



Fractyl Health Announces the Initiation of a Global Registry Study of the Revita System™ in Patients With Inadequately Controlled Type 2 Diabetes (T2D)

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Registry subjects will initially enroll in multiple hospitals in Germany, where the Revita System has already obtained a CE Mark and reimbursement through the NUB reimbursement process.

LEXINGTON, Mass.—(BUSINESS WIRE)— Fractyl Health, a commercial stage organ-editing metabolic therapeutics company focused on pioneering new approaches for the treatment of type 2 diabetes (T2D), today announces the initiation of its Revita® Global Registry Program in Germany. On April 20, the Ethics Committee of the University of Freiburg (Germany) granted a clearance for the initiation of a registry study of the Revita System in German hospitals. Patients who participate in the registry will be those with inadequately controlled type 2 diabetes (T2D) despite guideline-directed medical therapy and are interested in undergoing the Revita procedure. Data will be collected to understand the impact of Revita on important clinical, patient-relevant, and health-economic outcomes associated with T2D.

“Nearly 50% of patients remain inadequately controlled with T2D, and therefore, there is a need for new therapeutic options that can improve real-world outcomes in the disease,” said Prof. Jochen Seufert, FRCPE, Head of the Department of Endocrinology and Diabetology at University Hospital Freiburg and principal investigator for the registry study in Germany. “This registry study will enable us to collect valuable data on Revita under real-world conditions to help better understand the value it may provide to people with the disease.”

The registry aims to collect data from patients receiving the Revita procedure at Munich Municipal Hospital (Bogenhausen) and Evangelical Hospital Düsseldorf (EVK) in collaboration with the West German Diabetes and Health Centre (WDGZ) in Düsseldorf.

“There is a huge, global unmet need for people with inadequately controlled T2D,” said Harith Rajagopalan, MD, PhD, CoFounder and CEO of Fractyl Health. “We believe the Revita System has the potential to offer an important new solution for patients because targeting the gut may allow us to address a root cause of the disease for the first time.”

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.

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