Fractyl Health Announces Clinical Results from German Real-World Registry Showing Meaningful and Sustained Weight Loss for at Least One Year After a Single Revita® Endoscopic Procedure

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Median weight decreased from 111 kilograms (245 pounds) to 97 kilograms (214 pounds), representing nearly 13% total body weight loss at 12 months in a hard-to-treat patient population living with obesity and Type 2 Diabetes

Median HbA1c also decreased substantially from 9.6% to 7.2% at 12 months in these individuals who remained poorly controlled despite multiple glucose-lowering medications and advanced T2D

Real-world results demonstrate potential for Revita to meaningfully sustain weight loss and lower blood sugar for at least one-year post-treatment

Additional registry data from a larger number of patients will be presented at a scientific congress later this year

BURLINGTON, Mass., Aug. 08, 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), today announced new weight maintenance and blood sugar clinical results from the Company's German Real-World Registry for the first 11 patients who have completed at least 12 months of post-Revita procedure follow-up.

"These are compelling initial results for one of the hardest to treat patient populations – older people living with obesity and uncontrolled T2D. These one year post-procedure data confirm and build upon what we have seen from Revita in earlier clinical studies. What I am most impressed with is the magnitude of continued, sustained weight loss and blood sugar improvement these patients experienced despite multiple prior efforts via other means. This contrasts with the diminishing effectiveness of medicines over time due to non-adherence and other real-world issues," said Professor Stephan Martin, Director of the West German Diabetes Center of Excellence, Düsseldorf, Germany. "From what I have seen, I believe patients with obesity and T2D who are looking for an alternative to ongoing medication escalation should consider Revita in conjunction with a diet and exercise program to potentially change the trajectory of their disease. These data show that using Revita in this way could break the pattern of chronic medication and shift the treatment paradigm for obesity and T2D."

At baseline, prior to Revita, these patients were a median age of 62 years, with obesity and advanced T2D, a median body weight of 111 kilograms (245 pounds; BMI 32 kg/m^2) and median baseline HbA1c of 9.6% despite using up to three glucose lowering agents. Approximately two-thirds of these patients were male.

At 12 months, the patients' median weight decreased from 111 kilograms (245 pounds) to 97 kilograms (214 pounds), representing a nearly 13% total body weight loss, and their median HbA1c decreased from 9.6% to 7.2%. In addition, the number of glucose lowering medications remained stable or decreased for 10 out of the 11 patients at 12 months. It is important to note that weight loss was observed as early as 1-month post-Revita procedure, and weight loss was generally maintained through 1 year of follow-up (see data table), which demonstrates in a real-world setting the potential for a single Revita procedure to be a durable weight maintenance solution. Revita was well tolerated in these patients, and no procedure-related adverse safety events were observed.

Table. German Real-World Registry Weight and Blood Sugar Data Post-Revita Procedure

Endpoint	Baseline	3 Months	6 Months	12 Months
Weight (kg)	111	101	100	97
HbA1c (%)	9.6	7.1	7.6	7.2

Median values shown. Fractyl Health data on file, n=11. NCT06256497. HbA1c=glycated hemoglobin.

"Patients deserve a life free from disease, and these data show that Revita has the potential to offer a profound new option to lighten the burden for people living with obesity and/or T2D," said Harith Rajagopalan, M.D., Ph.D., Co-founder and Chief Executive Officer of Fractyl. "Further, we are reassured by how well-tolerated the procedure has been in real-world use and by the strength and durability of the clinical effects we have seen thus far. We continue to be encouraged as we ramp up our REMAIN-1 study for Revita in weight maintenance, which recently received FDA Breakthrough Device designation, and as we continue

enrollment in our REVITALIZE-1 study in T2D. We look forward to helping patients find a sustained solution for their obesity and T2D."

Revita is an outpatient endoscopic procedure designed to resurface the mucosal lining of the duodenum, the first part of the small intestine just after the stomach, which is responsible for nutrient sensing and signaling from the gut to the brain and rest of the body. The duodenal lining can become thickened and dysfunctional by high-fat and high-sugar diets, making it hard for the body to maintain a healthy weight and blood glucose levels. By resurfacing and reversing the pathology of the duodenal lining, Revita, if approved, has the potential to become the first disease-modifying therapy that targets a root cause of obesity and T2D.

To date, 37 patients have been treated with Revita in Germany and 31 have consented to participate in the Real-World Registry. Periodic updates on the Registry and clinical outcomes will be shared as the study continues to expand and enroll.

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 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. It 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 weight maintenance for 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 analysis of the REMAIN-1 in Q2 2025. 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.

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.

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 potential launch or commercialization of any of our product candidates or products, the potential treatment population 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. 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 May 13, 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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