Fractyl Health Presents Clinical Update on Revita® German Real-World Registry for Patients With Advanced Type 2 Diabetes (T2D)

May 13, 2024

First 14 participants with at least six months of follow up continue to demonstrate sustained improvements in blood glucose and weight with reduction in T2D medication utilization after a single Revita treatment

No device- or procedure-related serious adverse events have been observed to date in any registry participant

BURLINGTON, Mass., May 13, 2024 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the "Company"), a metabolic therapeutics company focused on pioneering new approaches for the treatment of obesity and type 2 diabetes (T2D), today announced 6-month follow-up data from its enrolling German real-world registry study of Revita for T2D.

The first 14 consented registry participants have now completed at least 6 months of post-Revita follow up. At baseline, prior to Revita, these participants were a median age of 62 years, had a median body weight of 111 kg and advanced T2D with an average of 14 years since diagnosis. Despite using up to three different glucose lowering medications, participants' T2D remained uncontrolled with a median baseline HbA1c of 9.2%.

These 14 participants underwent Revita and experienced an average total body weight loss of 8.1% at 6 months after the procedure, with generally sustained or improved weight loss from month 1 to month 6. These real-world findings further support the potential of Revita for durable maintenance of weight loss. Fasting blood glucose also improved after the procedure, falling from a baseline median of 153 to 116 mg/dL at 6 months, and HbA1c improved from a median of 9.2 to 7.6%, reflecting better glucose control, despite all patients stabilizing or reducing the number of glucose-lowering medications. No device or procedure-related serious adverse events have been reported to date.

Professor Stephan Martin, Director of the West German Diabetes Center of Excellence offering Revita combined with dietary and lifestyle support in Düsseldorf, Germany recently presented the Revita registry study 3-month follow-up results at the German Diabetes Association (DDG) annual meeting, held in Berlin May 8-11th.

"Early results from our real-world registry suggest that patients who undergo Revita can experience significant improvement in blood sugar, reduction in body weight, and stabilization or reduction of medication burden," said Timothy Kieffer, Chief Scientific Officer at Fractyl Health. "These results are particularly impressive considering that most patients in the registry have been struggling with advanced T2D and inadequate control despite treatment with standard-of-care polypharmacy for many years. In particular, the maintenance of body weight loss through 6 months of follow up is a promising indicator for our ongoing clinical development program in weight maintenance through our Remain-1 pivotal study."

To date, 26 of the 33 participants treated with Revita in Germany have consented to participate in the Revita Registry. Periodic updates on the Revita Registry and real-world clinical outcomes for patients in Germany undergoing Revita treatment will be shared as the study continues to expand and enroll.

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 inadequately controlled T2D despite multiple medicines and insulin, called 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 anticipated to initiate in H2 2024.

About Rejuva

Fractyl Health's Rejuva® platform focuses on developing next-generation adeno-associated virus (AAV)-based, locally delivered gene therapies for the treatment of obesity and T2D. The Rejuva platform is in preclinical development and has not yet been evaluated by regulatory agencies for investigational or commercial use. Rejuva leverages advanced delivery systems and proprietary screening methods to identify and develop metabolically active gene therapy candidates targeting the pancreas. The program aims to transform the management of metabolic diseases by offering novel, disease-modifying therapies that address the underlying root causes of disease.

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, expansion, progression and results of clinical enrollment and any clinical trials or readouts, the potential benefits or launch or commercialization of 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 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.

Contacts

Corporate Contact
Lisa Davidson, Chief Financial Officer
ir@fractyl.com, 781.902.8800

Media Contact
Beth Brett, Corporate Communications
bbrett@fractyl.com, 720.656.6544

Investor Contact
Stephen Jasper
Gilmartin Group
stephen@gilmartinir.com, 619.949.3681