Fractyl Health Announces Multiple Presentations at the Upcoming Digestive Disease Week (DDW) 2024 Conference and the German Diabetes Association (DDG) Annual Meeting

Apr 30, 2024

At DDG, Fractyl Health will present new clinical updates on its ongoing real-world registry study of Revita® in patients with T2D in Germany

At DDW, Fractyl Health will provide an oral presentation from its Rejuva® platform with new preclinical data demonstrating the potential of GLP-1 based pancreatic gene therapy (GLP-1 PGTx) to durably reduce liver fat in the diet-induced obesity model

BURLINGTON, Mass., April 30, 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 that it will present new data from its ongoing real-world registry study of Revita for T2D at the upcoming German Diabetes Association (DDG) Annual Meeting taking place May 8-11, 2024, in Berlin, Germany. The Company will also present an oral abstract with new preclinical data on the potential of Rejuva to durably impact liver metabolic health during the 2024 Digestive Disease Week (DDW) taking place May 18-24, 2024, in Washington, D.C.

Details of the presentations are provided below.

German Diabetes Association (DDG) Annual Meeting

- **Presentation Title:** *A Prospective Post-Market Clinical Follow-Up Registry to Evaluate Real-World Effectiveness of Duodenal Mucosal Resurfacing in Patients with Type 2 Diabetes*
- **Poster Number:** P01.02 (Paper-ID: 68228)
- **Poster Area:** Posterwalk 1: Prediabetes and Type 2 Diabetes (Clinical)
- **Location:** Level 1 – Poster Area
- **Presentation Date & Time:** Thursday, May 9, 2024, from 2:07 p.m. – 2:14 p.m. ET

Digestive Disease Week (DDW)

- **Presentation Title:** *Single-Dose GLP-1-Based Pancreatic Gene Therapy Maintains Weight Loss After Semaglutide Withdrawal and Reduces Hepatic Triglycerides in a Murine Model of Obesity*
- **Abstract Number:** 4029196
- **Session Title:** AGA Basic Science Plenary
- **Location:** 103AB at the Walter E. Washington Convention Center
- **Presentation Date & Time:** Sunday, May 19, 2024, from 4:00 p.m. - 5:30 p.m. ET

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 TD2 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 our participation at conferences, 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, 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 Company's reliance on third parties for the manufacture of the materials for its Rejuva gene therapy platform for preclinical studies and its ongoing clinical studies; the regulatory approval process of the FDA, comparable foreign regulatory authorities and notified bodies, are 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 April 1, 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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