Fractyl Health Announces Positive Initial Clinical Results Demonstrating Weight Maintenance Following GLP-1 Discontinuation and Revita Procedure in First Patient of the REVEAL-1 Cohort

Jan 13, 2025

Company also announces strong enrollment progress for REMAIN-1 weight maintenance pivotal study

High demand from patients and physicians indicates significant interest in REMAIN-1 study and GLP-1 discontinuation; mid-point analysis on-track and anticipated in Q2 2025

BURLINGTON, Mass., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the "Company"), a metabolic therapeutics company focused on pioneering pattern breaking approaches for the treatment of obesity and type 2 diabetes (T2D), today announces promising initial clinical results from the first patient in the REVEAL-1 open-label cohort of the REMAIN-1 study one-month post GLP-1 drug discontinuation and Revita procedure. These results align with trends observed in prior Revita clinical studies and the Company's German Real-World Registry. Additionally, the Company is reporting significant progress in its REMAIN-1 pivotal study, which is evaluating weight maintenance after discontinuation of GLP-1 drugs. The high demand to participate in the study underscores the growing need among patients and physicians for an effective alternative to GLP-1 therapy.

"These initial results from REVEAL-1 build upon extensive prior research in Revita clinical studies," said Dr. Shailendra Singh, Director of Bariatric Endoscopy at West Virginia University. "In obesity, people who stop taking GLP-1 drugs are at high risk of rapid weight and metabolic rebound, jeopardizing the hard-won clinical benefits achieved with the drugs initially. For this reason, the unmet need in obesity has shifted from achieving weight loss to achieving sustained maintenance of a lower weight. When combined with other progress in the field, today's initial data provides real hope that a scalable solution for weight maintenance, meaning the maintenance of clinically meaningful weight loss even in the absence of ongoing medical therapy, is possible."

"The overwhelmingly positive feedback we have received from patients and physicians for the REMAIN-1 study emphasizes the urgent, unmet need for innovative solutions in weight maintenance. Initial observations from REVEAL-1 suggest that GLP-1 drug discontinuation, followed by Revita treatment, was well tolerated without excess appetite, while also enabling maintenance of weight loss. These findings validate our commitment to addressing the most pressing challenges in obesity and metabolic disease management," said Harith Rajagopalan, Co-Founder and CEO of Fractyl Health. "As interest from key stakeholders continues to grow, we are increasingly confident in the transformative potential of our platform. Revita is more than a technological advancement – it represents a redefinition of how we approach metabolic disease treatment and raises the prospect of durably modifying the obesity epidemic without the need for burdensome drug therapy. For the millions of people struggling with obesity, this marks an exciting step forward in providing accessible and enduring solutions."

REVEAL-1 – Initial Data Demonstrate Weight Maintenance Following GLP-1 Discontinuation and Revita Procedure at One-Month Post Procedure

Preliminary REVEAL-1 data show the first study patient achieved a 15% total body weight loss with tirzepatide over a period of 7 months. After discontinuing the drug per study protocol, the patient underwent the Revita procedure and maintained their weight loss one-month post-procedure. By contrast, prior studies of tirzepatide withdrawal show an average 3% weight regain within four weeks of GLP-1 discontinuation.[1] These results suggest the Revita procedure may be a promising treatment option for long-term weight maintenance. Data from the REVEAL-1 cohort, delayed slightly due to holiday related scheduling issues, will be presented in Q1 2025.

REMAIN-1 –Mid-Point Data Analysis On-Track and Expected in Q2 2025

Amid the urgent need for solutions to sustain weight loss after discontinuing GLP-1 drugs, recruitment of the REMAIN-1 study has generated significant interest, with over 100 patients enrolled across the first 8 clinical study sites in less than 4 months since first site activation, reflecting strong engagement from both patients and physicians.

This recruitment momentum for Revita underscores the significant interest in addressing the challenges of post-GLP-1 weight maintenance. A mid-point data analysis from the study is on-track and expected in Q2 2025.

About Fractyl Health

Fractyl Health is a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including obesity and T2D. Despite advances in treatment over the last 50 years, obesity and T2D continue to be rapidly growing drivers of morbidity and mortality in the 21st century. Fractyl Health's goal is to transform metabolic disease treatment from chronic symptomatic management to durable disease-modifying therapies that target the organ-level root causes of disease.

Fractyl Health is based in Burlington, MA. For more information, visit www.fractyl.com.

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 reverse damage to intestinal nutrient sensing and signaling mechanisms caused by chronic high-fat and high-sugar diets that are a root cause of metabolic disease. Revita has received a CE mark in Europe and, in January 2022, received reimbursement authorization through NUB in Germany for the treatment of T2D. In the United States, Revita is for investigational use only under US law. Revita has US FDA Breakthrough Device designation in weight maintenance for people with obesity who discontinue GLP-1 based drugs, as well as in insulin-treated T2D. A pivotal study of Revita in patients with obesity after discontinuation of GLP-1 based drugs, called REMAIN-1, was initiated in the third quarter 2024. A pivotal study of Revita in patients with T2D who are inadequately controlled on any glucose lowering agent, REVITALIZE-1, is underway in the United States and Europe.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the promise and potential impact of our preclinical or clinical trial data, the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, the content, information used for, timing or results of any IND-enabling studies, IND applications or Clinical Trial Applications, the potential launch or commercialization of any of our product candidates or products, the potential treatment population or benefits for any of our product candidates or products, and our strategic and product development objectives and goals, including with respect to enabling long-term control over obesity and type 2 diabetes without the burden of chronic therapies, and the timing of any of the foregoing. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the Company's limited operating history; the incurrence of significant net losses and the fact that the Company expects to continue to incur significant net losses for the foreseeable future; the Company's need for substantial additional financing; the Company's ability to continue as a going concern; the restrictive and financial covenants in the Company's credit agreement; the lengthy and unpredictable regulatory approval process for the Company's product candidates; uncertainty regarding its clinical studies; the fact that the Company's product candidates may cause serious adverse events or undesirable side effects or have other properties that may cause it to suspend or discontinue clinical studies, delay or prevent regulatory development, prevent their regulatory approval, limit the commercial profile, or result in significant negative consequences; the Company's reliance on third parties to conduct certain aspects of the Company's preclinical studies and clinical studies; the regulatory approval process of the FDA, comparable foreign regulatory authorities and lengthy, time-consuming and inherently unpredictable, and even if we complete the necessary clinical studies, we cannot predict when, or if, we will obtain regulatory approval or certification for any of our product candidates, and any such regulatory approval or certification may be for a more narrow indication than we seek; and the potential launch or commercialization of any of Company's product candidates or products and our strategic and product development objectives and goals, and the other factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 12, 2024 and in our other filings with the SEC. These forward-looking statements are based on management's current estimates and expectations. While the Company may elect to update such forward-looking statements at some point in the future, the Company disclaims any obligation to do so, even if subsequent events cause its views to change.

Contacts
Media Contact
Jessica Cotrone, Head of Corporate Communications
jcotrone@fractyl.com, 978.760.5622

Investor Contact
Brian Luque, Head of Investor Relations and Corporate Development
IR@fractyl.com, 951.206.1200

---

[1] Aronne LJ, Sattar N, Horn DB, et al. Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity. Jama 2023;331(1):38–48.