Fractyl Health Reports Positive Early Data Showing Revita® Has Potential to Prevent Weight Regain After GLP-1 Discontinuation

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New REVEAL-1 study results show early signs of weight maintenance after GLP-1 discontinuation

REMAIN-1 pivotal study now more than 50% enrolled; midpoint data analysis anticipated in Q3 2025

BURLINGTON, Mass., April 01, 2025 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) ("the Company"), a metabolic therapeutics company focused on pattern breaking approaches that treat root causes of obesity and type 2 diabetes (T2D), today announced positive early data from the open-label REVEAL-1 cohort of its ongoing REMAIN-1 pivotal study. The results suggest that Revita, the Company's novel approach to targeting gut dysfunction, a root cause of obesity, may help prevent weight regain after patients stop GLP-1 drugs—addressing a growing unmet need in obesity treatment. As global GLP-1 adoption accelerates—and discontinuation rates climb—the need for scalable, non-pharmacologic solutions to sustain weight loss presents a significant, underleveraged commercial opportunity.

Early Data Shows Evidence of Weight Maintenance and Reinforces Revita's Favorable Safety and Tolerability Profile

To-date, 15 patients have been treated in the REVEAL-1 cohort, with 1-month data available for the first 7 patients. These patients have been treated with a GLP-1 drug for up to 3 years before discontinuing medication, undergoing a single Revita procedure, and continuing a structured diet and lifestyle program.

Key findings include:

- No safety or tolerability concerns reported in the 15 patients treated to date, consistent with Revita's favorable safety profile from pooled data across more than 100 treated patients.
- At 1-month post-procedure, 7 patients experienced an average weight regain of just 1.2%, compared to the ~3% typically observed at this time period after GLP-1 discontinuation based on prior clinical studies[1].

"Stopping GLP-1 drugs often feels like a cliff for many patients—they fear regaining the weight they worked so hard to lose," said Mohammad Othman, M.D., William T. Butler Endowed Chair and Professor of Medicine at Baylor College of Medicine. "These early data suggest that a well-tolerated, one-time procedure like Revita could offer patients a new, sustainable path forward without the need for ongoing medical treatment."

"The real challenge in obesity care isn't just helping patients lose weight—it's helping them keep it off," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and CEO of Fractyl Health. "For the first time, we're seeing early clinical data suggesting that Revita may offer a durable metabolic reset to help patients maintain their weight loss after GLP-1 therapy. I'm encouraged by these initial findings, and if they are confirmed in larger studies with longer follow-up, Revita has the potential to become a transformative option for patients at risk of weight regain."

Upcoming Data Milestones
Fractyl anticipates several key milestones for Revita in 2025:

- Additional REVEAL-1 patient follow-up data expected in Q2 2025
- Full REMAIN-1 pivotal study enrollment anticipated in summer 2025
- Midpoint analysis of REMAIN-1 pivotal study expected in Q3 2025

Revita is currently being studied under an open Investigational Device Exemption (IDE) in the U.S. and holds FDA Breakthrough Device designation for weight maintenance in patients discontinuing GLP-1 therapy. The Company aims to position Revita as the first approved intervention specifically for post-GLP-1 weight maintenance.

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. 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. In the U.S., Revita is for investigational use only under U.S. law. Revita has U.S. FDA Breakthrough Device designation in weight maintenance for people with obesity who discontinue GLP-1 based drugs. 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 of 2024 and is currently enrolling.

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, communications with regulators, 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 Company's reliance on third parties for the manufacture of sub-assembly components for Revita, and its ongoing 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 3, 2025 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.

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[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.