twice daily markedly and significantly improved iron saturation and iron stores in the studied patients. Primary and secondary objectives of the clinical trials have thus been achieved. Inofer was well tolerated, the patient group that received Inofer did experienced some well-known and mild side effects of oral iron therapy. Overall, the results from the pilot study indicate that Inofer given twice daily can be used for treatment of the iron deficiency in heart failure patients without having anemia. This is a significant benefit for the patients and for the health care, as treatment can be performed at home and without discomfort of intravenous injection. This is the first study showing that oral iron therapy by using iron succinate, in contrast to other oral iron preparations, can restore iron stores and saturation. These results motivate further clinical evaluation of the product. Results of the clinical trial will be presented by authors on the closest relevant scientific conference.

Drugsson AB, which is the subsidiary of Double Bond Pharmaceutical (DBP), has the rights to distribute Inofer in Sweden, Norway, Denmark and Finland.

More about clinical trials of Inofer: https://news.cision.com/dbp/r/clinical-trial-of-inofer--last-patient-out,c2812674

More about Drugsson AB: www.drugsson.com

This information is information that Double Bond Pharmaceutical International AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 28 of November 2019.

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Information on Double Bond Pharmaceutical International AB

DBP is a pharmaceutical company with the primary focus on development of therapies against cancer based on the company's own developed drug delivery technology BeloGal®. The company was

granted Orphan Drug Designation status by European Medicines Agency (EMA) in June 2015 for its first product, SA-033, for treatment of hepatoblastoma. Double Bond Pharmaceutical acquired rights to Temodex, a drug registered in Belarus for treatment of brain tumours, in October 2015, and was granted Orphan Drug Designation status by EMA for in July 2016 for this formulation of temozolomide for the treatment of glioma. The formulation is now being further developed for registration in EU and globally and has a working name SI-053 in DBP pipeline.