Fractyl Health Completes Randomization in REMAIN-1 Pivotal Cohort of Revita® for Post-GLP-1 Weight Maintenance

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Topline 6-month pivotal data expected in early Q4 2026 with potential FDA marketing application submission expected in late Q4 2026

Company reiterates cash runway guidance into early 2027, beyond anticipated pivotal data readout

BURLINGTON, Mass., Feb. 26, 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, today announced completion of participant randomization in its REMAIN-1 Pivotal Cohort, a double-blind, sham-controlled study evaluating Revita® for weight maintenance following GLP-1 therapy discontinuation.

“Completion of randomization in the REMAIN-1 Pivotal Cohort marks an important milestone as we advance Revita toward the definitive clinical evidence we believe will clearly establish its role in post-GLP-1 weight maintenance,” said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. “This study was prospectively designed and statistically powered to demonstrate Revita’s effect. The clinical insights from our REVEAL-1 and REMAIN-1 Midpoint Cohorts, as well as ongoing follow-up from our Germany Real-World Registry study, informed both the study design and our confidence in this program. With randomization now complete and our balance sheet positioned to support us through and beyond the pivotal readout, our focus is on disciplined execution as we prepare to report topline 6-month results in early Q4 2026. We are grateful to the participants, investigators, and clinical site teams whose commitment has made this progress possible.”

Pivotal Study Designed to Deliver Definitive Evidence

The REMAIN-1 Pivotal Cohort is a randomized, double-blind, sham-controlled study evaluating Revita in adults with obesity (BMI ≥30 kg/m^2 and ≤45 kg/m^2) who achieved ≥15% total body weight loss on tirzepatide. Following GLP-1 discontinuation, participants were randomized 2:1 to receive Revita or a sham endoscopic procedure. The co-primary endpoints are percent total body weight regain (Revita vs sham) at 6 months, and proportion of participants maintaining ≥5% total body weight loss at 12 months (responder rate). All participants receive standardized diet and lifestyle counseling throughout the study.

“The level of patient interest we experienced at Baylor was remarkable. We ultimately trained three endoscopists and installed two consoles to perform the Revita procedure to meet demand during the study,” said Mohammed Othman, M.D., Professor of Medicine, Baylor College of Medicine, and a REMAIN-1 Investigator. “Weight regain after GLP-1 discontinuation is a challenge I see regularly in clinical practice, and the enthusiasm from both patients and referring physicians throughout this trial reflects a real and urgent unmet need.”

2026 Revita Clinical and Regulatory Milestones

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:

- Q2 2026: U.S. Food and Drug Administration (FDA) feedback on potential for use of the De Novo pathway for Revita.
- Q2 2026: 1-year REVEAL-1 Cohort data.
- Q3 2026: 1-year REMAIN-1 Midpoint Cohort randomized data.
- Early Q4 2026: Topline 6-month randomized data from REMAIN-1 Pivotal Cohort.
- Late Q4 2026: Potential FDA marketing application submission in post-GLP-1 weight maintenance. The timing and form of submission may be informed by FDA feedback on the potential use of the De Novo pathway for Revita, which is currently expected in Q2 2026.

The Company reiterates its previously announced cash runway into early 2027, making it well-positioned to fund operations through key 2026 clinical and regulatory milestones, including the Revita pivotal readout.

About Fractyl Health
Fractyl Health is a clinical stage metabolic therapeutics company focused on pioneering novel approaches to treat 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 for investigational use only 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: our anticipated financial performance, including cash and cash equivalents, our expected cash runway, 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 REVEAL-1 Cohort, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the potential treatment population or benefits for any of our product candidates or products; our regulatory strategy, including potential use and benefits of the De Novo pathway; our strategic and product development objectives and goals, including with respect to enabling long-term weight maintenance following GLP-1 therapy discontinuation; 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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