Fractyl Health Announces Compelling 6-Month Randomized REMAIN-1 Midpoint Data Showing Durable Weight Maintenance with Revita® After GLP-1 Discontinuation

Jan 29, 2026

Revita-treated patients experienced sustained weight maintenance, improved cardiometabolic profile, and reduced food cravings at 6 months compared with sham, with continued excellent safety and tolerability

Patients with above median GLP-1-associated weight loss experienced ~ 70% less post-GLP-1 weight regain with Revita vs sham at 6 months

Results support pivotal study design and further substantiate Revita's potential to be the first durable procedural therapy for post-GLP-1 weight maintenance; topline 6-month pivotal data and potential FDA filing expected in H2 2026

Based on ongoing interactions and favorable safety data to date, the Company has requested FDA feedback on reclassifying Revita under the De Novo pathway, which is expected in Q2 2026

Company to host investor call and webcast today at 8:00 a.m. ET

BURLINGTON, Mass., Jan. 29, 2026 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the Company or Fractyl), a metabolic therapeutics company developing disease-modifying solutions for obesity and type 2 diabetes, today announced positive six-month randomized results from the ongoing REMAIN-1 Midpoint Cohort, a blinded, sham-controlled study evaluating Revita® for weight maintenance following GLP-1 drug discontinuation. These results reinforce the biological rationale for Revita, support the potential durability of effect, and provide increased confidence in the ongoing REMAIN-1 pivotal study.

"These pilot study results build on our prior clinical experience and represent another important validation and step toward establishing Revita as a potential first-in-class therapy for post-GLP-1 weight maintenance," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and CEO of Fractyl Health. "These findings reinforce our confidence in our development strategy, trial design and potential regulatory pathway as we advance toward pivotal readout and potential FDA submission later this year."

Key Six-Month Findings

Data reflect randomized outcomes through 6 months of follow-up. The REMAIN-1 Midpoint Cohort is ongoing, with 12-month randomized data expected in Q3 2026. The Midpoint Cohort was not designed to be sufficiently powered for efficacy analysis, and p-values are provided to describe the strength and consistency of observed treatment effects.

Strong, continued weight maintenance benefit:

- Across the prespecified efficacy population (n=40, with five participants excluded per protocol due to diet and lifestyle noncompliance and only included in the safety population), Revita-treated patients experienced a 4.5% weight regain vs 7.5% in the sham arm at 6 months (p=0.07, one-sided), consistent with meaningful and sustained attenuation of the expected post-GLP-1 rebound trajectory.
- An exploratory analysis of patients who achieved above median weight loss during GLP-1 run-in (n=20) showed that Revita-treated participants experienced 4.2% weight regain versus 13.3% with sham at 6 months, corresponding to an approximately 70% relative reduction in post-GLP-1 weight regain (LS mean difference -9.1%; p=0.004, one-sided).
- As expected, treatment-by-run-in weight loss interaction terms suggested a meaningful relationship between degree of GLP-1-associated weight loss and the magnitude of Revita benefit.

Supportive cardiometabolic and appetite-related exploratory endpoint results consistent with observed weight maintenance:

- Revita-treated patients demonstrated improvements in cardiometabolic lipid parameters versus sham at 6 months, including increased HDL cholesterol (15.5 vs 3.9 mg/dL; p=0.01, one-sided) and reduced triglyceride-to-HDL ratio (-0.2 vs +0.4; p=0.03, one-sided), suggesting improved metabolic regulation following GLP-1 discontinuation.
- Patient-reported outcomes showed meaningful reductions in sweet-food craving versus sham (1.8 vs 3.4; p=0.04, one-sided), supporting a gut-mediated mechanism for attenuated post-GLP-1 appetite drive and weight regain.

Excellent safety and tolerability:

- Revita continued to demonstrate favorable safety and tolerability results through six months, with no treatment-emergent serious adverse events related to the device or procedure, and no study discontinuations due to adverse events.
- No new related adverse events were observed between 3- and 6-month follow up.

“What is particularly compelling about these six-month data is the consistency of the metabolic signal,” said Dr. Adarsh Thaker, M.D., Assistant Professor of Medicine, David Geffen School of Medicine at UCLA. “These patients are typically at highest risk for rapid weight regain after discontinuation, with GLP-1 mediated weight loss followed by sudden drug discontinuation. Seeing a large attenuation in rebound in this population, together with supportive metabolic and appetite-related findings, provides even further evidence that Revita may be addressing underlying biological drivers of post-GLP-1 weight regain rather than simply delaying it. I cannot wait to see the pivotal REMAIN-1 results later this year.”

Progress in US Regulatory Strategy

Based on ongoing interactions with the U.S. Food and Drug Administration (FDA) and the encouraging safety and tolerability data observed to date, Fractyl requested FDA feedback on potentially reclassifying Revita under the De Novo pathway, rather than a Premarket Approval (PMA). The De Novo pathway is intended for novel medical devices with low-to-moderate risk profiles and may enable a more efficient, risk-based regulatory review process. The Company expects FDA feedback regarding the potential for use of the De Novo pathway in the second quarter of 2026.

Advancing Toward Value-Driving Anticipated Catalysts in 2026:

Fractyl is advancing toward multiple anticipated clinical and regulatory milestones across its REMAIN-1 weight maintenance program, supporting a clear and sequential path toward pivotal readout and potential U.S. regulatory submission:

- February 2026: Complete randomizations in REMAIN-1 Pivotal Cohort
- Q2 2026: FDA feedback on potential for use of De Novo pathway
- Q2 2026: 1-year REVEAL-1 Cohort data
- Q3 2026: 1-year REMAIN-1 Midpoint Cohort randomized data
- H2 2026: Topline 6-month randomized data from REMAIN-1 Pivotal Cohort
- H2 2026: Potential FDA marketing application submission in post-GLP-1 weight maintenance

Conference Call and Webcast

Fractyl Health will host a conference call and webcast today, January 29, 2026, at 8:00 a.m. Eastern Time. To access the live conference call by phone, dial 1-877-425-9470 (domestic) or 1-201-389-0878 (international), and provide the access code 13758486. A live webcast of the conference call can be accessed in the “Events” section of Fractyl’s website at **ir.fractyl.com.** The webcast will be archived and available for replay for at least 30 days after the event.

About Fractyl Health

Fractyl Health is a metabolic therapeutics company focused on pioneering disease-modifying treatments that address the root causes of obesity and type 2 diabetes. The Company’s approach targets organ-level dysfunction to enable durable metabolic control without the burden of chronic therapy. Fractyl is headquartered in Burlington, Massachusetts.

About Revita®

Revita is Fractyl Health’s lead product candidate, designed to remodel the duodenal lining via a one-time, minimally invasive endoscopic procedure intended to restore healthy nutrient sensing and signaling disrupted by chronic metabolic disease. Revita has received FDA Breakthrough Device designation for weight maintenance in people with obesity who discontinue GLP-1 therapies. Revita is investigational in the United States and is CE marked in the European Union and United Kingdom.

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 promise and potential impact of our product candidates, including Revita’s potential for preserving weight loss after GLP-1 drug discontinuation; the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, including readouts from the REMAIN-1 Midpoint Cohort; the potential treatment population or benefits for any of our product candidates or products; our regulatory strategy, including potential benefits of the De Novo pathway; 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, and positioning our Company at the forefront of the global opportunity for metabolic care or a late-stage, pre-commercial company poised to redefine 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 factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, filed with the Securities and Exchange Commission on November 12, 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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