

## Carbiotix reports promising results from CarbiAXOS metformin study

**Carbiotix (publ) ("Carbiotix" or the "Company") announces today promising preliminary results from the 4-month randomised controlled CarbiAXOS intervention study involving type-2 diabetes patients on metformin. The preliminary results reveal that 20% of patients in the intervention cohort responded positively to a prebiotic containing CarbiAXOS, experiencing an average improvement of 15% in HbA1c (blood glucose) levels and an upregulation of Short Chain Fatty Acid (SCFA) levels. These results are in line with our ambition, which was to replicate and substantiate the results from the 2018/2019 intervention study by Carbiotix, where participants also showed an upregulation of SCFAs after consuming a prebiotic for 3 months. Although the results are indicative at this stage, Carbiotix has submitted a 2.5 MEUR EU (EIC) application for funding a more extensive 400-person intervention study in 2024/2025 to investigate further. Carbiotix expects to present the final results from this study by the end of Q4 2023.**

### **Erik Deaner, CEO of Carbiotix, comments:**

"I am delighted to present these encouraging results from the CarbiAXOS metformin study. Our preliminary results indicate that we are on track to achieve our ambition, which was to replicate and substantiate the results from our previous study in 2018/2019. In the current study, we were able to see a significant improvement of HbA1c (blood glucose) levels in 20% of the intervention cohort and a correlation with an upregulation with SCFAs as well as more desirable bacteria strains. Now we look forward to presenting the final results later this year, where we will present the efficacy of CarbiAXOS in more detail."

### **About the study**

The study, a 4-month parallel randomised controlled trial, involved patients aged between 50-80. Participants consumed daily 10g of a prebiotic containing CarbiAXOS or maltodextrin (control). Clinical data and faecal samples were collected at the start, at 2 and 4 months. The patients filled in a quality-of-life questionnaire at these time points. In between scheduled visits, there was telephone contact with all the patients to check their health and well-being. Blood samples were analysed for haematological parameters, glucose, insulin, blood lipids, vitamin B12 and markers of low-grade inflammation. Intestinal microbial community analysis was performed by high-throughput next generation sequencing (NGS) of 16S rRNA and quantitative PCR.

Of the 79 patients screened for the study, 66 patients started, and 54 patients completed the study with an even distribution between the intervention and control cohorts. Initially, 100 patients were expected to start the study. However, due to limited interest and time pressure that followed Covid, the study commenced with 66 starters. Our aim with this study was to replicate and substantiate the results from our previous study conducted in 2018/2019. Preliminary results from the study showed that 20% of patients who used a prebiotic containing CarbiAXOS saw positive effects, improving their HbA1c (blood glucose) levels by 15%. These patients also experienced an upregulation of Short Chain Fatty Acid (SCFA) levels. The findings align with an earlier study conducted by Carbiotix in 2018/2019. In this study, involving 75 patients with high blood sugar, 20% of subjects also experienced an upregulation of SCFAs after 3 months on a prebiotic.

Although indicative at this stage, the study suggests that patients can be triaged into two general groups: early positive responders, and a second group consisting of negative responders, delayed positive responders and no responders. By sorting patients correctly using our LinkGut service in combination with blood samples, one can address issues with patient fatigue, unnecessary medical & insurance costs, and confidence in the adjuvant approach among medical professionals.

### **Going forward**

Given the size of the global type-2 diabetes patient population, this adjuvant approach has the potential of impacting the lives of numerous people and thus needs to be further investigated. To address this need, Carbiotix has submitted a funding application to the EU (EIC) on the 19<sup>th</sup> of October for 2.5M

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Euros to carry out a 400-patient follow-up study of CarbiAXOS with metformin. This follow-up study will focus on the 80% who did not respond positively in the short term by extending the study duration and testing both a customised CarbiAXOS prebiotic and synbiotic (prebiotic & probiotic), the latter of which will be developed in collaboration with a top 10 global probiotics company which was previously communicated<sup>1</sup>. Confirmation of funding and the study plan will be made in Q1 2024 unless delayed due to a resubmission of the application.<sup>(1)</sup>

This adjuvant approach also has the potential to improve the GI related side effects and pharmacokinetics of therapeutics in many patient populations, as dysbiosis is common to many chronic and metabolic diseases. This is further supported by improvements to cholesterol levels among intervention patients in the current study, suggesting that CarbiAXOS also has the potential to be used as an adjuvant with therapeutics targeting cardiovascular disease.

### **About type-2 diabetes**

Type-2 diabetes currently affects over 400 million people globally, with the therapeutics market valued at over 45 Billion EUR. Metformin, prescribed to over 120 million people, stands as one of the most prescribed drugs for type-2 diabetes. Unfortunately, its Gastro Intestinal (GI) side effects, such as diarrhea and flatulence, often hinder patient adherence, which can result in greater complications and higher overall healthcare costs<sup>234</sup>. The completed study funded by Vinnova through their SweLife and Medtech4Health, in collaboration with Lund University and Skåne University Hospital, aimed to significantly improve the clinical care of type-2 diabetes patients. It focused on demonstrating the efficacy of CarbiAXOS in conjunction with metformin to improve gut dysbiosis and overall gut health.<sup>(2)(3)(4)</sup>.

### **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.

*This is information that Carbiotix AB is obliged to make public according to the EU Market Abuse Regulation (MAR). The information was made publicly available by the Company's contact person set out below on 1 November 2023.*

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**Carbiotix AB** (CRBX) ([www.carbiotix.com](http://www.carbiotix.com)) is an award-winning biotechnology company pioneering microbiome healthcare through a portfolio of prebiotic modulators and diagnostic testing services.