Fractyl Health to Host Virtual Commercial Strategy Day on Tuesday, September 1, 2026: The Potential Path to Commercializing Revita®, a Procedural Therapy for Post-GLP-1 Weight Maintenance

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BURLINGTON, Mass., Aug. 20, 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 that it will host a virtual Commercial Strategy Day on Tuesday, September 1, 2026 at 11:00 AM ET to discuss the potential commercial opportunity and go-to-market strategy for Revita®. To register, click here.

The event follows the Company's positive one-year randomized data from the REMAIN-1 Midpoint Cohort, which showed weight maintenance one year after a single Revita procedure. The treatment effect was greatest in a pre-specified optimized population, combining complete duodenal ablation (>14 cm) with higher GLP-1-induced run-in weight loss (≥17.5%), where Revita-treated participants maintained approximately 84% of their GLP-1-induced weight loss compared to 46% in sham participants (least squares mean weight regain of 4.1% versus 13.5% of body weight; n=10 versus 8 for Revita versus sham).

An estimated 30 million U.S. adults are currently on GLP-1 therapy and Revita is designed to be their one-time procedural off-ramp when they stop. Ahead of the anticipated early Q4 2026 six-month topline readout of the REMAIN-1 Pivotal Cohort, Fractyl's management team will discuss the potential market opportunity for Revita, its plans for bringing the therapy to patients and providers if it receives FDA marketing authorization, the reimbursement path ahead, and the Company's potential FDA De Novo marketing application submission anticipated in late Q4 2026. Together, these milestones mark Fractyl's transition from late stage clinical development toward commercial readiness.

A live Q&A session will follow the formal presentations. A live webcast of the event can be accessed in the "Events" section of Fractyl Health's website at http://ir.fractyl.com. The webcast will be archived and available for replay for 90 days following the live event.

About Fractyl Health

Fractyl is a clinical-stage metabolic therapeutics company advancing two differentiated candidates designed to target the root causes of obesity and T2D: Revita, a procedural therapy in pivotal development for post-GLP-1 weight maintenance, and Rejuva, an AAV-based gene therapy platform with its lead candidate RJVA-001 entering first-in-human clinical studies. Fractyl's goal is to advance metabolic disease treatment from chronic management toward prevention and reversal of disease. Fractyl is headquartered in Burlington, Massachusetts.

About Revita

Revita is Fractyl'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: the promise and potential impact of Fractyl's preclinical or clinical trial data and product candidates, including Revita's potential for maintaining weight loss after GLP-1 based therapy discontinuation; the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, including readouts from the REMAIN-1 Pivotal Cohort; communications with regulators regarding the REVEAL-1 Cohort, the potential launch or commercialization of any of Fractyl's product candidates or products, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the potential treatment population or benefits for any of Fractyl's product candidates or products; Fractyl's regulatory strategy, including potential use and benefits of the De Novo pathway (FDA pre-submission feedback is advisory and non-binding, and there is no assurance that FDA will accept a De Novo marketing application submission or that the

Revita DMR System will receive marketing authorization); Fractyl's commercial readiness activities and the development of commercial infrastructure; Fractyl's strategic and product development objectives and goals; 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 Fractyl'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 Fractyl's filings with the Securities and Exchange Commission (the SEC) including the "Risk Factors" section of Fractyl's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents Fractyl subsequently files with or furnishes to the SEC, including Fractyl's 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 Fractyl may elect to update such forward-looking statements at some point in the future, Fractyl disclaims any obligation to do so, even if subsequent events cause Fractyl's views to change.

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