Fractyl Health Receives Reimbursement Authorization in Germany for Revita DMR® System

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- *The Revita DMR System (Revita) gains reimbursement authorization from the German Institute for Hospital Remuneration (InEK) with a NUB Status 1 designation*
- *NUB Status 1 entitles participating hospitals in Germany to begin to negotiate payment for Revita from statutory health insurers*

LEXINGTON, MA., February 8, 2022 – Fractyl Health, an organ-editing metabolic therapeutics company focused on pioneering a new approach to the treatment of type 2 diabetes (T2D), announced today a decision from InEK in Germany that Revita has been granted Status 1 designation under its NUB funding process. Hospitals in Germany that submitted a NUB application are now entitled to negotiate reimbursement for Revita® with the German statutory health insurance system. Revita has already received a CE Mark in Europe to improve glycemic control in patients with inadequately controlled T2D on antidiabetic agents and/or long-acting insulin therapy. German hospitals may now negotiate full reimbursement from the national health insurance system for its use in their patients in clinical studies and/or real-world evidence generation in a commercial setting. This reimbursement decision comes on the heels of a "Coverage with Evidence Development" decision for Revita from the German health technology assessment authority (the G-BA) in 2021.

"The challenge of T2D in Germany is continuously growing, and recent research advances have not reduced its endemic proportions. The need for new therapies has never been greater," said Professor Markus Lerch, President of the German Society for Internal Medicine. "A novel endoscopic approach that addresses a completely different pathophysiological mechanism of T2D could potentially change the landscape of our therapeutic arsenal."

In the United States, Revita is for investigational use only and received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) in 2021 to improve glycemic control and eliminate insulin needs in T2D patients who are inadequately controlled on long-acting insulin. Additionally, in 2021 the Centers for Medicare and Medicaid Services (CMS) in the United States approved CMS coverage of routine costs for Medicare patients in the ongoing pivotal Revitalize-1study.

"Given the accelerating global epidemic of T2D, new approaches are desperately needed in order to reduce disease burden, improve outcomes, and increase value. Despite the availability of a wide variety of therapeutic options, T2D remains a progressive, expensive, debilitating disease. There are limited options for patients and health systems to change the trajectory of this disease. We are enthusiastic about the decision from the German government to authorize reimbursement for Revita and particularly gratified for the support of the many German hospitals submitting the application," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and CEO of Fractyl Health. "We are eager to work with hospital systems, regulators and payers around the world to evaluate Revita and potentially implement what we believe may be the first broadly accessible, disease modifying therapy for patients with T2D."

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. In April 2016, Revita received a CE mark in Europe. In the United States, Revita is for investigational use only 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 being on an antidiabetic regimen including long-acting insulin. The Revitalize-2 study is a planned clinical 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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