



Fractyl Health Announces New Pooled Analysis From Revita® Clinical Studies Demonstrating Initial Weight Loss and Sustained Weight Maintenance Without Weight Regain Through at Least One Year Post-Revita Procedure

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A single Revita endoscopic procedure resulted in 3.4% mean total body weight loss by Week 4 in patients with advanced T2D that was maintained to 4% mean total body weight loss through Week 48 in the absence of any active ongoing diet or lifestyle intervention

Results provide evidence that a single Revita procedure has the potential to help durably prevent weight regain after weight loss achieved through other means

Based on these data, Fractyl Health plans to submit an investigational Device Exemption for a potentially pivotal clinical study to regulatory authorities in the first half of 2024 to study Revita in weight maintenance after the discontinuation of GLP-1 based drugs

LEXINGTON, Mass., Dec. 14, 2023 (GLOBE NEWSWIRE) — Fractyl Health, a metabolic therapeutics company focused on pioneering new approaches for the treatment of type 2 diabetes (T2D) and obesity, presented new weight maintenance data from a pooled analysis of subjects enrolled in Revita clinical studies across the EU and US. The analysis interrogated patterns of weight change (a prespecified secondary endpoint in all included trials) in patients with inadequately controlled T2D on multiple glucose-lowering agents who have been followed through at least 48 weeks post-treatment with Revita.

157 participants were included in the analysis, with an average baseline weight of 93 kg and a mean BMI of 31. Patients were on average 57 years of age with a T2D duration of 10 years and baseline HgA1c of 8.3%. 118 of these subjects underwent Revita, and another 39 underwent a sham endoscopy procedure. Following the procedure, all subjects in both Revita and sham cohorts were prescribed a short post-procedure graduated diet and continued glucose lowering agents without further active lifestyle intervention.

Subjects who underwent the Revita procedure demonstrated a 3.4%(± standard deviation of 2.9; n=100) reduction in total body weight by week 4, which increased to a 4.0% (± 5.0% standard deviation; n=94)reduction in total body weight by Week 48. These results were statistically significant, with p-values of <0.0001 for change from baseline at Week 4 and Week 48. Conversely, those who underwent the sham procedure showed a 2.1% (± 1.9% standard deviation; n=38)weight reduction at Week 4, but unlike in the Revita cohort, the initial weight loss in the sham arm was not sustained between Week 4 and Week 24, at which time sham subjects crossed over to Revita treatment.

“We now have potent GLP-1-based drugs that can induce weight loss while a patient is on therapy, but many patients would like to discontinue therapy without suffering from immediate weight regain,” said John Amatruda, MD, former Senior Vice President and franchise Head of Diabetes and Obesity at Merck & Co, and scientific advisor to Fractyl Health. “We therefore need interventions to help maintain weight loss in patients who cannot remain on chronic pharmacotherapy for the duration of their lives. These Revita results demonstrating sustained weight loss maintenance represent a promising potential approach to addressing this massive problem.”

The new data presented here are consistent with prior publications of weight maintenance through two years of follow up after a single Revita treatment from the Revita-1 study.¹

“These new results in over 100 human subjects from our controlled clinical studies build on earlier data demonstrating that a single treatment with Revita can enable sustained weight maintenance in people who are at risk of weight gain,” said Harith Rajagopalan, MD PhD, Fractyl Health Co-Founder and CEO. “The data raise the urgent question of whether Revita may help maintain weight in individuals who wish to discontinue GLP-1-based drugs, and we are eager to address this question in our ongoing clinical program.”

About Fractyl Health

Fractyl Health is a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including T2D and obesity. Despite advances in treatment over the last 50 years, T2D and obesity continue to be rapidly growing drivers of morbidity and mortality in the 21st century. Fractyl Health’s goal is to develop durable disease-modifying therapies that are designed to provide long-term maintenance of metabolic health without requiring lifetime treatment by targeting the organ-level root causes of T2D and obesity. Fractyl Health is based in Lexington, MA. For more information, visit www.fractyl.com or www.twitter.com/FractylHealth.

About Revita

Fractyl Health’s lead product candidate, Revita, is based on the company’s insights surrounding the potential role of the gut in obesity and T2D. Revita is designed to remodel the duodenal lining via hydrothermal ablation (i.e., duodenal mucosal resurfacing) to edit abnormal intestinal nutrient sensing and signaling mechanisms that are a potential root cause of metabolic disease. Revita has received aCE mark in Europe and, in January 2022, received reimbursement authorization through NUB in Germany. In the United States, Revita is for investigational use only under US law. A pivotal study of Revita in patients with inadequately controlled T2D despite multiple medicines and insulin, called Revitalize-1, is currently enrolling in the United States and Europe.

[1] van Baar et al “Durable Metabolic Improvement 2 Years After Duodenal Mucosal Resurfacing (DMR) in Patients with Type 2 Diabetes (REVITA-1 Study),” Diabetes Research and Clinical Practice vol 184, February 2022.

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