Fractyl Health Reports Potent and Durable Two-Year Real-World Outcomes with Revita® Showing Sustained Weight Loss and Improved Glucose Control After a Single Procedure

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Two-year follow-up in Germany Real-World Registry study showed median 9.6% weight loss and 1.6% HbA1c reduction after a single Revita procedure in participants with type 2 diabetes, with no device- or procedure-related serious adverse events to date

New real-world findings are consistent with prior two-year clinical data from studies conducted outside the United States, reinforcing Revita's potential for long-term metabolic control ahead of pivotal REMAIN-1 readouts

Company anticipates key data readouts from randomized Revita studies in post-GLP-1 weight maintenance starting in Q3 2025

BURLINGTON, Mass., Aug. 05, 2025 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the Company or Fractyl), a metabolic therapeutics company focused on pattern-breaking approaches that treat root causes of obesity and type 2 diabetes (T2D), today announced 2-year follow-up data from the Germany Real-World Registry study that showed a single Revita procedure led to durable weight loss and improved glucose control in people with obesity and advanced T2D. These data underscore Revita's potential to provide a potent and durable non-drug alternative for patients struggling with long-term metabolic control.

Two-Year Data in Germany Show Sustained Weight Loss and Glycemic Improvement in Patients with Obesity and Advanced T2D

The Germany Real-World Registry study is a prospective, post-market, clinical follow-up study to evaluate the Revita procedure in patients with inadequately controlled T2D. Participants had a baseline HbA1c between 7–10% (inclusive), BMI ≤45 kg/m², and were on at least one glucose-lowering agent (GLA).

At baseline, the first 9 participants with 2 years of follow-up had a median age of 62 years, median weight of 104 kg (229 lbs.; BMI 32 kg/m²), and a median HbA1c of 9.6%, despite being on up to three GLAs.

After a single Revita procedure, these 9 participants achieved a median weight loss of 9.6% with weight decreasing from 104 kg to 97 kg at 1 year, a result that was sustained throughout 2 years. Notably, 7 of 8 participants experienced at least a 5% weight reduction, and 5 of 8 saw reductions of ≥10%. Only one participant, with a history of cortisone therapy known to cause weight gain, experienced modest weight gain (4.5%). In parallel, median HbA1c reduced by 1.6%, from 9.6% at baseline to 7.2% at 1 year, and this improvement was sustained throughout 2 years (7.0%), even as participants reduced or stabilized their use of GLAs. Three patients were on a GLP-1 drug at the time of study entry and were still on a GLP-1 drug through 2 years of follow-up. No device- or procedure-related serious adverse events have been reported to date.

In this cohort, weight loss and glucose improvements began as early as one month after the Revita procedure and were sustained through 2 years of follow-up (see data table). These findings highlight the potential of a single Revita treatment to deliver durable weight maintenance in a real-world setting.

Table. Germany Real-World Registry Study Weight and Blood Sugar Data Post-Revita Procedure

Endpoint	Baseline	3 Months	6 Months	1 Year	2 Years
Weight (kg)	104	92	94	97	97
HbA1c (%)	9.6	7.0	7.0	7.2	7.0

Median values shown. Fractyl Health internal data, n=9.

"We now have real-world evidence that a single Revita procedure can deliver durable improvements in both weight and glucose control that last for two years," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. "These results reinforce what we saw in earlier clinical studies in people living with obesity and type 2 diabetes. The consistency of these outcomes, across both controlled studies and real-world care, speaks to the potential impact of Revita as a one-time, non-drug solution. With randomized data from our pivotal REMAIN-1 study expected in the third quarter of this year, we are moving closer to offering a new option for long-term weight maintenance after GLP-1 therapy."

Thirty-four participants are currently enrolled in the Germany Real-World Registry study. While the study is no longer enrolling new patients, Fractyl will continue protocol-defined follow-up of participants and share outcomes on an ongoing basis.

Revita is being studied in an ongoing IDE-approved REMAIN-1 pivotal study to evaluate its potential safety and efficacy in post-GLP-1 weight maintenance. These new findings from Germany add real-world momentum to Fractyl's upcoming pivotal trial readouts, including Midpoint Cohort data from its ongoing REMAIN-1 study, which is expected in Q3 2025, and primary endpoint data from the Pivotal Cohort, anticipated in H2 2026. Together, these clinical milestones are designed to demonstrate Revita's potential to help maintain weight loss after GLP-1 discontinuation and inform its possible role in supporting durable metabolic outcomes for patients with obesity.

About Fractyl Health
Fractyl Health is a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including obesity and T2D. Despite advances in treatment over the last 50 years, obesity and T2D continue to be rapidly growing drivers of morbidity and mortality in the 21st century. Fractyl's goal is to transform metabolic disease treatment from chronic symptomatic management to durable disease-modifying therapies that target the organ-level root causes of disease. The Company has a robust and growing IP portfolio, with 32 granted U.S. patents and approximately 40 pending U.S. applications, along with numerous foreign issued patents and pending applications. Fractyl is based in Burlington, MA. For more information, visit www.fractyl.com.

About Revita®
Fractyl Health's lead product candidate, Revita, is based on the Company's insights surrounding the potential role of the gut in obesity. Revita is designed to remodel the duodenal lining via hydrothermal ablation (i.e. duodenal mucosal resurfacing) to reverse damage to intestinal nutrient sensing and signaling mechanisms caused by chronic high-fat and high-sugar diets that are a root cause of metabolic disease. In the U.S., Revita is for investigational use only under U.S. law. Revita has U.S. FDA Breakthrough Device designation in weight maintenance for people with obesity who discontinue GLP-1 based drugs. A pivotal study of Revita in patients with obesity after discontinuation of GLP-1 based drugs, called REMAIN-1, was initiated in the third quarter of 2024 and enrollment is now complete.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding our anticipated financial performance, including cash and cash equivalents, for any period of time, the promise and potential impact of our preclinical or clinical trial data, the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, communications with regulators, the potential launch or commercialization of any of our product candidates or products, the potential treatment population or benefits for any of our product candidates or products, and our strategic and product development objectives and goals, including with respect to enabling long-term control over obesity and type 2 diabetes without the burden of chronic therapies, redefining the future of metabolic disease treatment, positioning our Company at the forefront of the global opportunity for metabolic care, and the timing of any of the foregoing. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the Company's limited operating history; the incurrence of significant net losses and the fact that the Company expects to continue to incur significant net losses for the foreseeable future; the Company's need for substantial additional financing; the Company's ability to continue as a going concern; the restrictive and financial covenants in the Company's credit agreement; the lengthy and unpredictable regulatory approval process for the Company's product candidates; uncertainty regarding its clinical studies; the fact that the Company's product candidates may cause serious adverse events or undesirable side effects or have other properties that may cause it to suspend or discontinue clinical studies, delay or prevent regulatory development, prevent their regulatory approval, limit the commercial profile, or result in significant negative consequences; the Company's reliance on third parties to conduct certain aspects of the Company's preclinical studies and clinical studies; the Company's reliance on third parties for the manufacture of sub-assembly components for Revita, and its ongoing clinical studies; the regulatory approval process of the FDA, comparable foreign regulatory authorities and lengthy, time-consuming and inherently unpredictable, and even if we complete the necessary clinical studies, we cannot predict when, or if, we will obtain regulatory approval or certification for any of our product candidates, and any such regulatory approval or certification may be for a more narrow indication than we seek; and the potential launch or commercialization of any of Company's product candidates or products and our strategic and product development objectives and goals, and the other factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on May 13, 2025 and in our other filings with the SEC. These forward-looking statements are based on management's current estimates and expectations. While the Company may elect to update such forward-looking statements at some point in the future, the Company disclaims any obligation to do so, even if subsequent events cause its views to change.

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