Fractyl Health Announces Market Research Highlighting Substantial Patient Interest in a One-Time Procedural Approach to Post-GLP-1 Weight Maintenance

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- Company estimates approximately one million U.S. patients each month discontinue GLP-1 medications and face the risk of weight regain
- One-third of surveyed GLP-1 users expressed a preference for an endoscopic procedure over continued GLP-1 medication
- A one-time procedure and freedom from daily or weekly medication were the most frequently selected positive attributes, supporting commercial planning for Revita

BURLINGTON, Mass., Oct. 29, 2026 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the Company or Fractyl), a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes (T2D), today announced findings from company-sponsored market research highlighting strong patient interest in a one-time procedural approach to weight maintenance following GLP-1 therapy. The findings reinforce the potentially substantial commercial opportunity for investigational Revita and help inform the Company's ongoing commercial planning.

Fractyl estimates that approximately one million patients each month in the United States face the challenge of weight regain following GLP-1 discontinuation. 65% of those taking a GLP-1 for weight loss (without type 2 diabetes) stop within one year, and only about 1 in 12 people prescribed a GLP-1 for obesity are still on it after three years [1,2]. For patients who stop treatment, the immediate question is how to preserve the weight loss they achieved. Revita is being developed to address this post-GLP-1 weight maintenance need.

The Company's market research provides meaningful evidence of interest in a procedural treatment option. Among nearly 300 current or recent GLP-1 users surveyed, 33% preferred stopping GLP-1 therapy and receiving a hypothetical procedure. These findings suggest a sizable number of patients are actively interested in alternatives to chronic medications for maintaining weight loss.

"Many patients discontinue GLP-1 therapy due to cost, insurance coverage, side effects, or concerns about long-term medication use. However, growing evidence shows that most patients experience weight gain after discontinuation," said Dr. Pichamol Jirapinyo, MD, MPH, DABOM, FASGE, FACG, AGAF, Assistant Professor of Medicine at Harvard Medical School and Director of the Bariatric Endoscopy Fellowship at Brigham and Women's Hospital. "In clinical practice, we are seeing increasing numbers of patients seeking minimally invasive treatment options that could help them discontinue GLP-1 therapy while maintaining their weight loss. There is a substantial unmet need for safe, effective, and durable weight management solutions. A scalable, single-session outpatient procedure that could help patients maintain or achieve additional weight loss after GLP-1 discontinuation would represent a meaningful advancement in obesity care."

"In addition to the large number of patients already discontinuing GLP-1s who are at immediate risk of weight regain, our research shows that 1 out of 3 patients who are still currently on a GLP-1 would choose a one-time procedural therapy over ongoing medication," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. "This research reinforces our belief that there is meaningful patient interest in a procedural approach to weight maintenance. Together with the encouraging six-month results from REMAIN-1, these findings strengthen our confidence in Revita's potential to address this need and are helping inform our preparations for future commercialization."

Addressing a Maintenance Decision Patients Already Face

In the market research, respondents who had discontinued GLP-1 therapy identified the following as their top three reasons for stopping: 1) cost or coverage, 2) concerns about long-term use or safety, and 3) achievement of a weight-loss plateau. 84% selected a one-time procedure as their most valued feature, making it the most frequently selected attribute. Freedom from daily or weekly medication ranked second, selected by 64%. These findings provide further insight into patient priorities and help inform the Company's planning for potential patient access.

Building on Physician Interest in a One-Time Procedural Alternative

These patient preference results build on Fractyl's belief that metabolic interventionalists are highly enthusiastic about offering Revita to their patients as an alternative to lifelong GLP-1 therapy. There are approximately 1,000 bariatric and metabolic centers

of excellence in the United States, with each center managing an estimated 2,000 patients on GLP-1 therapy today. The patients at these centers represent potential initial candidates for Revita, if authorized. The Company's planning addresses physician education, treatment-center readiness and potential reimbursement pathways. Additionally, the newly issued Category III CPT code 1122T takes effect on January 1, 2027.

Advancing the Clinical Evidence for Revita

Revita is being evaluated for weight maintenance in adults with obesity following GLP-1 discontinuation. In the REMAIN-1 Pivotal Cohort, participants treated with Revita retained approximately 80% of their GLP-1-induced weight loss on average at six months, meeting the prespecified six-month co-primary endpoint vs sham (p=0.0023).

Revita was generally well tolerated, with no device- or procedure-related serious adverse events reported through the September 24, 2026, interim data cutoff. Fractyl expects to report 12-month topline results from the REMAIN-1 Pivotal Cohort, including the second co-primary endpoint, in the first quarter of 2027.

About Revita

The Revita® DMR System is Fractyl's lead product candidate, designed to remodel the duodenal lining via a single, minimally invasive endoscopic procedure intended to restore healthy nutrient sensing and signaling disrupted by chronic metabolic disease. By targeting duodenal dysfunction, Revita is designed to address an underlying driver of obesity and enable durable weight maintenance following GLP-1 discontinuation. Revita has received FDA Breakthrough Device Designation for weight maintenance in people with obesity who discontinue GLP-1 therapies. Revita is for investigational use only in the United States and is CE marked in the European Union and United Kingdom.

About Fractyl Health

Fractyl is a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes. The Company's lead product candidate, Revita, is an endoscopic procedural therapy in pivotal development for post-GLP-1 weight maintenance. Fractyl's goal is to change the course of metabolic disease, advancing treatment from chronic management toward prevention and reversal of disease. Fractyl is headquartered in Burlington, Massachusetts.

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 are forward-looking statements. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words.

Forward-looking statements in this press release include, without limitation, statements regarding: the potential benefits of the Company's sharpened strategic focus and reprioritization, including the proposed workforce reduction and its anticipated impact on the Company's expenditures and financial runway; the promise and potential impact of the Company's clinical trial data and product candidates, including Revita's potential for maintaining weight loss after GLP-1 based therapy discontinuation and its potential to be the first procedural therapy for post-GLP-1 weight maintenance; the design, initiation, timing and results of clinical studies or readouts, including readouts from the REMAIN-1 Pivotal Cohort, including 12-month data; the potential launch or commercialization of any of the Company's product candidates or products; the Company's regulatory strategy, including the timing of any potential De Novo marketing application submission and the potential use and benefits of the De Novo pathway (FDA pre-submission feedback is advisory and non-binding, or as to the timing of any such authorization); the potential treatment population or benefits for any of the Company's product candidates or products; the Company's strategic and product development objectives and goals; the Company's expected quarterly cash burn and cash runway; the Company's exploration of strategic alternatives for Rejuva and the potential benefits thereof; 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 risks that are discussed more fully in its filings with the Securities and Exchange Commission (the SEC), including the "Risk Factors" section of its Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents it subsequently files with or furnishes to the SEC, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the SEC on August 10, 2026.

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, it disclaims any obligation to do so, even if subsequent events cause its views to change.

1. Rodriguez PJ, et al. JAMA Netw Open. 2025;8(1):e2457349. jamanetwork.com
2. Prime Therapeutics, three-year GLP-1 persistence analysis, June 25, 2025 (commercial claims, n=5,780, 60-day gap). primetherapeutics.com

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