



## Fractyl Announces First Patient Enrolled in Pivotal Study of Novel Procedural Therapy Revita® DMR for Type 2 Diabetes

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– Landmark REVITA-T2Di study will assess potential of outpatient Revita DMR treatment to eliminate need for daily insulin –

**LEXINGTON, Mass., March 22, 2021** — Fractyl Laboratories Inc. ([Fractyl](#)), a life sciences company dedicated to developing novel therapeutic interventions aimed at reversing the metabolic disease epidemic, today announced the enrollment of the first patient in a pivotal clinical trial of Revita® DMR for patients with type 2 diabetes. The trial, called REVITA-T2Di, will evaluate the ability of a single Revita DMR treatment to allow patients currently on insulin therapy but with inadequate glycemic control to achieve durable insulin-free glycemic control. This pivotal trial is designed to form the basis for a marketing application to the U.S. Food and Drug Administration (FDA).

“We are pleased to initiate this global pivotal study of Revita DMR, a procedural therapy which we believe could significantly impact the lives of people living with type 2 diabetes whose blood sugar levels remain uncontrolled despite being on insulin therapy,” said Harith Rajagopalan, M.D., Ph.D., co-founder and CEO of Fractyl. “In collaboration with clinical sites in the United States and Europe, we look forward to evaluating Revita DMR in a segment of the type 2 diabetes population who are most at risk for hypoglycemia, weight gain and other significant complications of insulin therapy.”

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 United States and Europe. It will evaluate the efficacy of Revita DMR (duodenal mucosal resurfacing), a first-in-class intervention targeting the role of the intestine 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 trial has begun enrolling patients at its first clinical site at Indiana University Health, and additional trial sites will be announced in the coming months. More information about the study can be found at [revitalize1study.com](#).

“We would like to thank our investigators and partners for their collaboration in bringing this trial to patients whose only treatment option available today is insulin dose escalation,” said Juan Carlos Lopez-Talavera, M.D., Ph.D., Chief Medical Officer of Fractyl. “By targeting the root cause of type 2 diabetes in the intestine, our preliminary clinical findings suggest that treatment with Revita DMR may be able to decrease insulin resistance. If these data are borne out in the REVITA-T2Di trial, Revita DMR may, in the future, represent an additional option for addressing the significant health and economic burden of type 2 diabetes for patients, healthcare systems, and society at large.”

### 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. The Revita DMR System may be available for investigational use in other regions.

### About Fractyl

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 type 2 diabetes. 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/FractylLabs](#).

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