

Carbiotix completes metformin study and provides EU funding update

Carbiotix (publ) ("Carbiotix" or the "Company") announces today that the metformin study has now been completed after aligning with the project group. While the Polymerase Chain Reaction (PCR) results communicated on November 1st, 2023, indicated 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, the Next Generation Sequencing (NGS) results after bioinformatic analysis were inconclusive due to the study's limited time frame. Overall, these results satisfied the objective of the study, which was to demonstrate that in a 4-month period a blend of prebiotics containing a first generation CarbiAXOS ingredient could provide an early indication of gut health benefits, as measured by the growth of bacteria that promote the production of Short Chain Fatty Acids (SCFAs) and improvements in HbA1c levels. Carbiotix also announces today that its focus on EU funding will shift from applying for funding for further clinical studies to funding projects related to the NutraCycle service, in line with the Company's strategic re-focus.

Metformin study

The metformin 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, and after 2 and 4 months. The patients filled in a quality-of-life questionnaire at these time points. In between scheduled visits, telephone contact was maintained 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 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. One aim of this study was to replicate and substantiate the results from a previous study conducted in 2018/2019. While the PCR results showed that 20% of patients who used a prebiotic containing CarbiAXOS saw positive effects, improving their HbA1c levels by 15% and experiencing an upregulation of SCFA levels, the NGS results after bioinformatic analysis were inconclusive due to the study's limited time frame. The findings align with the earlier study conducted by Carbiotix in 2018/2019, where 20 % of the 75 patients with high blood sugar also experienced an upregulation of SCFAs as measured by PCR after 3 months on a prebiotic.

EU funding

Carbiotix's previous focus regarding EU funding was to apply for financing for additional clinical studies, but this is now shifting towards applying for funding for projects related to the NutraCycle service. To carry out a follow-up study, as previously communicated, the Company will submit one final new application in accordance with its contractual obligation. The first two applications were rejected, which the Company expected, as only 3% of applications were approved in this particular call. Carbiotix will submit its final application through its partner in the coming months.

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Erik Deaner, CEO of Carbiotix, comments:

“We were generally satisfied with the study results with regards to providing an early indication of gut health benefits, especially since the intervention used in the study was a blend of prebiotics containing a first generation CarbiAXOS prebiotic ingredient from three years ago not at all reflecting the efficacy of the current generation of Carbersol. This study however should only be considered preliminary since we were unable to generate conclusive data from the NGS analysis.

The study also highlighted the short comings of microbiome testing and nutraceutical modulation in disease populations over short-duration studies and the need for many months of longitudinal data and modulation to see patterns and a significant effect. This was always a risk given our past experience in previous studies, which was the original motivation of developing the low-cost LinkGut service allowing for multiple samples over a long period of time.

Regarding the EU funding, our application to carry out a follow up study communicated earlier, we will pursue one last resubmission as contractually obligated through our partner in the coming months after receiving two rejections. The outcomes of the first two submissions were expected as only 3% of applications have been successful for this particular call. Our focus going forward will instead be on submitting applications connected to the NutraCycle service which has a higher likelihood of being approved given that the service is more unique, competitive, has stronger partners, higher potential impact, and less challenging to pursue given the natural polarity between the therapeutics and nutraceutical industries. We will revisit adjuvant funding opportunities once we have a well-established base of NutraCycle customers producing Carbersol ingredients for high-end prebiotic and symbiotic applications.”

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.

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Carbiotix AB (CRBX) (www.carbiotix.com) is an award-winning biotechnology company pioneering the onsite upcycling of plant-based side-streams. Carbiotix mission is to improve the health of people by increasing the consumption of prebiotics and other active ingredients from upcycled side-streams. Carbiotix offers one core service today called NutraCycle, an on-site upcycling and fortification service allowing food & beverage, ingredient, and feed producers to turn plant-based products into healthier, more profitable, and sustainable products.