



Fractyl Health Provides Clinical Update on 24-Week Data from Open Label REVITA-T2Di Cohort

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- *Revita-T2Di is an open-label cohort evaluating Revita® in patients with insulin-treated Type 2 Diabetes*
- *Revita in the T2Di cohort has been observed to be well tolerated, with clinically meaningful improvements in glycemic and metabolic parameters in patients on long-acting insulin through a 24-week follow-up*

LEXINGTON, Mass.—([BUSINESS WIRE](#))— Fractyl Health, an organ-editing metabolic therapeutics company focused on pioneering a new approach to the treatment of type 2 diabetes (T2D), announced today 6-month interim data from human clinical experience in its REVITA-T2Di (T2Di) long-term open-label cohort. Revita has previously obtained 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. In T2Di, clinical assessments observed in nine treated patients followed through at least six months demonstrated that all patients successfully improved glycemic and metabolic control while reducing insulin requirement.

In the T2Di study, patients with inadequately controlled T2D with an HbA1c of 7.5-9.5% despite long-acting insulin therapy were enrolled. Prior to the study procedure, all antidiabetic agents other than metformin and basal insulin were washed out for at least eight weeks, followed by an additional four-week run-in period. Post-Revita procedure, all patients discontinued their insulin and received only metformin and newly added empagliflozin. Patients were closely monitored for glucose control, and pre-specified criteria for insulin re-introduction were followed to ensure the safety and effectiveness of glucose control.

All nine procedures were successfully completed across four treating centers by five different endoscopists, including three endoscopists new to Revita as part of this trial. Average procedure time was less than one hour in this outpatient endoscopic procedure. There have been no device-related adverse events to date, including no prespecified Adverse Events of Special Interest (such as nausea, vomiting, GI discomfort, etc.) related to the device. One subject discontinued participation in the study for reasons that were not related to Revita. Mean HbA1c improved by 1% from a baseline of 8.5% to 7.5%, and all subjects reduced their daily insulin dose from baseline. Three of the eight subjects followed through 24 weeks did not require ongoing insulin therapy, though they had required insulin therapy prior to study participation. Mean total body weight improved by 6.8% from a baseline of 100 kg.

“We are encouraged by the 24-week data from this clinical experience with Revita in showing improvements in glucose control and weight with a significant reduction in insulin requirement,” said Prof Geltrude Mingrone, M.D., Ph.D., Professor of Internal Medicine at the Catholic University, Rome, and Professor of Diabetes and Nutrition at King’s College, London. “Aside from bariatric surgery, physicians do not have accessible tools today to improve glucose control and reduce drug burden. What is exciting about this cohort is that it shows Revita may offer the potential to not only improve glucose control for patients with advanced disease but also potentially help to reduce or eliminate their need for insulin.”

Regular updates on the extended follow up of the Revita T2Di cohort, including 48-week durability data after a single intervention, will be presented later this year.

About Revita®

Fractyl Health’s lead product candidate, Revita, is based on emerging scientific evidence linking gut dysfunction to the development of 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 in Europe. 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.

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 multiple ADAs and insulin. The T2Di cohort were the first ten enrolled subjects in Revitalize-1’s open-label training phase who underwent a per protocol eight-week drug washout period that other subjects in the Revitalize-1 study will not undergo. 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

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