Fractyl Announces Tenth Trial Site Opened in REVITA-T2Di Study of Revita® DMR for Type 2 Diabetes

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-REVITA-T2Di study is assessing potential of outpatient Revita DMR treatment to improve glycemic control and reduce or eliminate need for daily insulin –

LEXINGTON, Mass., September 1, 2021 – Fractyl Health, a life sciences company dedicated to developing novel therapeutic interventions aimed at reversing the metabolic disease epidemic, today announced the activation of the tenth clinical site in the company's pivotal REVITA-T2Di trial taking place across the U.S. and Europe. The trial is now enrolling patients with type 2 diabetes who are currently on insulin therapy at the following locations: Saint Joseph's Medical Center in Paterson, N.J.; The Academic Medical Center in Amsterdam; Tulane Medical Center in New Orleans; Baylor St. Luke's Medical Center in Houston; Beth Israel Deaconess Medical Center in Boston; Erasmus Hospital in Brussels; Policlinico Agostino Gemelli in Rome; Brigham and Women's Hospital in Boston; and Weil Cornell Medicine in New York; in addition to the initial site at Indiana University Health.

"This exciting clinical trial is the first to evaluate the ability of a procedural therapy to reduce or eliminate the need for insulin in patients with advanced type 2 diabetes, a critical therapeutic need. We are grateful to the prestigious medical centers who have partnered with us to carry out this study," said Juan Carlos Lopez-Talavera, M.D., Ph.D., chief medical officer of Fractyl. "As we continue to enroll and treat patients at numerous sites in the U.S. and Europe, we remain focused on strong clinical execution with a sense of urgency for the patients we seek to serve."

Fractyl has obtained Breakthrough Device Designation from the FDA for Revita DMR in the insulin-treated T2D patient population. REVITA-T2Di (NCT #04419779) is a prospective, randomized, double-blind, sham-controlled study that is expected to enroll more than 300 patients at up to 35 sites in the U.S. and Europe. It will evaluate the efficacy of Revita DMR (duodenal mucosal resurfacing), a first-in-class intervention targeting the role of the duodenum in metabolic disease. The trial's primary endpoint is the percentage of patients who are able to achieve target glycemic control (HbA1c less than or equal to 7%) without the need for insulin at 24 weeks, comparing Revita DMR to the sham arm.

"The insulin-treated type 2 diabetes patient population is most at risk for complications of insulin, including hypoglycemia and excessive weight gain, but yet we as clinicians have the fewest tools to effectively treat these individuals," said Vivian Fonseca, M.D., assistant dean for clinical research and Tullis-Tulane alumni chair in diabetes at Tulane University School of Medicine and a principal investigator of the REVITA-T2Di study. "Our team is excited to be participating in this study to evaluate a potentially important addition to the therapeutic armamentarium of physicians treating diabetes."

More information about the study can be found at revitastudy.com

About the Revita® DMR Treatment

Revita DMR is based on Fractyl's breakthrough insights surrounding the role of the gut in metabolic diseases. An outpatient endoscopic procedure, Revita DMR resurfaces the lining of the upper intestine (duodenal mucosa). Revita DMR has been studied in clinical trials involving close to 300 patients. In April 2016, the Revita DMR System received a CE mark in the European Union. In the United States, the device has not yet been authorized for marketing, but is the subject of an FDA-approved Investigational Device Exemption (IDE) study and has received Breakthrough Device Designation (BDD). Revita DMR System may be available for investigational use in other regions.

About Fractyl Health

Fractyl is pioneering treatments for metabolic diseases based on revolutionary scientific insights into the root causes of metabolic dysfunction. Fractyl's lead program is Revita DMR, an outpatient endoscopic procedural therapy designed to treat insulin resistance in T2D. The company's groundbreaking discoveries offer the potential to address other metabolic diseases in the future, including nonalcoholic fatty liver disease/nonalcoholic steatohepatitis (NAFLD/NASH), in an effort to reduce the global economic and healthcare burden of metabolic disease. Fractyl is a private biotechnology company based in Lexington, Mass. For more information, visit www.fractyl.com or www.twitter.com/FractylHealth

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