Fractyl Health Expands Leadership with Appointment of Adrian Kimber as Chief Commercial Officer to Spearhead Anticipated Launch Preparation as the Company Conducts Two Pivotal Studies for Revita in Obesity and Type 2 Diabetes

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BURLINGTON, Mass., April 02, 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 the appointment of Adrian Kimber as Chief Commercial Officer.

Mr. Kimber joins Fractyl with over two decades of experience in the biotechnology and medical devices sectors. Throughout his career, he has showcased a commendable history of introducing groundbreaking therapies to worldwide markets. Renowned for his adeptness in formulating go-to-market strategies, assembling and leading commercial teams, and implementing operational excellence, he has left a profound mark on the healthcare landscape.

“We are delighted to welcome Adrian to Fractyl, where his breadth of commercial and strategic leadership experience will be instrumental as we prepare for the launch of our Revita® system,” said Dr. Harith Rajagopalan, CEO of Fractyl Health. “We believe Revita has the potential to deliver sustained, durable benefit to patients struggling with obesity and Type 2 diabetes and the resulting health complications, and Adrian’s proven track record in bringing transformational products to market will be critical to help Revita achieve this goal.”

“I am excited to join the Fractyl team and for the opportunity to work alongside leaders in the space with a shared mission to transform the treatment of metabolic diseases and hopefully provide a cure for obesity and Type 2 Diabetes (T2D),” said Mr. Kimber. “We have several key Revita milestones approaching ahead of a potential launch, and I look forward to leading our commercial strategy during this pivotal time.”

Mr. Kimber most recently served as Global VP & Commercial Head at Biotronik Neuro, where he spearheaded the introduction of daily remote monitoring and Proactive Care for patients with spinal cord stimulation devices. Under his guidance, the product journeyed from inception to successful commercialization in the United States. Adrian held progressively senior commercial roles at prominent companies such as Biotronik, Abbott, Olympus, and Medtronic, spanning across regions including the United Kingdom, Australia, and the United States. Mr. Kimber holds a B.Sc. in Sports Science from London Metropolitan University.

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 potential of Revita to deliver sustained, durable benefit to patients struggling with obesity and Type 2 diabetes; and our strategic and product development objectives, goals, and missions, including with respect to transforming the treatment of metabolic diseases and providing a cure for obesity and T2D. 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 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; additional time may be required to develop and obtain regulatory approval or certification for the Company's Rejuva gene therapy candidates; 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; changes in methods of the Company's Rejuva gene therapy candidate manufacturing or formulation; any contamination or interruption in the Company's Rejuva gene therapy candidates' manufacturing process, shortages of raw materials or failure of the Company's suppliers of plasmids and viruses to deliver necessary components could result in delays in the Company's Rejuva gene therapy candidates' preclinical and clinical development or marketing schedules; and 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 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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