



Fractyl Health Announces Commercial Availability of Revita® in Germany and Successful First Procedure at 25th Düsseldorf International Endoscopy Symposium

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- First patient in Germany with Type 2 Diabetes (T2D) received Revita® in Germany, where the Revita DMRSysTM has a CE Mark and insurance coverage through the NUB reimbursement process
- Live demonstration of a Revita procedure was successfully conducted at the Evangelical Hospital (EVK) Düsseldorf as part of the 25th International Endoscopy Symposium
- Commercial availability of Revita at the EVK Hospital marks the transition of Fractyl Health into a commercial stage company

LEXINGTON, Mass.–([BUSINESS WIRE](#))– Fractyl Health, an organ-editing metabolic therapeutics company focused on pioneering a new approach to the treatment of type 2 diabetes (T2D), announced today the commercial availability of its Revita DMR SystemTM in Germany. Fractyl Health further announces that a live demonstration of a Revita procedure was successfully performed on February 3rd at EVK Hospital in Düsseldorf, Germany, at the 25th International Endoscopy Symposium. Revita is an endoscopic procedural therapy that is based on emerging scientific evidence linking gut dysfunction to metabolic diseases and is designed to remodel the duodenal lining to provide a minimally invasive approach to tackling a root cause of T2D. The Revita System has a CE Mark in Europe and has recently established reimbursement in Germany under the NUB reimbursement process.

Initially, Revita will be available to patients at the EVK Hospital in Düsseldorf, where procedures will be conducted by a senior advanced endoscopist, Associate Prof. Torsten Beyna, Head Physician of the Medical Clinic. Patients referred for Revita will be managed in close collaboration with the West-German Centre of Diabetes and Health (WDGZ) in Düsseldorf by Prof Stephan Martin, Head Physician and Director. Revita will first be available at select hospitals in Germany with the close collaboration of clinical leaders in both endoscopy and endocrinology, with additional centers to be added in the future.

“We are enthusiastic about the availability of Revita in Düsseldorf for our patients with T2D who are inadequately controlled and at risk of disease progression,” said Prof Martin. “Current medical therapies for T2D focus on treating symptoms of the disease and – despite numerous options – nearly 50% of German patients remain inadequately controlled. Revita addresses a root cause of their disease in the gut for the first time, thereby potentially enabling patients to improve their underlying disease rather than treating symptoms alone. In conjunction with an appropriate modification of diet and lifestyle, Revita may offer a crucial opportunity for a metabolic reset for patients and society.”

“We have been looking forward to the availability of Revita in Germany for quite some time,” said Associate Prof Beyna. “The clinical development of the technology and procedure has demonstrated the key role of the gut in metabolic diseases, and specifically in T2D. Revita is an innovation that can complement the offerings of modern interventional gastroenterology in a manner that has the potential to become an important paradigm shift in how we think about treating the disease.”

About the 25th International Endoscopy Symposium

Led by the endoscopists of the Evangelical Hospital Düsseldorf, the Symposium represents a renowned event at which the advances in gastroenterological practice and associated current developments in endoscopic medical technology are presented to an international audience. The Symposium was held in Düsseldorf, Germany, and online between February 2-4, 2023. For more information, please visit <https://endo-duesseldorf.com>

About Revita®

Fractyl Health’s lead product candidate, Revita, is based on emerging scientific evidence linking gut dysfunction to the development of 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 2022, received reimbursement in Germany through the NUB process. In the United States, Revita is for investigational use only under US Law 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 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 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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