Fractyl Health Reports Durable Improvement in Glucose Control, Weight Loss, and Insulin Reduction in T2D Patients Using Revita® in Open Label Phase of Revitalize 1 Pivotal Study at the American Diabetes Association 83rd Scientific Sessions

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Revita®, in conjunction with empagliflozin, provided a median HbA1c reduction of 1.6% and weight loss of 9.3% after 48 weeks while reducing insulin use by 44% in this inadequately controlled, insulin-dependent cohort

Revita®, recognized with Breakthrough Device Designation from the FDA, presents a promising approach to treat patients with T2D previously inadequately controlled with multiple glucose-lowering agents

Fractyl Health targets completing enrollment for the ongoing Revitalize 1 pivotal study in H1 2024

LEXINGTON, Mass.–(BUSINESS WIRE)– Fractyl Health, an organ-editing metabolic therapeutics company pioneering novel treatments for type 2 diabetes (T2D), unveiled compelling 48-week results from the open-label phase of the ongoing Revitalize 1 pivotal study at the American Diabetes Association's 83rd Scientific Sessions. The study explored the safety and efficacy of Revita®, an endoscopic procedure using hydrothermal ablation to target the duodenum in conjunction with empagliflozin.

Seven subjects in the study, previously treated with multiple glucose lowering agents (GLAs) and insulin, have thus far completed 48-week follow-up after undergoing the outpatient Revita procedure and subsequent administration of empagliflozin. In subjects enrolled in the study thus far, treatment with Revita has shown rare and mild device-related adverse events.

After 1-year post-treatment, subjects treated with Revita plus empagliflozin experienced a median HbA1c reduction of 1.6%, Fasting Plasma Glucose (FPG) reduction of 77 mg/dl, 9.3% total body weight loss, and 44% reduction in insulin dosage. Prior studies of empagliflozin alone in a similar T2D population have reported HbA1c reduction of 0.7%, FPG reduction of 29 mg/dL, 12% reduction in insulin usage, and up to 3% total body weight loss[1].

The data highlight the potential of the combined approach of Revita in conjunction with SGLT2 inhibition in effectively treating T2D, especially for patients inadequately controlled with multiple glucose-lowering agents, including insulin.

The Revitalize 1 pivotal study is ongoing, with Fractyl Health set to complete enrollment in the first half of 2024. The study design is a randomized, double-blind, sham-controlled trial in up to 420 subjects. The study's primary objective is to assess the efficacy of Revita in improving glycemic control at 24 weeks compared to sham.

"Revita® aims to address duodenal dysfunction, a potential root cause of T2D. It is not only about controlling symptoms but intervening at the root cause. These promising results bring us closer to our goal at Fractyl Health, which is to control and, ultimately, eradicate T2D. With the continued progress of the Revitalize 1 study, we hope to offer a truly revolutionary treatment for the millions living with this disease," said Dr. Harith Rajagopalan, CEO of Fractyl Health.

About Fractyl Health

Fractyl Health is focused on pioneering new approaches 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 is a private organ-editing metabolic therapeutics company based in Lexington, MA. For more information, visit www.fractyl.com or www.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 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. Revita has received a CE mark in Europe and, in January 2022, received reimbursement authorization through NUB in Germany. In the United States, Revita is for investigational use only under US law 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. A pivotal study of Revita in patients with inadequately controlled Type 2 Diabetes despite multiple medicines and insulin, called Revitalize 1, is currently enrolling in the United States and Europe.

References

[1]Rosenstock J et al. *Diabetes Obes Metab*. 2015 Oct;17(10):936-48

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