

Carbiotix receives GRAS regulatory approval for CarbiAXOS

Carbiotix (publ) ("Carbiotix" or the "Company") announces today that the Company has received GRAS Self Affirmation (SA) regulatory approval for its first CarbiAXOS prebiotic ingredient based on corn bran. This is a major milestone for the Company and now opens the door to ramp-up commercial sales activities of CarbiAXOS in the US market through direct sales and the building up of distributors, following up on current potential customer and research inquiries, as well as other partner leads. This approval also facilitates the acceleration of GRAS SA approvals for other CarbiAXOS ingredients and paves the way for Novel Foods approval in Europe.

Erik Deaner, CEO of Carbiotix, comments:

"I am extremely excited to announce that we have received our first GRAS SA approval for a Corn Bran based CarbiAXOS ingredient. As we are targeting high end prebiotic applications, where the prebiotic effect is the value driver, the complex nature of CarbiAXOS should position it as an extremely attractive backbone ingredient for nutraceutical and cosmetic prebiotic and synbiotic consumer products. We will also maintain our focus on positioning CarbiAXOS as a high-end prebiotic adjuvant for therapeutics, where we will continue to explore opportunities in the areas of Type-2 Diabetes, weight management, cardiovascular disease, and gastrointestinal related diseases. The complex nature and consequent high prebiotic effect CarbiAXOS will also allow us to better leverage our LinkGut diagnostic service. This synergy enables us to validate the efficacy of our prebiotic ingredients more effectively and provide value for our customers. The approval process has taken longer than first anticipated due to a decision to use a third-party enzyme, a delay in the regulatory approval of this enzyme, a decision to develop a second-generation process to make the enzyme an optional component, and the consequent upgrading of our production site in Bjuv. These steps, however, have resulted in a more competitive process and an improved prebiotic product.

This milestone also paves the way for accelerating the GRAS SA approval for other CarbiAXOS ingredients in the US leveraging the same dossier. Furthermore, it will also accelerate Novel Foods approval in Europe, eventual No Objection status in the US, and compliance with regulations in other key markets around the world. We will now also ramp up commercial activities through direct sales and the building up of distributors in select markets, following up on current potential customer and research inquiries, and well as other partner leads. Marketing activities will also ramp up and we now aggressively position CarbiAXOS as an ingredient that all competitive prebiotic consumer product companies should evaluate as being part of their prebiotic mix.

I would like to send a special thanks to the entire Carbiotix team for their dedication and hard work over the past three years. The prebiotics market has reached a key inflection point with regards to consumer recognition of their importance and the role they will play in developing the probiotics industry in the formulation of synbiotics. This should translate into double digit industry growth over the next decade and positions Carbiotix in a great position to capture this growth."

Prebiotics market

The global market for prebiotics is estimated to be worth over 6 Billion Euros, with Europe being the largest market and Asia the fastest growing market. The global market for nutraceutical prebiotic ingredients, which Carbiotix is targeting, is estimated to be 1 Billion Euros, with the US market estimated to be worth in excess of 300M Euros. [\(1\)](#)

Press Release
16 January 2024

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 16 January 2024.

For further information:

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