Fractyl Announces FDA Breakthrough Device Designation for Revita® DMR in Insulin-Treated Type 2 Diabetes

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- REVITA-T2Di study is underway to evaluate the effectiveness of Revita DMR in improving glucose control while reducing or eliminating the need for insulin -

LEXINGTON, Mass., April 27, 2021 – Fractyl Laboratories Inc. (Fractyl), a life sciences company dedicated to developing novel therapeutic interventions aimed at reversing the metabolic disease epidemic, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for Revita® DMR in patients with insulin-treated type 2 diabetes (T2D). Fractyl's REVITA-T2Di study is now enrolling in this patient population.

"We are thrilled to work closely with the FDA to accelerate the introduction of a potentially significant therapy for patients with type 2 diabetes who continue to struggle with the burden and risks of their disease," said Harith Rajagopalan, M.D., Ph.D., co-founder and CEO of Fractyl. "Breakthrough Designation provides recognition from the FDA of the potential value that Revita DMR can bring to patients and an opportunity for accelerated access for patients who need better treatment options."

The goal of the Breakthrough Device program is to provide patients and health care providers with timely access to certain medical devices that deliver more effective treatment of life-threatening or irreversibly debilitating diseases or conditions by speeding up their development, assessment and review.

Fractyl also announced that the Centers for Medicare and Medicaid Services (CMS) has approved CMS coverage of routine costs for Medicare patients in the REVITA-T2Di trial. All eligible participants will receive study-related health assessments at no cost; this CMS decision allows for reimbursement coverage to clinical research centers for certain trial-related expenses.

Revita DMR (duodenal mucosal resurfacing) is a first-in-class intervention targeting the role of the intestine in metabolic disease. It is an outpatient procedural therapy that uses heat to resurface the lining of the upper intestine, an organ which plays an integral role in metabolic regulation. Fractyl's preliminary clinical findings suggest that treatment with Revita DMR may decrease insulin resistance, improve glucose control, lower weight and reduce liver fat.

"Type 2 diabetes is not simply a disease of blood sugar, but a multi-organ pathology that leads to progressive pancreatic beta-cell failure, fundamentally caused by insulin resistance. We know that treatment alternatives to current drug therapy are desperately needed to address the type 2 diabetes epidemic," said Juan Carlos Lopez-Talavera, M.D., Ph.D., Chief Medical Officer of Fractyl. "Providing a therapy that could improve glucose to target range while reducing the need for injectable insulin would be a quantum leap forward for patients. Fractyl is committed to advancing Revita DMR through the clinical and regulatory process to make a potentially meaningful difference in the lives of patients who are affected by this serious, chronic disease."

Fractyl is now enrolling patients in the REVITA-T2Di trial, which is designed to form the basis for a premarket submission to the FDA in the insulin-treated T2D patient population. The trial is a prospective, randomized, double-blind, sham-controlled study enrolling 300 patients at up to 35 sites around the world. To learn more about the REVITA-T2Di study and enrollment eligibility, visit revitastudy.com.

About Type 2 Diabetes

Type 2 diabetes is a disease that affects nearly 30 million people in the U.S. and is a severely debilitating, progressive disorder leading to gradually worsening blood sugar levels and increased risk of serious morbidity and mortality. Approximately 5 million people in the U.S. with type 2 diabetes are treated with insulin, and over 50% of these patients continue to have inadequate glucose control despite insulin therapy. Insulin, along with other currently available drug therapies, address the symptoms but not the root cause of type 2 diabetes.

About the Revita® DMR Treatment

Revita DMR is based on Fractyl's groundbreaking 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. Revita DMR has received FDA Breakthrough Device Designation and a European Union CE mark. 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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