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Positive One-Year Randomized REMAIN-1 Midpoint Cohort Results

July 15, 2026
NASDAQ:GUTS

Revita is for investigational use only in the United States. Revita has a CE mark in the EU/UK.

Legal disclaimer

The study database has not been locked as this is an ongoing study, and the data are subject to further cleaning and validation.

Forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation 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 presentation include, without limitation, statements regarding: the promise and potential impact of our clinical trial data and product candidates, including Revita’s potential for maintaining weight loss after GLP-1 based therapy discontinuation and stabilizing cardiometabolic parameters; the translatability of results and scalability of technique related to Revita; the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, including readouts from the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the potential launch or commercialization of any of our product candidates or products; our 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 Revita will receive marketing authorization); the potential treatment population or benefits for any of our product candidates or products; our 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 our 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 our filings with the Securities and Exchange Commission (the SEC), including the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents we subsequently file with or furnish to the SEC, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 12, 2026. These forward-looking statements are based on management’s current estimates and expectations. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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Agenda

REMAIN-1 Midpoint Cohort One-Year Results

01

REMAIN-1 Midpoint Cohort One-year results

Up to 84% of weight loss retained with Revita vs 46% with sham at one year when an adequate dose of ablation is used

02

KOL Discussant: Dr. Adarsh Thaker

Co-lead, UCLA Bariatric Endoscopy Program and a Principal Investigator in REMAIN-1

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Four pillars driving our conviction in Revita for post-GLP-1 weight maintenance

Topline pivotal data expected early Q4 ‘26 and potential FDA De Novo submission late Q4 ‘26[1]

1

The Clinical Signal Is Real

- **Up to 84% of weight loss retained with Revita vs 46% with sham at one year in REMAIN-1 Midpoint Cohort**
- **Ablation-length dose-response drives efficacy and durability through one year**

2

Pivotal Is Built to Win

- **Powered at >95%** with conservative assumptions
- **Dose-response and high-responder subgroup** are well represented and pre-specified in pivotal SAP

3

Clear Path to Commercial Value

- **Favorable FDA De Novo feedback received**
- **Large, defined, and growing market** with new introduction of GLP-1 coverage to CMS patients via Bridge program as of July ‘26

4

Funded Through Definitive Data[1]

- **$63M cash on hand at end of Q1’26**
- **Cash runway extends into early 2027 and through pivotal readout in early Q4 2026**
- **Funded to key value inflection** without planned incremental capital raise

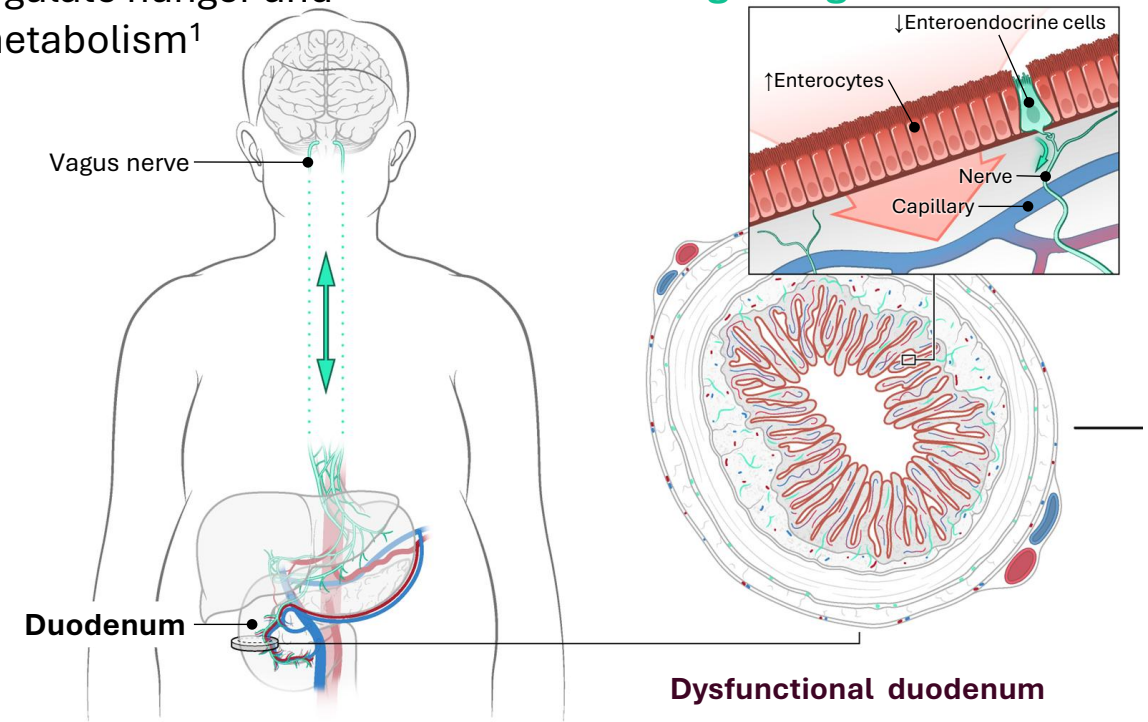
[1] These forward-looking statements are based on management’s current estimates and expectations. Refer to the latest disclosures filed with the SEC for a discussion regarding Risk Factors to these and other estimates and expectations.

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Duodenal mucosa: A compelling target for durable metabolic control

Nutrient signals from the duodenum travel via the vagus nerve to regulate hunger and metabolism[1]



Diet-induced mucosal changes lead to **increased nutrient uptake** and **impaired gut-to-brain signaling**[2]

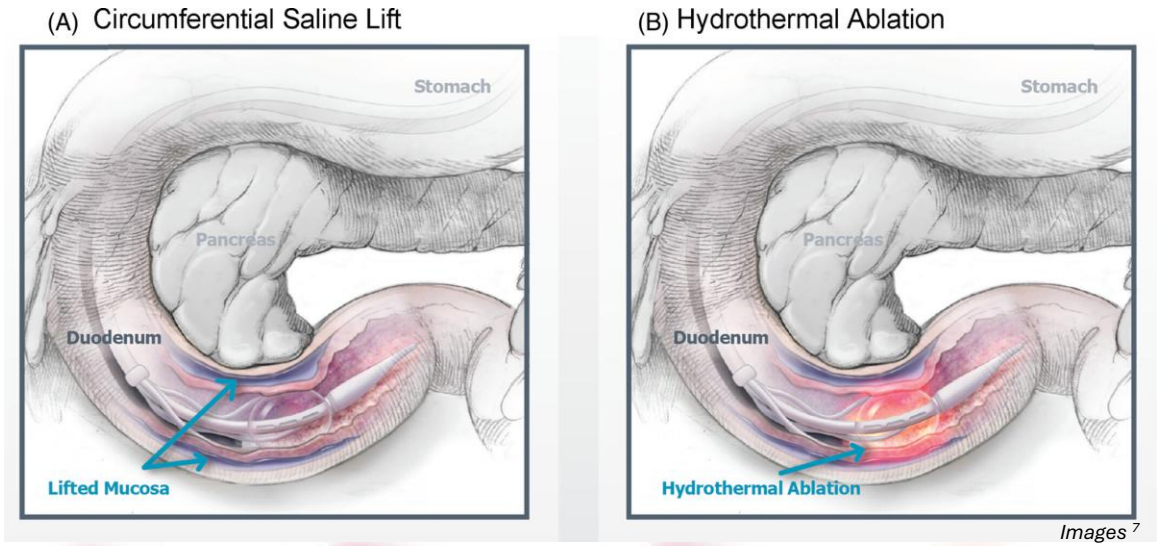
- **Duodenum:** First part of small intestine and critical metabolic signaling center in the gut.
- **Diet link:** Modern high-fat, high-sugar diets damage the duodenal mucosa, driving metabolic dysfunction.
- **Root cause:** Duodenal dysfunction, observed in animal models and in humans, is now considered a root cause of obesity and metabolic disease.[3]

[1] Kentish SJ, Page AJ. J Physiol. 2015;593(4):775-786. [2] Aliluev A, et al. Nat Metab. 2021;3(9):1202-1216. [3] D'Alessio DA, Campbell JE. Diabetes Obes Metab. 2026;28(S3):3-15.

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Revita targets duodenal dysfunction: designed to durably reset abnormal weight setpoint[1-4]



- **Extent of dysfunction:** In animal models, duodenal dysfunction extends along the entire length of the duodenum, potentially into the proximal jejunum.[5]
- **Revita technical innovation:** Device development now enables routine ablation of the full duodenum to its end, allowing longer ablation lengths for profile optimization and dose-ranging.

Revita is for investigational use only in the United States; CE marked in the EU/UK. 1. Mah AT, et al. Endocrinology. 2014;155:3302-3314. 2. Mao J, et al. Diabetes. 2013;62:3736-3746. 3. de Moura EGH, et al. Endosc Int Open. 2019;7:E685-E690. 4. Haidry RJ, et al. Gastrointest Endosc. 2019;90:673-681. 5. Hoyt J, et al. Diabetes Obes Metab. 2024;1-12.

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REMAIN-1 Midpoint Cohort weight maintenance pilot

Designed to inform design and execution of REMAIN-1 Pivotal Cohort

Patient population

- Adults with obesity (BMI 30-45 kg/m^2)
- GLP-1 naïve; no T2D
- n≈45

Efficacy endpoints

- % TBW change Revita vs sham at 3 and 6 months

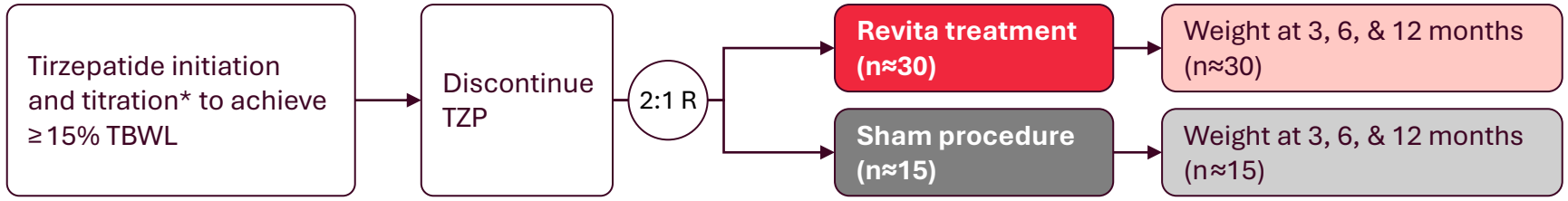
Study design

- Randomized (2:1 Revita vs Sham), double-blind, sham-controlled
- TZP administration to achieve ≥ 15% TBWL, then discontinued
- Diet and lifestyle counseling throughout

Key milestones

- **Midpoint cohort 3-mo data:** Sept '25
- **Midpoint cohort 6-mo data:** Jan '26
- **Midpoint cohort 12-mo data:** July '26

Study design



*Tirzepatide run-in modeled from SURMOUNT-4 trial. Abbreviations: BMI, body mass index; GLP-1, glucagon-like peptide 1; R, randomization; TBW, total body weight; TBWL, total body weight loss; TZP, tirzepatide; T2D, type 2 diabetes.

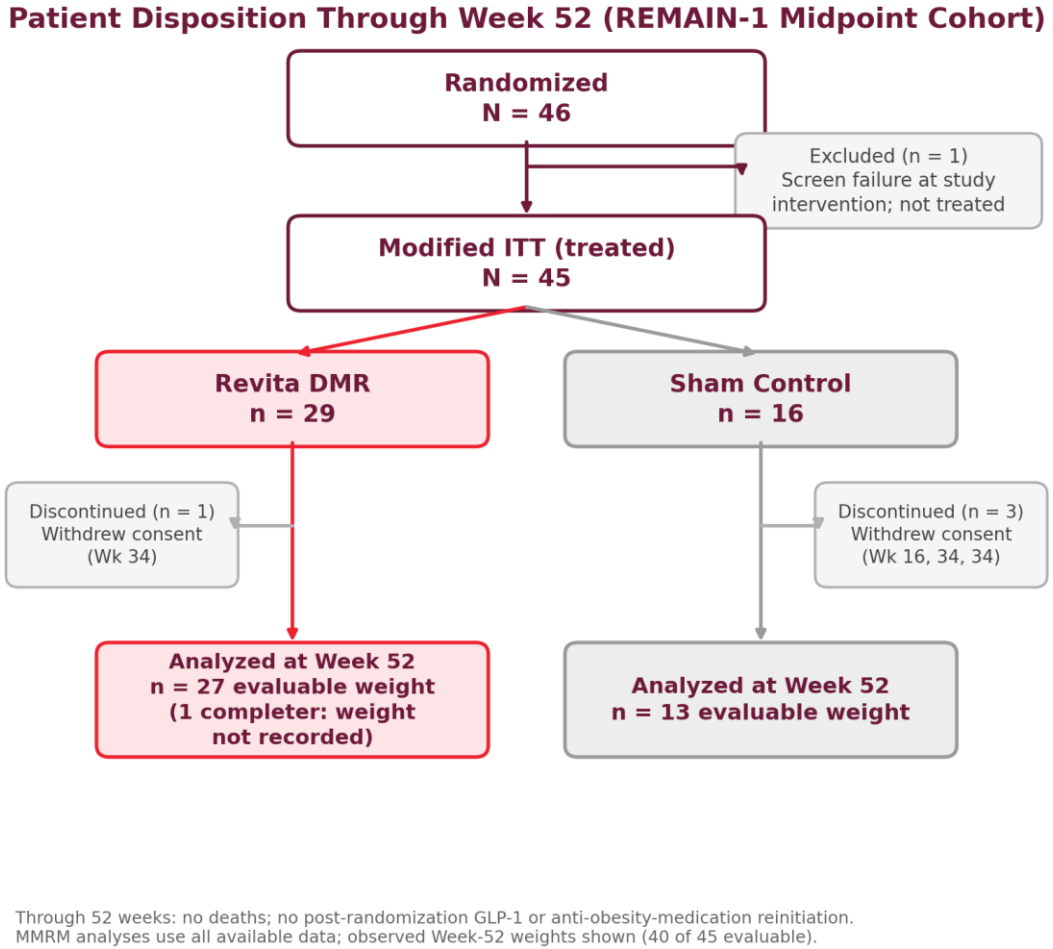
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REMAIN-1 Midpoint Cohort patient disposition

High retention through one year of follow-up

- 41 of 45 treated participants (91%) remained on study through Week 52 (12 months)
- Only 4 discontinued (1 Revita, 3 sham): all withdrew consent
- No post-randomization GLP-1 reinitiation through 52 weeks
- Safety and efficacy analyses use all available data (n=45)
- Treatment policy estimand and efficacy estimand are identical



Through 52 weeks: no deaths; no post-randomization GLP-1 or anti-obesity-medication reinitiation.
MMRM analyses use all available data; observed Week-52 weights shown (40 of 45 evaluable).

REMAIN-1 Midpoint Cohort. N=46 randomized; 1 screen-failure excluded (not treated); N=45 modified intention-to-treat (mITT). Abbreviations: DMR, duodenal mucosal resurfacing; GLP-1, glucagon-like peptide-1; mITT, modified intention-to-treat; MMRM, mixed-model repeated measures; R, randomization.

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Two key observations from Midpoint Cohort 6-month results informed pivotal Statistical Analysis Plan

MIDPOINT COHORT OBSERVATION	IMPLICATION	PIVOTAL SAP DEFINITION
Dose Response: Effect size relates to ablation length: more complete ablation, more weight maintenance at 6 months (all 29 patients; consistent with prior DMR work in T2D[1]).	The procedure has a controllable 'dose response'; ablation completeness drives clinical effect.	Per-Protocol population defined as complete ablation of >14 cm; pre-specified as a key secondary endpoint
Responder Population: Effect size relates to magnitude of prior GLP-1 loss: high GLP-1 responders (≥17.5% TBWL) show widening separation vs sham.	Run-in weight loss (RWL) on GLP-1 modifies effect size; high GLP-1 responders are the patients most prone to regain after GLP-1 discontinuation.	RWL fitted as a covariate (LS means at the 20% reference) in mITT; ≥17.5% enrichment subgroup is pre-specified as a key secondary endpoint.

[1]Rajagopalan et al Diabetes Care 2016 Dec;39(12):2254-2261. MMRM model with Treatment x RWL interaction term , evaluated at RWL=20%. DMR, duodenal mucosal resurfacing; mITT, modified intention-to-treat; MMRM, mixed-model repeated measures; RWL, run-in weight loss; TBWL, total body weight loss

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Midpoint Cohort analysis populations



Full cohort (mITT)

All randomized, treated participants. N = 45 (29 Revita, 16 sham); the primary analysis set for Co-Primary #1 at 6 months in pivotal study



High run-in loss

Participants who lost ≥17.5% of body weight on tirzepatide during run-in: high GLP-1 responders. Key secondary endpoint #1 in pivotal study



Complete ablation

Revita participants who received > 14cm duodenal ablation (the pivotal per-protocol 'dose'). Key secondary endpoint #2 in pivotal study



Optimized

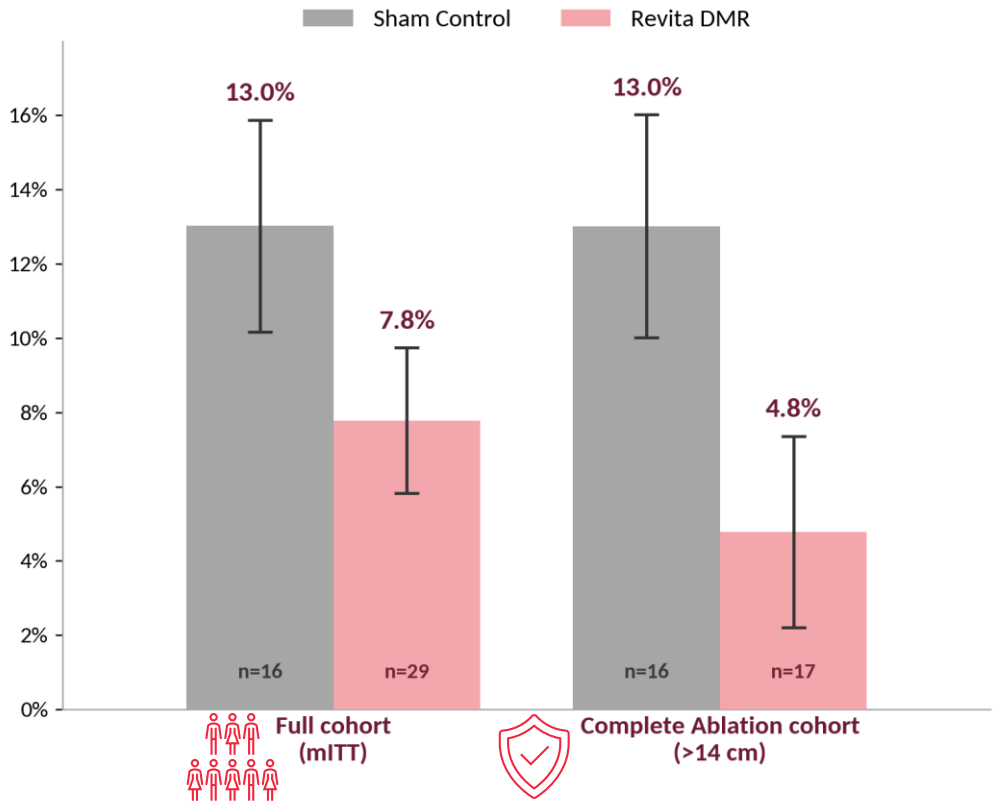
Responder population identified in the intersection: high run-in loss and complete ablation, most consistent with ultimate clinical profile. Key secondary endpoint #3 in pivotal study

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Revita reduces weight regain and benefits patients most when adequate dose of ablation is used

% Weight Change from Baseline at 12 months



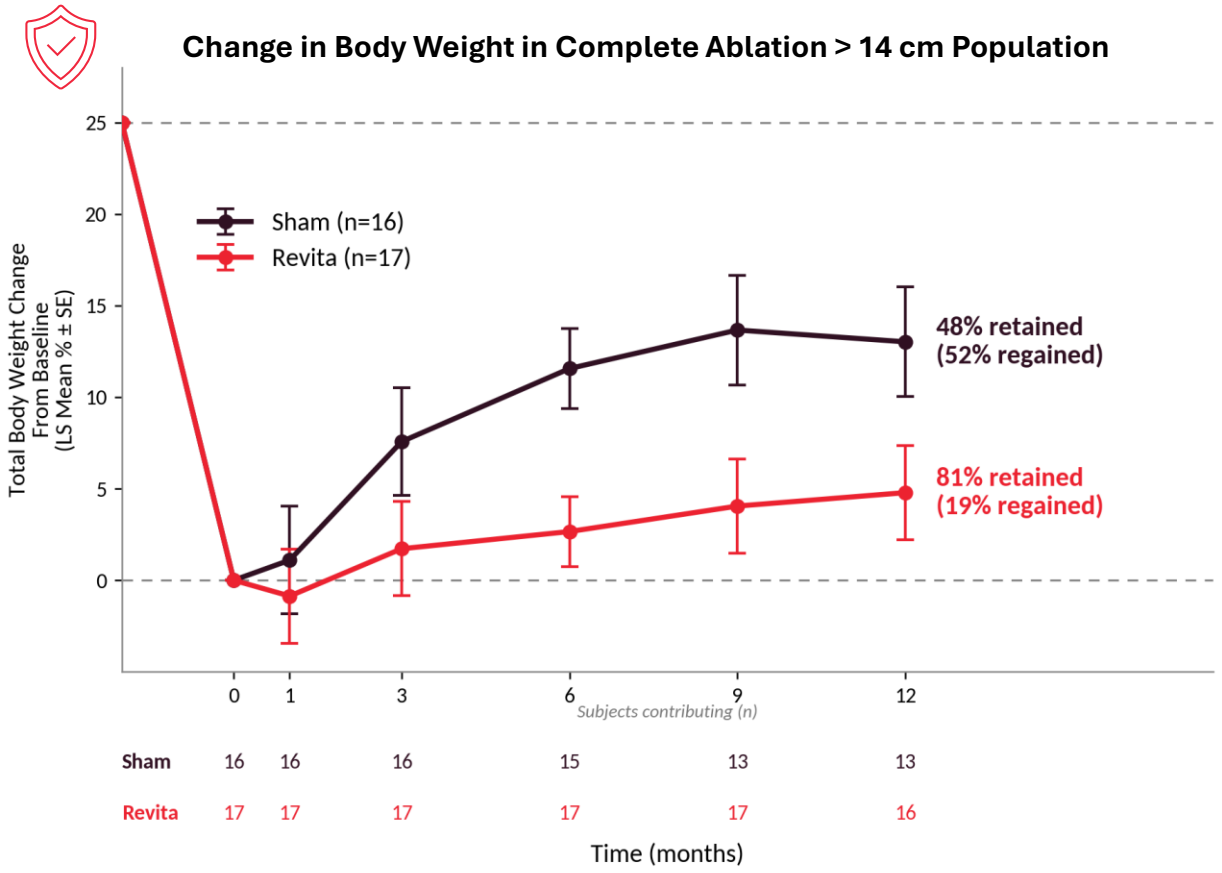
- At 12 months, Revita reduced weight regain vs sham: 40% in the full cohort, rising to > 60% in patients with complete ablations > 14 cm
- Sham regain at 12 months consistent with 14% regain reported in SURMOUNT-4[1]

Full cohort (mITT): Sham n=16, Revita n=29. Complete Ablation cohort (> 14 cm ablation): Sham n=16, Revita n=17. LS-mean % total body-weight change from baseline at 12 months; MMRM, compound-symmetry covariance, estimated at 20% run-in weight loss; error bars ±SE. Exploratory REMAIN-1 Midpoint Cohort analysis; not powered for formal inference. 1. Aronne LJ, et al. Continued treatment with tirzepatide for maintenance of weight reduction (SURMOUNT-4). JAMA. 2024;331(1):38-48. Abbreviations: mITT, modified intention-to-treat; MMRM, mixed-model repeated measures; LS-mean, least-squares mean; SE, standard error.

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Revita cohort retained 81% of weight loss at 12 Months vs 48% in sham arm in complete ablation population



Ablation-length dose-response drives efficacy

Incorporated into Pivotal SAP as "Per Protocol" population

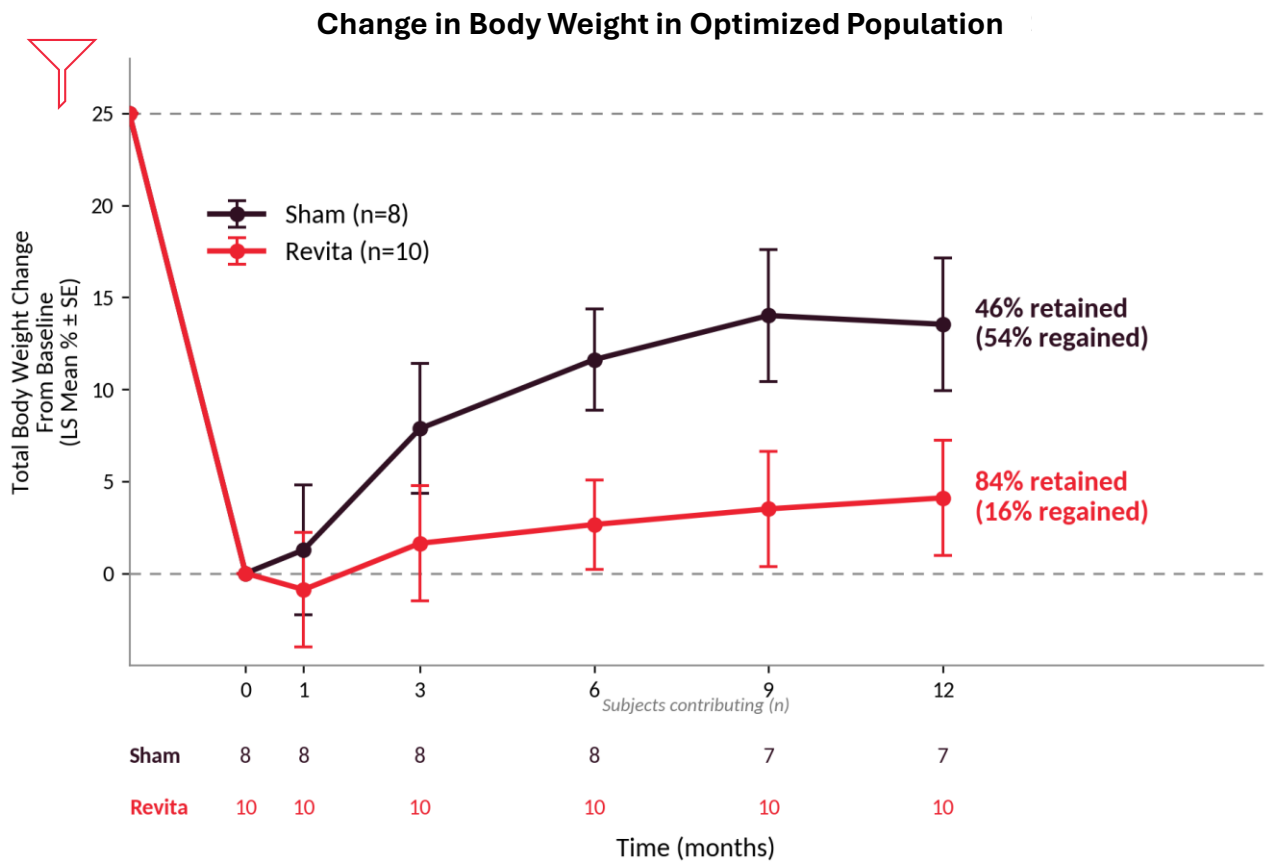
Pivotal Cohort implication:
Pivotal Cohort median ablation length is 16cm, implying that a majority of pivotal participants received complete ablations

Complete Ablation population: > 14 cm duodenal ablation, no run-in weight-loss restriction (Sham n=16, Revita n=17). Y-axis: LS-mean % total body-weight change from baseline; MMRM, compound-symmetry covariance, estimated at 20% run-in weight loss; error bars ± SE; n contributing shown per visit below axis. Retention = % of run-in weight loss maintained at 12 months. Exploratory REMAIN-1 Midpoint Cohort analysis; not powered for formal inference. Abbreviations: MMRM, mixed-model repeated measures; LS-mean, least-squares mean; SE, standard error; SAP, statistical analysis plan.

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84% of weight loss retained at 12 months in Optimized Population (complete ablations & ≥ 17.5% RWL)



Right "dose" in the right patient

16% regain in Revita Cohort vs 54% regain in sham **represents > 70% reduction vs sham.**

Pivotal Cohort implication:

Pivotal Cohort mean TBWL on run-in is 18.3%, implying that a majority of pivotal participants have ≥ 17.5% RWL

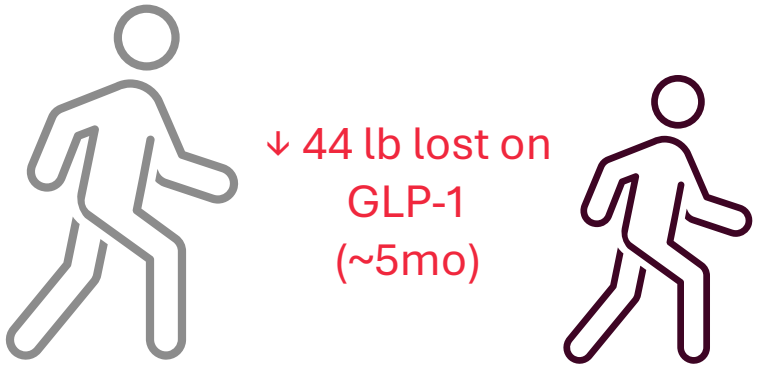
Optimized population: complete ablation (> 14 cm) and run-in weight loss ≥ 17.5% (Sham n=8, Revita n=10). Y-axis: LS-mean % total body-weight change from baseline; MMRM, compound-symmetry covariance, estimated at 20% run-in weight loss; error bars ± SE; n contributing shown per visit below axis. Retention = % of run-in weight loss maintained at 12 months. Exploratory REMAIN-1 Midpoint Cohort subgroup; not powered for formal inference.
Abbreviations: MMRM, mixed-model repeated measures; LS-mean, least-squares mean; SE, standard error; RWL, run-in weight loss; TBWL, total body weight loss.

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Effect size in Midpoint Cohort at 12 Mo is clinically meaningful and commercially attractive

Mean results as illustrative example[1]



220 lb at screening **176 lb at randomization**

SHAM · 1 YEAR

199 lb, regains 23 lb

21 lb

kept off at one year

REVITA · 1 YEAR

184 lb, regains 8 lb

36 lb

kept off at one year

1. Complete ablation population in REMAIN-1 Midpoint Cohort

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Favorable safety and tolerability through 12 months

No device-related serious AEs: a mild, periprocedural profile that supports outpatient use

- **No new device-related TEAEs between 6 and 12 months.**
- **No device-related SAEs:** one SAE (blocked bile duct) adjudicated as unrelated to the device or procedure.
- **No excess AEs with Revita:** any-TEAE rates matched sham (24% vs 25%).
- **Mild and periprocedural:** all 4 related events were Grade 1, on procedure day, and transient.
- **1 new diagnosis of Type 2 Diabetes in sham arm vs zero in Revita arm**

Treatment-Emergent Adverse Events (TEAEs)	Revita (n=29)	Sham (n=16)	Total (N=45)
Patients experiencing any TEAE, n (%)	**7 (24)**	**4 (25)**	**11 (24)**
TEAEs by grade, n (events)	**12**	**5**	**17**
Grade ≥3 TEAEs	1 (8)	0	1*
Grade 2 TEAEs	1 (8)	1 (20)	2**
Grade 1 TEAEs	10 (83)	4 (80)	14 (82)
Related TEAEs (probably related), n	**4**	**0**	**4**
Abdominal discomfort	1	0	1
Nausea	1	0	1
Dry mouth	1	0	1
Sore throat	1	0	1

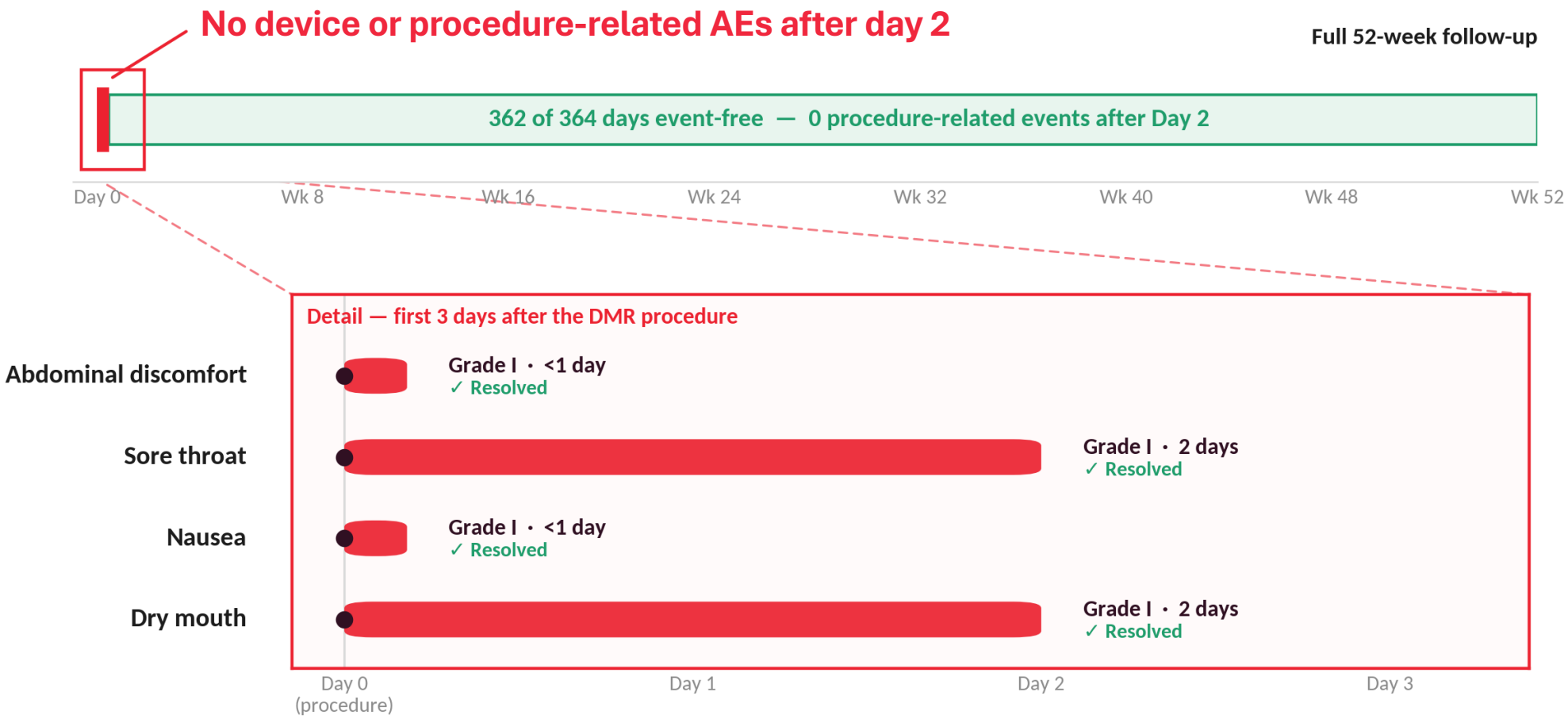
*1 SAE: blocked bile duct (Grade IIIb, day 65); unrelated to device or procedure.
**2 Grade 2 AEs: Revita worsening hypertension (day 258); Sham urinary tract infection (day 239); both unrelated.
Related TEAEs = probably related to device/procedure; all Grade 1, onset day 0. Two Sham AEs previously ungraded in EDC: nausea (day 0), Type 2 diabetes (day 363) are now classified Grade 1.REMAIN-1 Stage 2a, through 52 weeks (12 months). AE, adverse event; TEAE, treatment-emergent adverse event; SAE, serious adverse event.

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Procedure-related AEs: Mild, immediate, short-lived

No related SAEs: a mild, periprocedural profile that supports outpatient use



Abbreviations: DMR, duodenal mucosal resurfacing; AE, adverse event; SAE, serious adverse event.

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REMAIN-1 pivotal study in weight maintenance

Pivotal Cohort fully randomized; 6-mo topline pivotal data anticipated in early Q4 2026

Patient population

- Adults with obesity (BMI 30-45 kg/m^2)
- GLP-1 naïve; no T2D
- n≈315

Co-primary endpoints

- % TBW regain: Revita vs sham at 6 months *and*
- Responder rate: % participants who maintain weight loss at 12 months

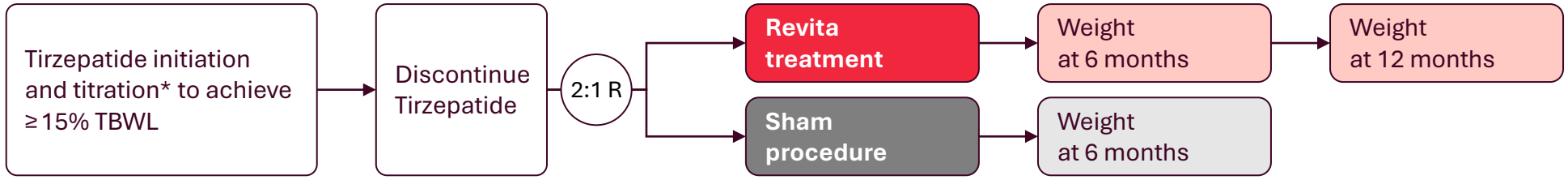
Study design

- Randomized (2:1 Revita vs Sham), double-blind, sham-controlled
- TZP administration to achieve ≥ 15% TBWL, then discontinued
- Diet and lifestyle counseling throughout

Anticipated milestones[1]

- **Complete randomizations:** Feb '26
- **Topline 6-month pivotal data:** Early Q4 '26
- **Potential De Novo marketing application submission:** Late Q4 '26

Study design



*Tirzepatide run-in modeled from SURMOUNT-4 trial. [1]These forward-looking statements are based on management's current estimates and expectations.Refer to the latest disclosures filed with the SEC for a discussion regarding Risk Factors to these and other estimates and expectations. Abbreviations: BMI, body mass index; GLP-1, glucagon-like peptide 1; R, randomization; TBW, total body weight; TBWL, total body weight loss; TZP, tirzepatide; T2D, type 2 diabetes.

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Co-primary endpoints very well powered for pivotal trial success

First co-primary: % TBW regain: Revita vs sham at 6 months

Illustrative sham 6-mo regain in mITT[1]	Revita regain needed to win[1,2]	Observed in Midpoint Cohort[1,3]	Projected pivotal p-value[4]
10%	≤ 7.4%	5.1%	*p<0.05*
11.6% (base case, current)	≤ 9.0%	5.1%	*p<0.05*
12.5%	≤ 9.9%	5.1%	*p<0.05*

Second co-primary: Responder rate: % of Revita patients maintain ≥ 5% TBWL at 12 months



1 Values shown are model-based estimates (mITT MMRM at the 20% run-in weight-loss reference). REMAIN-1 Midpoint Cohort, exploratory.
2 Maximum Revita weight regain at which the pivotal reaches statistical significance vs the sham scenario shown (~ 2.5-point gap at pivotal N=315).
3 5.1% = LS-mean percent total body-weight regain from post-run-in baseline at 6 months (Week 26); mITT MMRM at 20% run-in weight-loss reference; n=29 Revita. REMAIN-1 Midpoint Cohort, exploratory.
4 Two-sided; Revita vs sham, pivotal N=315, randomized 2:1 (Revita:sham). Sham values illustrative.
Abbreviations: LS-mean, least-squares mean; mITT, modified intention-to-treat; MMRM, mixed-model repeated measures; TBW, total body weight; TBWL, total body weight loss; .

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Key takeaways from REMAIN-1 Midpoint Cohort results

Substantial Weight Loss Retained at One Year

- Up to 84% of on-drug weight loss retained with Revita at one year off GLP-1 when adequate dose of ablation is used vs 46% in sham
- All physicians achieved complete ablations in the pivotal, which bodes well for commercial training program
- Given absence of any dose-limiting toxicity, there is potential room for even further profile optimization

Excellent Safety and Tolerability Profile

- Essentially no safety signal observed over sham upper endoscopy in this Cohort through 1 year.
- Periprocedural AE profile supports potential broad outpatient endoscopic use

Well-Powered Pivotal

- Pivotal study well powered to deliver clinically and commercially valuable results.
- Topline pivotal data expected in early Q4 2026, with potential De Novo regulatory filing in late Q4 2026.[1]

[1] These forward-looking statements are based on management's current estimates and expectations. Refer to the latest disclosures filed with the SEC for a discussion regarding Risk Factors to these and other estimates and expectations. AE, adverse event

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A Treating Physician's Perspective from the Endoscopy Suite

Adarsh M Thaker, MD
Assistant Professor of Medicine,
David Geffen School of Medicine at UCLA
Co-lead, UCLA Bariatric Endoscopy Program
Principal Investigator, REMAIN-1

Disclosure: Dr. Thaker is a paid Fractyl Health clinical advisor and a REMAIN-1 investigator.

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A clear, near-term path to potential launch

Now · Jul 2026

1

REMAIN-1 Midpoint Cohort 12-Mo randomized results

Q3 2026

2

Fractyl Health ($GUTS) investor day
Details coming soon

Early Q4 2026

3

Pivotal topline: 6-month randomized trial results

Late Q4 2026

4

Potential FDA De Novo submission

5

Potential clearance and launch with reimbursement in place

These forward-looking statements are based on management's current estimates and expectations. Refer to the latest disclosures filed with the SEC for a discussion regarding Risk Factors to these and other estimates and expectations. Revita is investigational: commercialization is subject to REMAIN-1 results and FDA marketing authorization, neither of which is assured.

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Appendix

Revita Reduces Weight Regain and Benefits Patients Most When Adequate Dose of Ablation is Used

Complete Ablation (>14 cm)	Sham (n=16)	Revita (n=17)
Weight regain, % of baseline	13.0%	4.8%
Weight regain, % of pre-tirzepatide weight	10.4%	3.8%
GLP-1 weight loss retained	48%	81%

Full cohort (mITT): Sham n=16, Revita n=29. Complete Ablation cohort (> 14 cm ablation): Sham n=16, Revita n=17. LS-mean % total body-weight change from baseline at 12 months; MMRM, compound-symmetry covariance, estimated at 20% run-in weight loss; error bars ±SE. Exploratory REMAIN-1 Stage 2a Midpoint Cohort analysis; not powered for formal inference.

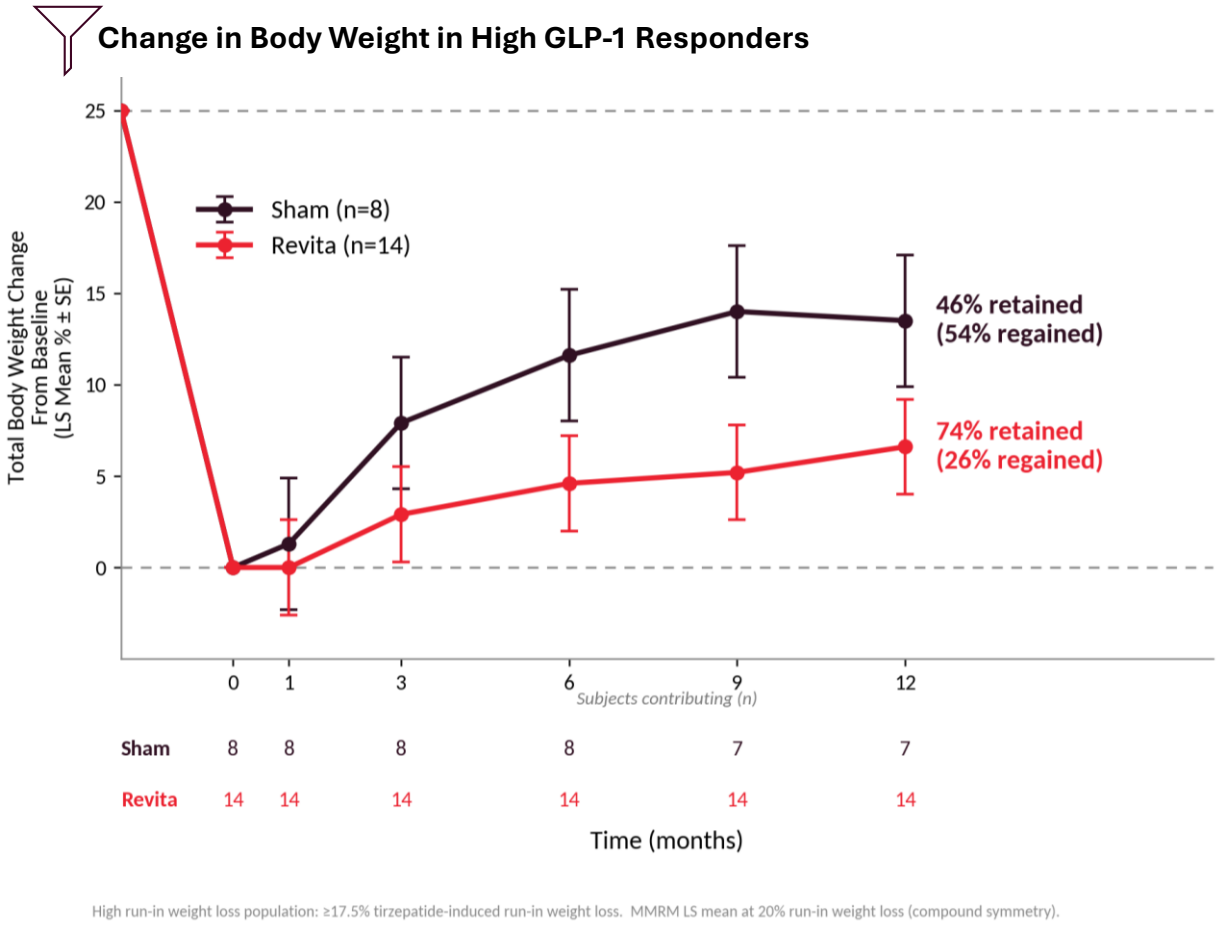
1. Aronne LJ, et al. Continued treatment with tirzepatide for maintenance of weight reduction (SURMOUNT-4). JAMA. 2024;331(1):38-48.

Abbreviations: mITT, modified intention-to-treat; MMRM, mixed-model repeated measures; LS-mean, least-squares mean; SE, standard error.

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Benefit is strong in patients who lost the most on GLP-1



High run-in weight loss population: ≥17.5% tirzepatide-induced run-in weight loss. MMRM LS mean at 20% run-in weight loss (compound symmetry).

Response tracks GLP-1 weight loss

Revita retained 74% of run-in weight loss vs 46% in sham.

Pivotal Cohort implication:

Pivotal Cohort mean run-in TBWL is 18.3%, implying most pivotal participants are high GLP-1 responders.

Y-axis: LS-mean % total body-weight change from baseline; MMRM, compound-symmetry covariance, estimated at 20% run-in weight loss; error bars ± SE; n contributing shown per visit below axis. Retention = % of run-in weight loss maintained at 12 months. Exploratory REMAIN-1 Midpoint Cohort analysis; not powered for formal inference. Abbreviations: MMRM, mixed-model repeated measures; LS-mean, least-squares mean; SE, standard error; SAP, statistical analysis plan.

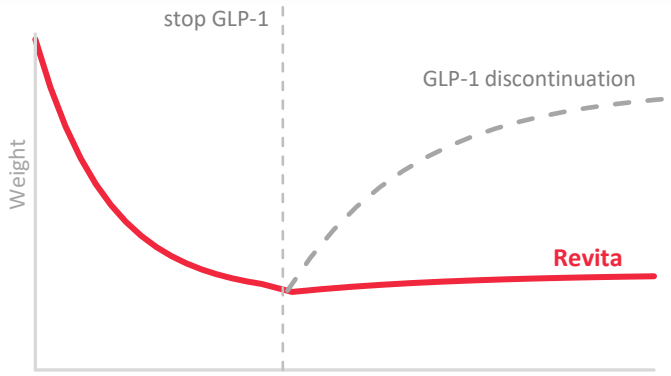
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One Durable Metabolic Reset, Three Potential Use Cases in Obesity

STEP 1 · PROVE IT

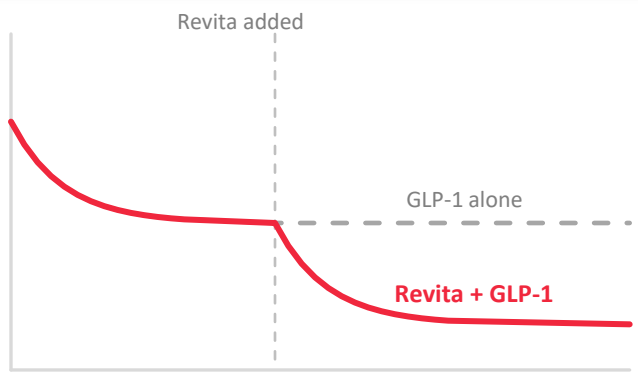
Maintenance after GLP-1



Off-ramp: preserve weight and metabolic benefit after discontinuation

STEP 2 · COMBINE

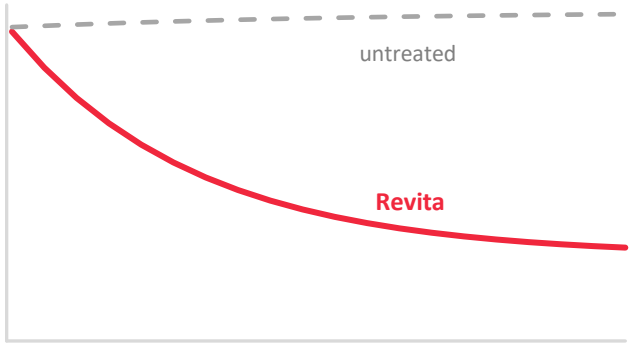
Adjunct to orals, injectables, procedures



Add-on: Pair with drugs to deepen and sustain response, enabling lower doses, drug holidays, and durable step-down

STEP 3 · FRONT LINE

Front-line, drug-free



Kick-start : An earlier one-time option for patients who can't tolerate, afford, or stay on chronic drugs.

Illustrative and hypothetical; schematic, not clinical data; contingent on pivotal results.

Illustrative, forward-looking expansion framework contingent on pivotal success and future studies; not FDA-assessed. Timelines are management estimates. Subject to the risks described in the Company's SEC filings.

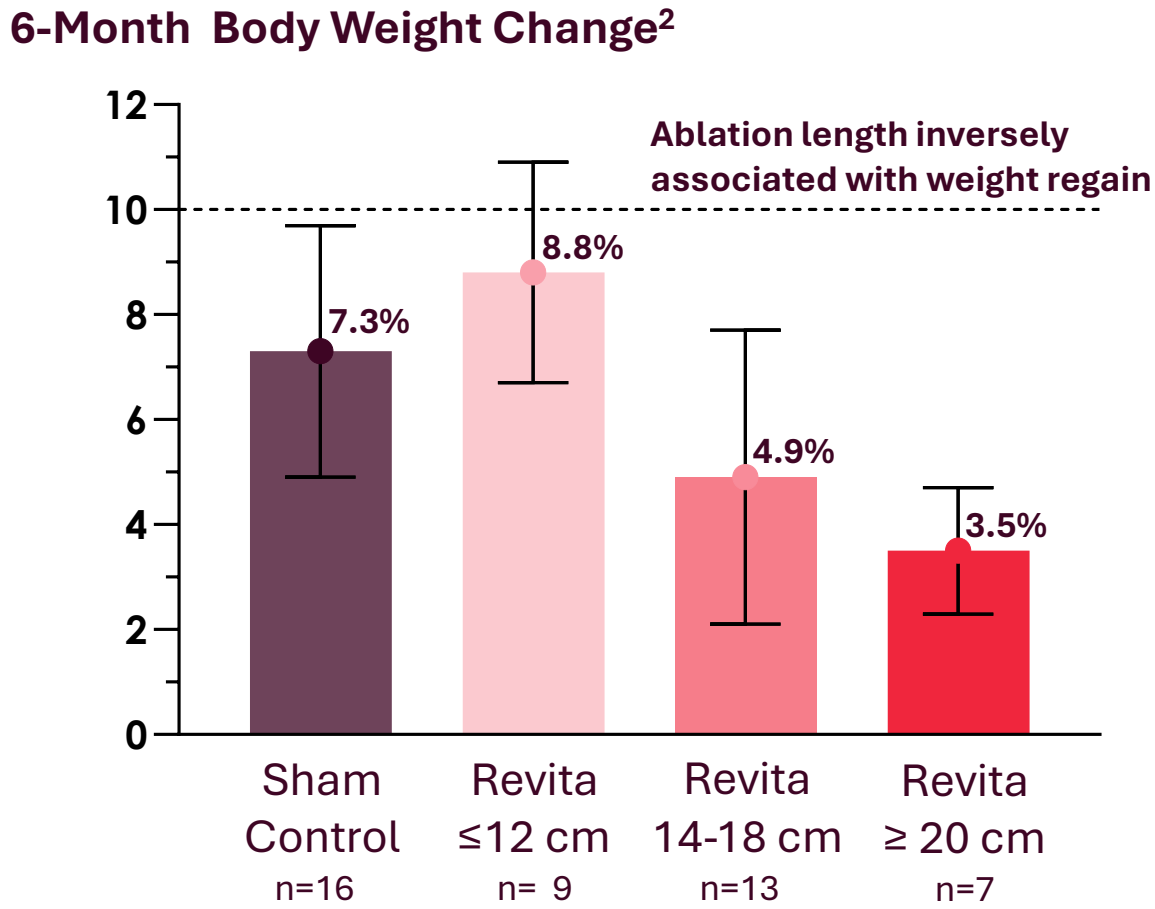
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Reminder: Ablation length correlates with effect size, defining target treatment length for Pivotal Cohort

- **Dose-response:** Significant correlation between ablation length and weight maintenance treatment effect observed in Midpoint Cohort at 6 mo (p=0.048 per Pivotal Cohort key secondary endpoint; n=29 Revita arm[1])
- Participants receiving >14 cm ablations regained ~ 50% the weight of sham at 6-months

Midpoint Cohort dose-response findings defines threshold of effect dose and informs > 14 cm adopted for Pivotal Cohort Per-Protocol population



[1]Dose-response assessed by Spearman rank correlation between ablation length and weight regain at week 26 within the blinded DMR arm. [2]Observed means and SEM at Week 26. DMR patients (n=29) stratified by ablation tercile. Dashed line = expected weight regain based on SURMOUNT-4 GLP-1 withdrawal data. Mean run-in TBWL balanced across groups.

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