

The recruitment of patients has started for Lund University type-2 diabetes clinical study together with Carbiotix AXOS medical food

Carbiotix (publ) ("Carbiotix" or "Company") today announces that the previously communicated study from the 3rd of April 2020 regarding the use of CarbiAXOS as a medical food to co-treat type-2 diabetes with metformin has started to recruit patients. The 16-week randomized, controlled, parallel intervention study involving 100 patients will be carried out by Lund University and Skåne University Hospital between Q2 and Q4 2022. The results from the study will provide key clinical data for regulatory approvals in the US and Europe and evidence for a potential commercial launch of a metformin medical food co-intervention product targeting type-2 diabetes patients in accordance with Carbiotix product road-map.

There are currently well over 400 million people globally diagnosed with type-2 diabetes, with over 120 million people who have been prescribed metformin as a therapeutic. This makes metformin one of the most prescribed drugs for type-2 diabetes in the world. Unfortunately, the negative gastrointestinal side effects of using metformin, which include diarrhea and flatulence, have resulted in low adherence to the therapeutic, resulting in greater complications and higher overall costs. The current study funded by Vinnova through their SweLife and Medtech4Health call aims to significantly improve the clinical care of type-2 diabetes patients by demonstrating the efficacy of Carbiotix CarbiAXOS medical food as an effective co-intervention with metformin that can address gut dysbiosis by improving overall gut health.

(1)(2)

The study will be a four-month parallel randomised controlled trial of 100 people aged 50-80. During four months, participants will consume daily 10-40g of CarbiAXOS medical food or maltodextrin (control). Clinical data and fecal samples will be collected at the start, at 2 and 4 months. The patients will also fill in a quality-of-life questionnaire at these time points. In between scheduled visits, there will be telephone contact with all the patients to check their health and well-being. Blood samples will be analysed for haematological parameters, glucose, insulin, blood lipids, vitamin B12 and markers of low-grade inflammation. Intestinal microbial community analysis will be performed by high-throughput next-generation sequencing of 16S rRNA amplicons and quantitative PCR.

Kristofer Cook, CEO of Carbiotix, comments

"After almost a two-year delay due to Covid-19, I am extremely pleased by this news and look forward to working closely with Lund University to ensure a successful outcome. This study falls perfectly within our plans and road map to launch a medical food co-intervention and eventually complementary therapeutic co-treatment product targeting type-2 diabetes. Since the global market for medical foods exceeds 15 Billion Euros, and the market for type-2 diabetes therapeutics is valued at over 45 Billion Euros, targeting a type-2 diabetes medical food makes perfect sense, especially given the role gut health plays in patient adherence to metformin." (3)(4)

Forward-looking statements

This communication contains forward-looking statements, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their nature, as is research and development work in the biotechnology segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios as described in this press release.



Press Release
24 March 2022

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Carbiotix AB (CRBX) (www.carbiotix.com) is an award-winning biotechnology company pioneering microbiome healthcare through a portfolio of microbiome modulators covering prebiotic ingredients, medical foods, and therapeutics, along with cost-effective gut health testing services.