Fractyl Health Presented New Analysis from Pooled Data of Revita® Clinical Studies Demonstrating Durable Weight Loss Maintenance for One Year at ObesityWeek® 2024

Single Revita procedure led to sustained, clinically meaningful weight loss in majority of patients with Type 2 Diabetes

REMAIN-1 weight maintenance pivotal study on-track to report mid-point data analysis in Q2 2025

Company will report weight maintenance data after discontinuation of GLP-1 drugs in open-label REVEAL-1 cohort in Q4 2024

BURLINGTON, Mass., November 4, 2024 (GLOBE NEWSWIRE) – Fractyl Health, Inc. (Nasdaq: GUTS) (the "Company"), a metabolic therapeutics company focused on pioneering new approaches that treat root causes of obesity and Type 2 Diabetes (T2D), presented the poster, "Duodenal Mucosal Resurfacing (DMR) Durably Maintains Weight Loss in Metabolic Disease," on Sunday, November 3, 2024, during The Obesity Society's Annual Meeting at ObesityWeek 2024 in San Antonio, Texas.

The poster showcased compelling results of a pooled data analysis from five clinical studies, n=118, where participants were followed for 48 weeks post-Revita procedure. At baseline, prior to treatment, participants had longstanding, inadequately controlled T2D. Most had obesity (62%) or were overweight (34%), with a mean BMI at baseline of 31.1 kg/m2. The relatively low baseline BMI, coupled with inadequately controlled T2D, as well as a population of advanced age, all represent demographic factors that indicate a hard-to-treat patient population for obesity. The results still show that 90% of patients lost weight at one-month post-procedure; 84% of these patients maintained their body weight loss through one year of follow-up, even in the absence of any prescribed diet or lifestyle intervention. The early body weight loss after a single Revita procedure, with a durable weight loss plateau reached after week four, represents a differentiated therapeutic time-action profile compared to current obesity drugs, which require prolonged dose titration and ongoing persistence to achieve weight loss. The procedure was well tolerated without any device or serious adverse events observed.

Revita is an outpatient endoscopic procedure that involves resurfacing the mucosal lining of the duodenum, the first part of the small intestine just after the stomach, which is responsible for breaking down food into absorbable nutrients. Revita targets the duodenal lining, which can become thickened by high-fat and high-sugar diets, making it hard for the body to maintain a healthy metabolism and blood glucose levels. By resurfacing and reversing the pathology of the duodenal lining, if approved by the U.S. Food and Drug Administration (FDA), Revita has the potential to become the first disease-modifying therapy that targets a root cause of obesity and T2D.

"We are moving towards a new frontier in the treatment of obesity. While current GLP-1 drugs have helped patients lose weight, the critical unmet need is now how to durably keep this weight off," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. "These data show that a single Revita procedure results in durable weight maintenance and holds the potential to advance the treatment of obesity by providing an off-ramp from GLP-1 therapies. We believe these data were valuable in the FDA Breakthrough Device designation granted to Revita for weight maintenance for people with obesity who discontinue GLP-1 drugs. This designation is only given to those technologies that address high unmet needs and may improve the lives of people with life-threatening or debilitating conditions. This validates the critical unmet need that Revita may be able to fill. We look forward to reporting data from our pivotal trial in weight maintenance in the fourth quarter of this year."

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 or https://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 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. A pivotal study of Revita in patients with T2D who are inadequately controlled on any glucose lowering agent, REVITALIZE-1, is currently enrolling in the United States and Europe. A pivotal study of Revita in patients with obesity after discontinuation of GLP-1 based drugs, called REMAIN-1, is underway with anticipated data readouts from the open-label study in weight maintenance in the fourth quarter of 2024 and an anticipated mid-point randomized analysis of the REMAIN-1 pivotal study in Q2 2025.

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 trials or readouts, the content, information used for, timing or results of any IND-enabling studies or IND applications, the potential launch or commercialization of any of our product candidates or products, the sufficiency of our cash, cash equivalents, and investments to fund our operating activities for any specific period of time, 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. 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 August 14, 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.

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