Fractyl Health Announces the FDA's Authorization of Expanding the Revitalize-1 Study's Sample Size

Nov 30, 2021

– Revitalize-1, formerly REVITA-T2Di, is the first new study in Fractyl Health's Revitalize T2D clinical development program –

– Revitalize T2D is designed to evaluate the potential of the Revita® DMR System in approximately 1,000 patients across the spectrum of type 2 diabetes and prediabetes –

LEXINGTON, Mass., November 30, 2021 – Fractyl Health, an organ-editing metabolic therapeutics company focused on pioneering a new approach to the treatment of type 2 diabetes (T2D), announced today the United States Food and Drug Administration's (FDA's) authorization to expand its Revitalize-1 pivotal clinical study (formerly known as REVITA-T2Di) sample size from 288 to 420. The newly authorized Revitalize-1 pivotal study protocol amendment also allows the inclusion of a broader set of patients who have inadequately controlled T2D despite being on metformin, other antidiabetic agents (ADAs), and long-acting insulin. In March 2021, the Revita DMR System (Revita) was granted Breakthrough Device designation from the FDA for the hydrothermal ablation of the duodenal mucosa to improve glycemic control and eliminate insulin needs in T2D patients who are inadequately controlled on long-acting insulin.

The Revita DMR system has been tested in multiple early pilot clinical studies in approximately 300 patients with various stages of T2D. Based on this earlier clinical experience, the company also announced today a deepening of its clinical development program in T2D, the Revitalize T2D program. The Revitalize T2D clinical development program is designed to represent multiple parallel ongoing and planned clinical studies aiming to test the use of Revita in different patient populations ranging from prediabetes to long-acting insulin-treated T2D. The Revitalize-1 pivotal study is the first of these clinical studies and is already underway. The studies in the Revitalize T2D program have the potential to generate data on the use of Revita in patients across the spectrum of T2D and prediabetes.

"We are looking forward to continuing our expanded Revitalize-1 study and concurrently embarking on our Revitalize T2D clinical development program, which will be informed in close collaboration with leading academic experts. We believe the importance of these clinical studies, and the reason patients across the spectrum of T2D are interested in participating, is that we are seeking to address a very important residual unmet need in T2D for patients who remain at risk of the significant complications of the disease," said Juan Carlos Lopez-Talavera, M.D., Ph.D., Chief Medical Officer of Fractyl Health.

About Revita®

Fractyl Health's lead product candidate, Revita, is based on the company's insights surrounding the potential role of the gut in metabolic diseases. 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 diseases. In April 2016, Revita received a CE mark from the European Union. In the United States, Revita is for investigational use only and has received Breakthrough Device designation from the FDA to improve glycemic control and eliminate insulin needs in T2D patients who are inadequately controlled on long-acting insulin.

About the Revitalize T2D Clinical Development Program

The Revitalize T2D program is a series of ongoing and planned clinical studies sponsored by Fractyl Health to investigate the potential utility of Revita in patients with, or at high risk for, T2D. The company's ongoing pivotal clinical study, Revitalize-1, is designed as a randomized, double-blind crossover, sham-controlled, multi-center study in patients with inadequately controlled T2D despite being on metformin or multiple ADAs, and long-acting insulin. The Revitalize-2 study is a planned profile optimization study in T2D patients who qualify for insulin and are failing guideline-directed therapy. The Revitalize-3 proof-of-concept pilot study is a planned study in patients with high-risk prediabetes to evaluate the effects of hydrothermal ablation of the duodenal mucosa using Revita to reduce the risk of developing T2D.

About Fractyl Health

Fractyl Health is focused on pioneering a new approach to the treatment of T2D. Despite advances in treatment over the last 50 years, metabolic diseases in general, and T2D in particular, continue to be a principal and rapidly growing driver of morbidity and mortality in the 21st century. Fractyl Health's goal is to transform T2D treatment from chronic blood glucose management to disease-modifying therapies that target the organ-level root causes of the disease. Fractyl Health's lead product candidate, Revita, is designed to remodel the duodenal lining via hydrothermal ablation (i.e., duodenal mucosal resurfacing) in order to edit abnormal

intestinal nutrient sensing and signaling mechanisms that are a potential root cause of metabolic diseases. Fractyl Health is a private organ-editing metabolic therapeutics company based in Lexington, MA. For more information, visit www.fractyl.com or www.twitter.com/FractylHealth

Corporate Contact:

Lisa Davidson, Chief Financial Officer

Lisa@fractyl.com, 781.902.8800

Media Contact:

Lisa Raffensperger, Ten Bridge Communications

lisa@tenbridgecommunications.com, 617.903.8783