



REMAIN-1 Pivotal Study

Positive Topline 6 Month Results for
Revita in Post-GLP-1 Weight
Maintenance

October 2026

NASDAQ:GUTS

Revita is for investigational use only in the United States.

Revita has a CE mark in the EU/UK. REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.

Legal disclaimer

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.

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Today's speakers and agenda



Harith Rajagopalan, MD, PhD

Co-Founder & CEO

REMAIN-1 Pivotal Topline Results

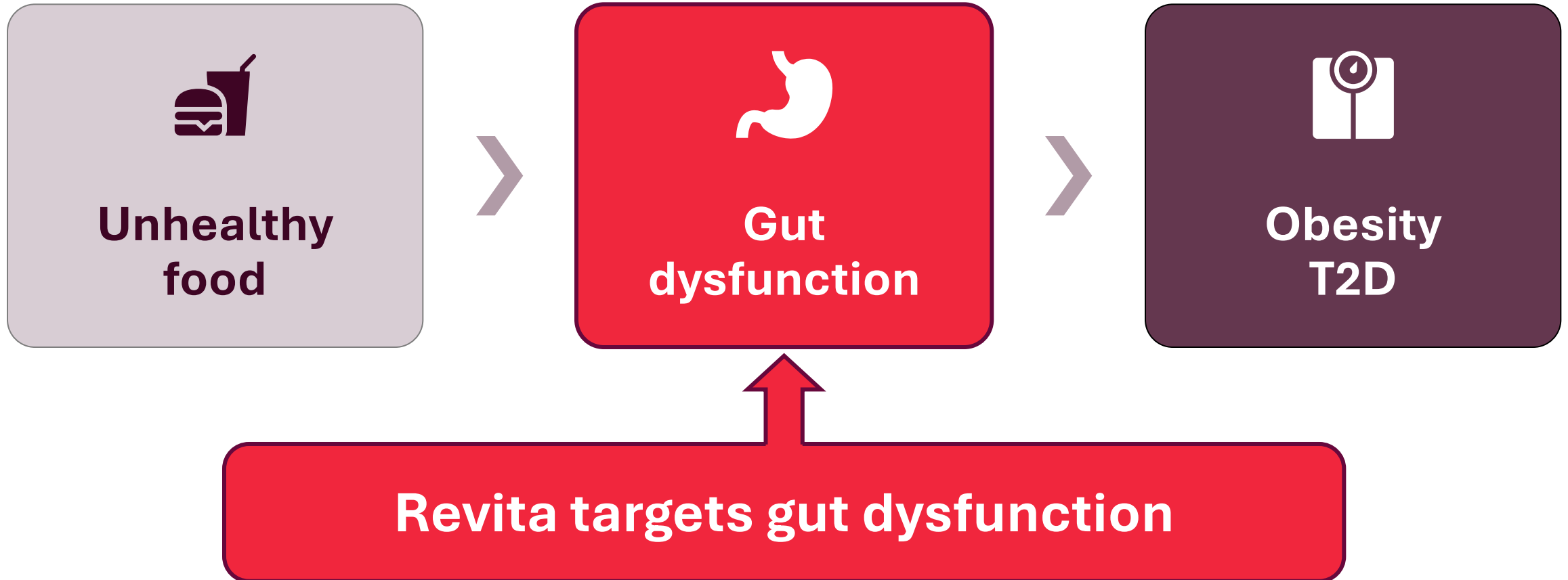


**Adrian Dan, MD, FACS,
FASMBS, DABS-MBS, DABOM**

Medical Director, Weight Management Institute, Summa Health
Professor of Surgery, Northeast Ohio Medical University

A clinician's perspective: what REMAIN-1
means for patients and practice

The future of metabolic care does not require medicine



References: 1. Mah AT et al. Endocrinology. 2014 Sep;155(9):3302-3314. 2. Baldassano S, et al. J Endocrinol. 2013 Mar 15;217(1):11-20; 3. Mao J et al. Diabetes. 2013 Nov;62(11):3736-3746. 4. Dailey MJ. Physiol Behav. 2014; 5. Aliluev A et al. Nat Metab. 2021;3(9):1202-1216; 136:74-78; 6. Theodorakis MJ, et al. Am J Physiol Endocrinol Metab. 2006 Mar;290(3):E550-559. 7. Verdam FJ et al. J Clin Endocrinol Metab. 2011;96(2):E379-E383, 8. Gniuli et al. Diabetologia. 2010 Oct;53(10):2233-40 Revita is for investigational use only in the United States. Revita has a CE mark in the EU/UK.

REMAIN-1 study addresses one of the hardest problems in obesity today: **post GLP-1 weight maintenance**

The Post-GLP-1 Weight Maintenance Problem

1 GLP-1 Initiation



2 Weight Loss



>\$100 Bn
Market¹

3 Discontinuation



4 **Rapid Regain**



Massive
unmet need

REMAIN-1 study



Highest need population in obesity



Largest unmet market opportunity
in obesity



FDA Breakthrough Device
Designation



Efficient regulatory path

REMAIN-1 topline 6-month data met our three study goals

GOALS AT FIRST CO-PRIMARY ENDPOINT

RESULTS

- 1 Efficacy in the full population: first co-primary endpoint at 6 months**
- 2 Greater efficacy with more complete treatment**
- 3 Safety consistent with prior Revita experience**

MET **p = 0.0023**

80% of GLP-1 weight loss retained with Revita vs 67% with sham (mITT; n=176 vs 76)

MET **53% less regain**

3.8% vs 8.2% at 20 cm or more (n=47)
Post hoc, nominal p=0.003

MET **0 related serious AEs**

0 device- or procedure-related serious adverse events¹

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months. Goal 1: mITT, pre-specified MMRM at the 20% run-in weight loss reference. Goal 2: post hoc, site-adjusted observed means, outside the pre-specified testing hierarchy. Goal 3: TEAEs through Week 26; relatedness per CEC and DSMB adjudication. 1 As of the September 24th, 2026 data cutoff

Revita[®]

One procedure – lasting results

- 🕒 A single outpatient endoscopic procedure
- 🧩 Standardized training and delivery
- 🏆 Compounding profile optimization
- 🛡️ Robust IP portfolio protecting first-mover leadership



CONSOLE

Revita: a potential new backbone therapy in obesity

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

REMAIN-1 randomized pivotal study in weight maintenance

Two co-primary endpoints

1

CO-PRIMARY ENDPOINT 1

Weight regain at 6 months

% total body weight regain, **Revita vs sham**

Topline reported

2

CO-PRIMARY ENDPOINT 2

Responder rate at 12 months

% of Revita participants who **maintain at least 5% total body weight loss** at 12 months

Topline Q1 '27

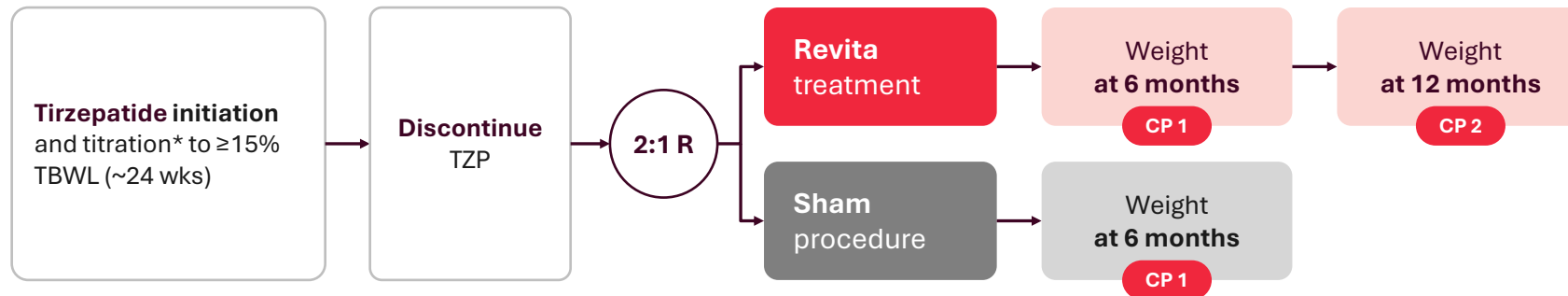
Patient population

n=308

Adults with obesity, BMI 30–45 kg/m²
GLP-1 naïve; no type 2 diabetes

Study design

Randomized 2:1 · double-blind · sham-controlled · diet and lifestyle counseling throughout



Anticipated milestones¹

- ✓ **Reported**
Topline 6-month pivotal data
- Late Q4 '26
Potential De Novo marketing application submission
- Q1 '27
Topline 12-month pivotal data

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months. NCT06484114

*Tirzepatide run-in modeled from SURMOUNT-4 trial. ¹These 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; CP, co-primary endpoint; GLP-1, glucagon-like peptide 1; R, randomization; TBW, total body weight; TBWL, total body weight loss; TZP, tirzepatide.

Baseline demographics were balanced across both arms

80%
female

Mostly female participants
80% Revita and 81% sham

30
kg/m² BMI

BMI at randomization
30.4 Revita vs 29.8 sham (mean), after the
tirzepatide run-in

66%
comorbidity

At least 1 weight-related
comorbidity
64% Revita vs 70% sham

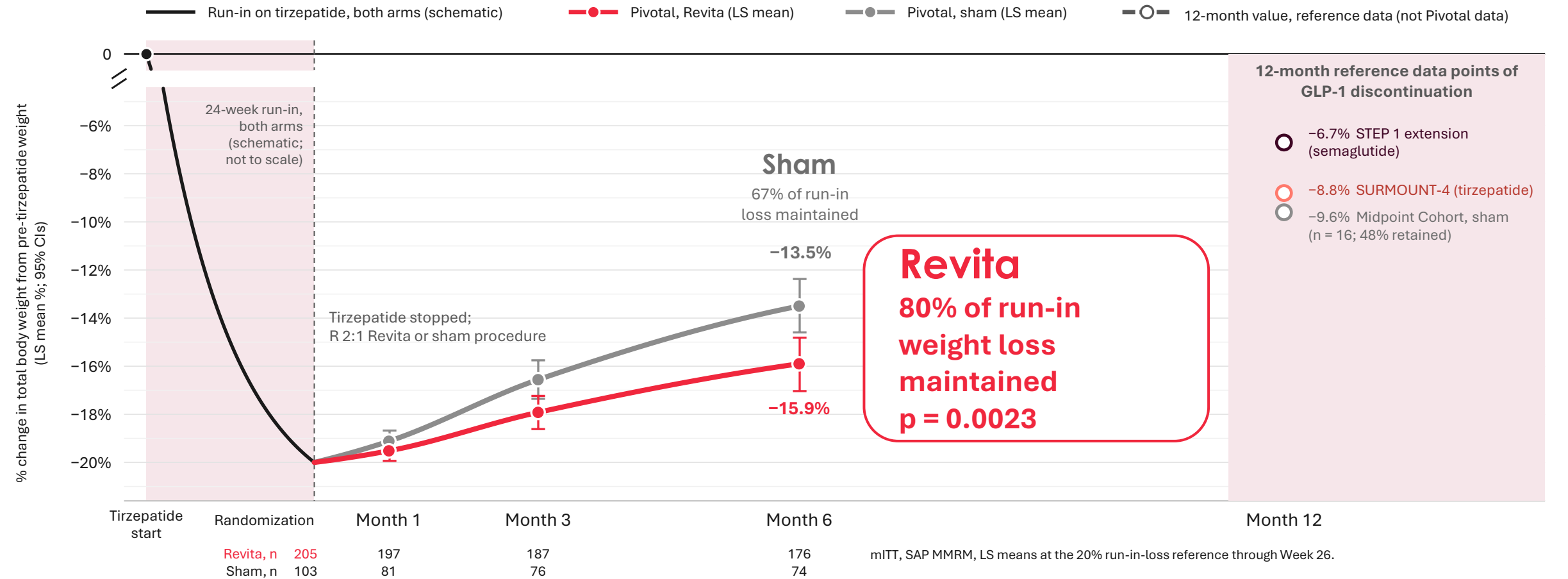
Demographics and baseline characteristics	Revita (n=205)	Sham (n=103)	Total (N=308)
Age, years, mean (SD)	46.5 (12.7)	47.1 (12.2)	46.7 (12.5)
Female, n (%)	164 (80%)	83 (81%)	247 (80%)
Hispanic or Latino, n (%)	44 (21%)	32 (31%)	76 (25%)
Race, n (%)			
White	164 (80%)	75 (73%)	239 (78%)
Black or African American	29 (14%)	14 (14%)	43 (14%)
Asian	4 (2%)	1 (1%)	5 (2%)
Other, multiple or not reported	8 (4%)	13 (13%)	21 (7%)
Anthropometrics			
BMI at screening, kg/m ² , mean (SD)	37.2 (4.1)	36.4 (4.0)	36.9 (4.1)
Pre-tirzepatide weight (V2), kg, mean (SD)	102.9 (16.2)	99.0 (13.9)	101.6 (15.5)
Weight at randomization (V07), kg, mean (SD) ²	84.1 (13.9)	80.9 (11.9)	83.0 (13.3)
BMI at randomization, kg/m ² , mean (SD) ²	30.4 (3.6)	29.8 (3.6)	30.2 (3.6)
Comorbidities			
≥1 weight-related comorbidity ¹ , n (%)	131 (64%)	72 (70%)	203 (66%)
Prediabetes at screening, n (%)	65 (32%)	34 (33%)	99 (32%)
Tirzepatide run-in			
Run-in weight loss, % of pre-tirzepatide weight, mean (SD) ²	18.3 (2.6)	18.3 (3.5)	18.3 (2.9)
Run-in weight loss ≥17.5% (KSE#1 subgroup), n (%) ²	113 (55%)	47 (46%)	160 (52%)
Run-in duration, weeks, mean (SD)	24.7 (6.0)	25.1 (6.3)	24.9 (6.1)
Reached tirzepatide 15 mg, n (%)	97 (47%)	48 (47%)	145 (47%)

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.
REMAIN-1 pivotal cohort, mITT (randomized and procedure attempted, N = 308).
¹Medical history of hypertension, dyslipidemia, prediabetes, type 2 diabetes, sleep apnea, cardiovascular disease or MASLD/NAFLD. ² Efficacy estimand population.

Goal 1: REMAIN-1 pivotal 6-month co-primary endpoint

Sham-adjusted effect size demonstrated strong growth from Month 1 to Month 6

6 Month co-primary endpoint Run-in loss maintained: 80% Revita vs 67% Sham **p=0.0023** LS-mean difference -3.06 points (95% CI -5.02, -1.10)

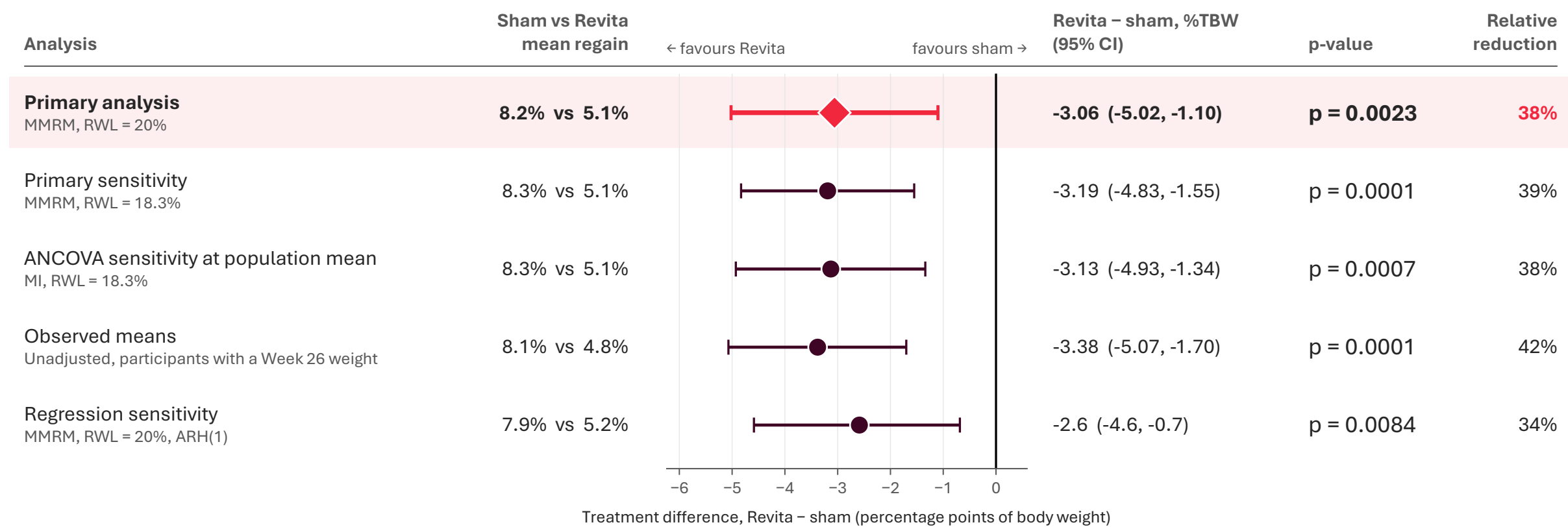


Run-in is schematic, compressed and not to time scale (median 24 weeks; SAP 20% run-in-loss reference). Pivotal: CP#1 MMRM LS means re-expressed as -20% + LS mean × 0.8; Week 26 n = 176 / 74; 80% vs 67% and 38%. Dotted segments join Pivotal Week 26 (all participants) to 12-month values from the separate REMAIN-1 Midpoint Cohort (N = 45); not Pivotal data or a projection. Revita 12-month value is the Midpoint complete-ablation (>14 cm) subgroup, n = 17; sham is the full Midpoint sham arm, n = 16 (LS-mean regain 4.8% vs 13.0%; exploratory, not powered; Fractyl, July 15, 2026). SURMOUNT-4 and STEP 1 lines start at the sham Week 26 value and are other-study data. SURMOUNT-4 placebo arm after a 36-week tirzepatide lead-in regained 14.0% over 52 weeks (Aronne et al., JAMA 2024), shown as -20% + 14.0% × 0.8. STEP 1 extension placebo-switched arm regained two-thirds of prior loss in 1 year (Wilding et al., Diabetes Obes Metab 2022), shown as -20% × (1 - 2/3). Cross-trial comparisons are illustrative. Month 6 diamonds: 12-18 cm and ≥20 cm observed mean regain 4.7% and 3.8% (post hoc; slide 8), shown as -20% + regain × 0.8

Revita’s effect on post-GLP-1 weight maintenance was robust across prespecified analyses

Weight regain at 6 months

Co-primary endpoint #1, mITT. Treatment difference in LS mean change from baseline total body weight at Week 26



REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.

More Revita patients kept their GLP-1 weight loss at Month 6

Exploratory post hoc responder analysis in primary mITT analysis population

1 in 3 Revita participants maintained or lost weight

32%

of Revita
participants

Weight stable or further weight loss

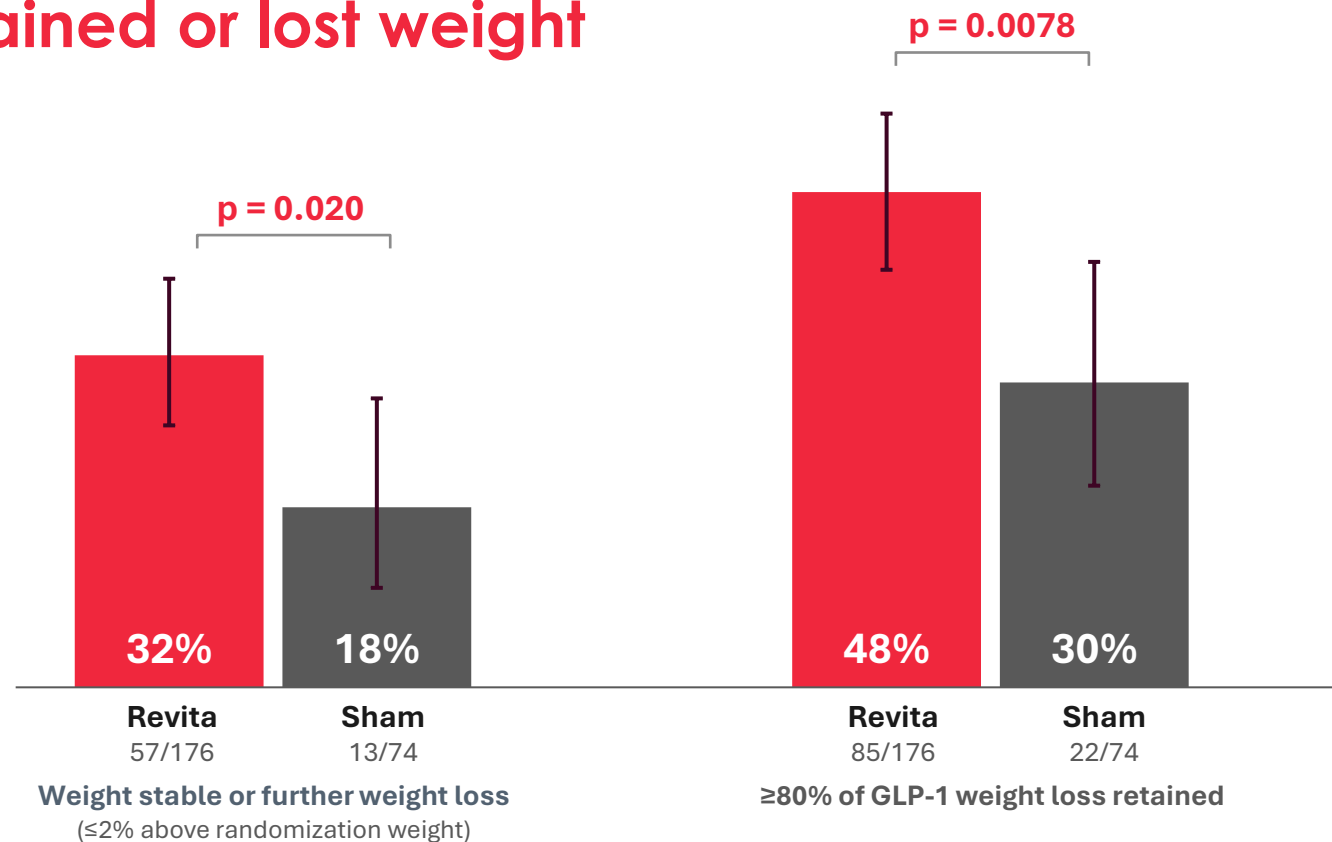
Week 26 weight $\leq 2\%$ above randomization weight,
vs 18% with sham (post hoc $p = 0.020$)

48%

of Revita
participants

Kept $\geq 80\%$ of GLP-1 weight loss

Regained $\leq 20\%$ of run-in weight loss by Week 26,
vs 30% with sham (post hoc $p = 0.0078$)



Participants at Month 6, % (95% CI) (difference vs sham; nominal p)

REMAIN-1 Pivotal Cohort, mITT participants with a Week 26 weight; efficacy estimand. Post hoc responder analysis; nominal p-values.

Responder = Week 26 weight at or below the threshold. Weight stable or further weight loss = Week 26 weight no more than 2% above the randomization weight. Share of run-in loss regained = Week 26 change from randomization weight divided by each participant's own tirzepatide run-in weight loss, both as % of randomization weight. Bars = observed proportions with Clopper-Pearson 95% CI; p = Fisher exact test, two-sided, nominal and unadjusted for multiplicity (post hoc). Efficacy estimand: weights after an intercurrent event (GLP-1 receptor agonist or other weight-affecting medication, systemic corticosteroid, pregnancy) set to missing. Zelta EDC export 24 September 2026; database lock for the 6-month co-primary endpoint analysis 5 October 2026.

Goal 2: Demonstrated meaningful efficacy with more complete Revita treatment

Exploratory ablation length dose analysis

43%

less regain
vs sham

≥12 cm: potential efficacy threshold

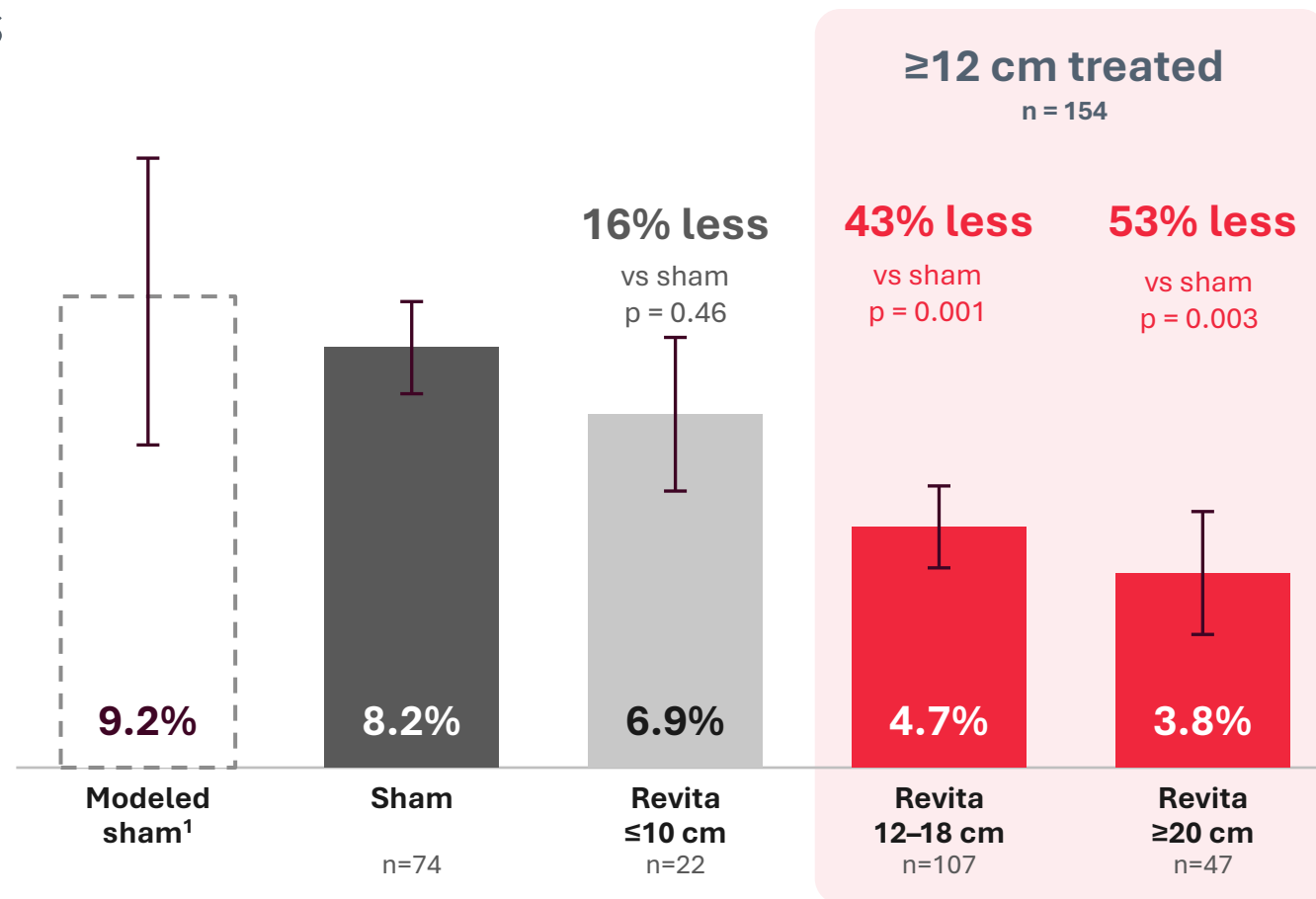
less regain than sham ($p = 0.001$) and **about half** the regain modeled from historical controls (4.7% vs 9.2%)

53%

less regain
vs sham

≥20 cm: Only 6.7 lbs regained at 6 Months

less regain than sham ($p = 0.003$) and **~60% less** than modeled from historical controls (3.8% vs 9.2%)



Weight regain at Week 26, % TBW (% less regain vs sham; nominal p vs sham)

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.

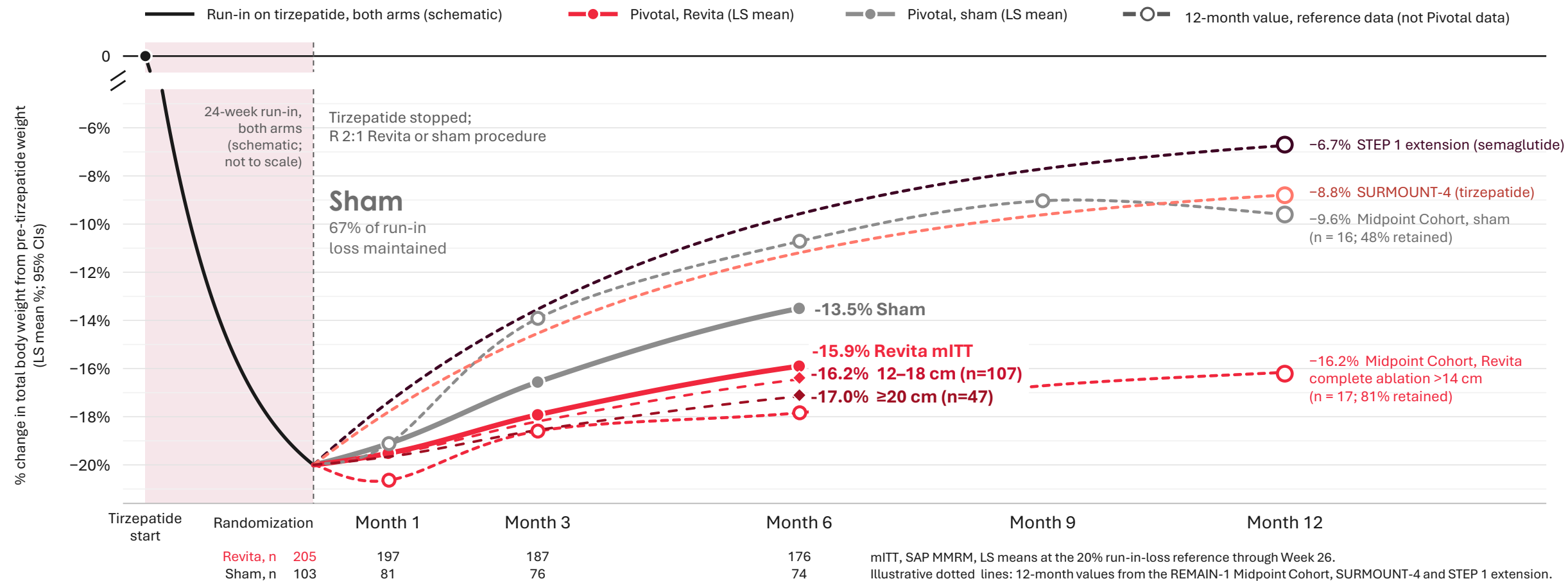
REMAIN-1 pivotal cohort, mITT with a Week 26 weight; post hoc, exploratory analysis outside the pre-specified testing hierarchy. Site-adjusted observed means ($\pm$ SE) among participants with Week 26 weight by length of duodenum treated; p-values vs sham are nominal and unadjusted. Expected sham regain from a meta-regression of GLP-1 RA withdrawal studies (41% of lost weight regained at 26 weeks; bar = 28–53% range), applied at the sham participants' own run-in weight loss. Efficacy estimand. TBW, total body weight.

¹Modeled sham regain: meta-regression of GLP-1 RA withdrawal studies, applied at participants' own run-in weight loss per Budini et al eClinicalMedicine. 2026;103796.

Goal 2: REMAIN-1 pivotal 6-month co-primary endpoint

Revita weight trajectory in line with prior experience; sham outperforming historical data

6 Month co-primary endpoint Longest ablation length cohort regained 3% of their starting weight at 6 months



Run-in is schematic, compressed and not to time scale (median 24 weeks; SAP 20% run-in-loss reference). Pivotal: CP#1 MMRM LS means re-expressed as $-20\% + \text{LS mean} \times 0.8$; Week 26 n = 176 / 74; 80% vs 67% and 38%. Midpoint dotted lines follow reported Month 1-12 LS means (Fractyl, July 15, 2026, Fig. 1; read from figure), shown as $-20\% + \text{regain} \times 0.8$. SURMOUNT-4 and STEP 1 dotted lines are modeled curves from randomization to each reported 12-month value (assumed exponential regain, $\tau \approx 20$ weeks; interim shape not observed); Midpoint values are from the separate REMAIN-1 Midpoint Cohort (N = 45), not Pivotal data. Revita 12-month value is the Midpoint complete-ablation (>14 cm) subgroup, n = 17; sham is the full Midpoint sham arm, n = 16 (LS-mean regain 4.8% vs 13.0%; exploratory, not powered; Fractyl, July 15, 2026). SURMOUNT-4 and STEP 1 are other-study data. SURMOUNT-4 placebo arm after a 36-week tirzepatide lead-in regained 14.0% over 52 weeks (Aronne et al., JAMA 2024), shown as $-20\% + 14.0\% \times 0.8$. STEP 1 extension placebo-switched arm regained two-thirds of prior loss in 1 year (Wilding et al., Diabetes Obes Metab 2022), shown as $-20\% \times (1 - 2/3)$. Cross-trial comparisons are illustrative. Month 6 diamonds: 12-18 cm and ≥ 20 cm observed mean regain 4.7% and 3.8% (post hoc; slide 8), shown as $-20\% + \text{regain} \times 0.8$.

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Goal 3: Revita was generally well tolerated with no related SAEs

Predominantly mild peri-procedural related events¹

0
related SAEs

No related serious adverse events

No device- or procedure-related SAEs, deaths, or unanticipated device effects (UADEs)

94%
within 7 days

Related events occurred early

94% of related events occurred within 7 days of the procedure; vast majority within 2 days



Mostly mild and transient

Most common related events were **oropharyngeal pain, nausea and abdominal pain**, consistent with upper GI endoscopy

Treatment-emergent adverse events through Week 26	Revita (n=205)	Sham (n=103)	Total (N=308)
Patients with any TEAE, n (%)	144 (70%)	57 (55%)	201 (65%)
TEAE events, n	520	131	651
Serious TEAEs (Modified Clavien-Dindo Grade ≥III, per SAP §4.5)¹			
Patients, n (%)	2 (1%)	4 (4%)	6 (2%)
Events, n	3	4	7
Device-related (probably/definitely), events (patients)	0 (0)	0 (0)	0 (0)
Procedure-related (probably/definitely), events (patients)	0 (0)	0 (0)	0 (0)
Possibly related to device or procedure, events (patients)	2 (1)	0 (0)	2 (1)
Deaths, n	0	0	0
TEAE leading to study discontinuation, n	0	0	0
Related TEAEs (probably/definitely related to device or procedure)			
Patients, n (%)	86 (42%)	31 (30%)	117 (38%)
Events, n (Grade I / II / III)	169 (155 / 14 / 0)	44 (43 / 1 / 0)	213 (198 / 15 / 0)
Events with onset on Days 0–7, n (%)	159 (94%)	42 (95%)	201 (94%)
Most common related TEAEs, patients, n (%)			
Oropharyngeal pain	39 (19%)	18 (17%)	57 (19%)
Nausea	32 (16%)	3 (3%)	35 (11%)
Abdominal pain	31 (15%)	6 (6%)	37 (12%)
Vomiting	17 (8%)	0 (0%)	17 (6%)
Abdominal distension	12 (6%)	4 (4%)	16 (5%)
Constipation	6 (3%)	2 (2%)	8 (3%)

TEAE = treatment-emergent adverse event through Week 26; Grades as recorded on the CRF (Clavien-Dindo style I–III).
¹ Grade III events — Revita: GI hemorrhage and acute blood-loss anaemia in one participant with dual NSAID use and no evidence of duodenal bleeding on endoscopy, acute cholecystitis (Day 79); sham: post-operative flap thrombosis (Day 13), gastric hemorrhage (Day 31), intervertebral disc protrusion (Day 75), limb abscess (Day 154).
CEC and DSMB adjudication of AEs and SAEs. No UADE (unanticipated adverse device effects).

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.
1. As of the September 24th, 2026 data cutoff

Greater anti-obesity medication re-initiation in sham

Yet high study retention

94%
retention

High retention through 6 months

Week 26 visit attended by **94%** in both arms

~3x
in sham

More sham participants restarted AOM

6% Revita vs 21% sham restarted anti-obesity medication (post hoc, nominal $p<0.001$)



Intercurrent events accounted for

Prespecified efficacy estimands and sensitivity analyses account for intercurrent events in SAP

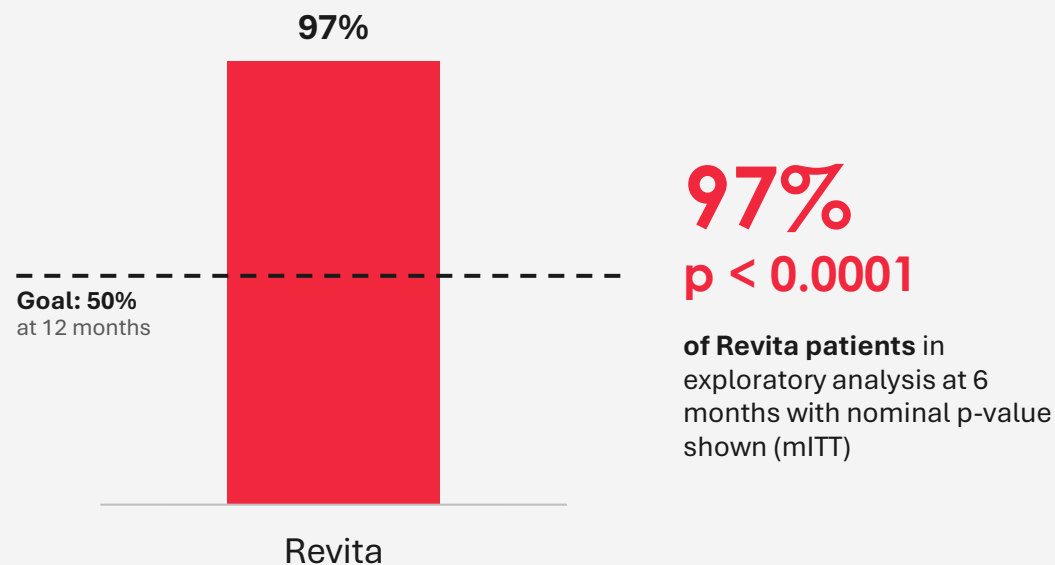
Disposition and intercurrent events through Week 26	Revita (n=205)	Sham (n=103)	Total (N=308)
Modified ITT (randomized and procedure attempted), n	205	103	308
Discontinued study through Week 26, n (%)	13 (6%)	4 (4%)	17 (6%)
Lost to follow-up	4	2	6
Withdrawal of consent	3	1	4
Physician decision	2	0	2
Other	4	1	5
Flagged intercurrent events before the Week 26 visit, participants, n (%)	18 (9%)	23 (22%)	41 (13%)
Anti-obesity medication	13	22	35
Systemic corticosteroid	3	1	4
Pregnancy	2	0	2
Week 26 weight contributing to the efficacy analysis, n (%)	176 (86%)	74 (72%)	250 (81%)

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.

Second co-primary endpoint well-powered with data expected Q1 2027

SECOND CO-PRIMARY ENDPOINT | READS OUT Q1 2027

Patients maintaining $\geq 5\%$ TBW at 6 months



6 month data support potential to maintain weight loss at 12 months

Key secondary endpoints (complete ablation >14 cm, run-in weight loss $\geq 17.5\%$, optimized population) formally tested after both co-primaries read out in Q1 2027

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months. Second co-primary endpoint responder rate defined as model based estimate per pivotal SAP.

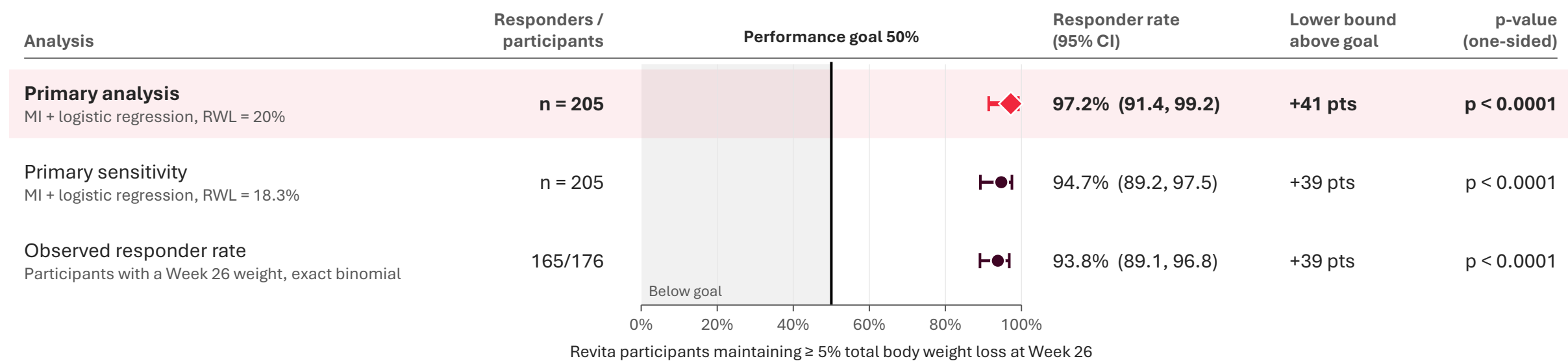
Second co-primary endpoint on track

> 97% of Revita patients maintained clinically meaningful weight loss at 6 months

Month 6 evaluation of the second co-primary endpoint; prespecified endpoint assessment will be at Month 12

Durability of weight loss at 6 months

Co-primary endpoint #2 method applied at Week 26, Revita mITT (n = 205). Responder = total body weight loss ≥ 5% from pre-tirzepatide baseline; tested against the 50% performance goal

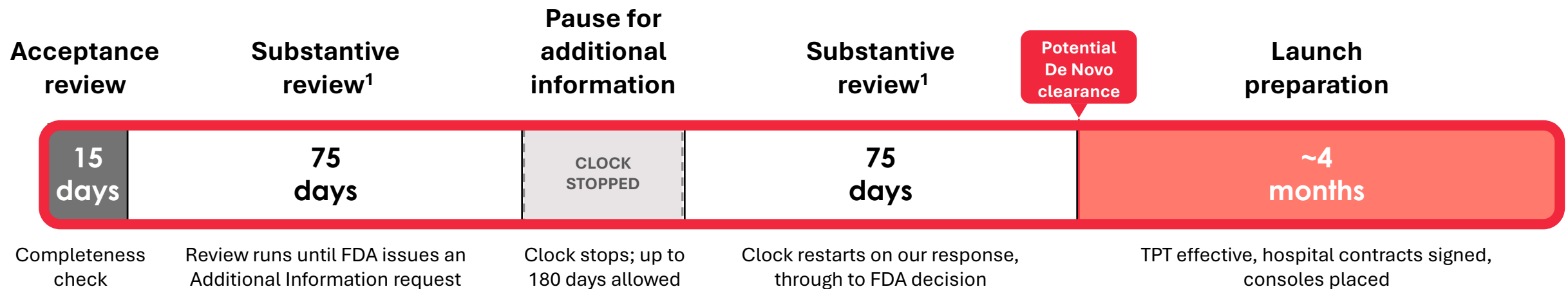


Primary method per SAP 4.4.1.2.5: logistic regression of responder status on run-in weight loss (RWL), predicted at RWL = 20% and at the mITT mean (18.3%), with within-arm multiple imputation of the 29 missing Week 26 weights (FCS, M = 100), HCO variance and Rubin’s rules; one-sided test of the lower 97.5% confidence bound against 50%. The observed responder rate uses a Clopper–Pearson interval and an exact binomial test. Efficacy estimand (weights after an intercurrent event set to missing). The prespecified CP#2 assessment is at Week 52; this Week 26 application is post hoc.

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.

Potential pathway from De Novo filing to commercial launch

Illustrative review path from regulatory submission to potential clearance



REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.

Illustrative only; durations are assumptions, not FDA commitments. FDA days are calendar days between receipt and decision, excluding time on hold for an Additional Information request; the acceptance review falls within that count. Under MDUFA V the goal is a decision within 150 FDA days for 70% of De Novo requests. A refusal to accept would restart the clock. Timing of TPT, coverage and launch is not assured.

1) FDA may request additional information at any point in the process

Reimbursement Updates – October 2026

A potential path to permanent reimbursement, all while CMS's GLP-1 Bridge Program is expanding



Coding

Cat III CPT code 1122T approved in October 2026

Code effective as of January 1st, 2027



Payment

Potential Transitional Pass-Through (TPT)

Device offset + HOPD payment for 2-3 yrs → New Tech APC after.



Coverage

CMS has explicitly asked how to include products that are not in the pre-submission stage in the new RAPID coverage pathway

...we are also interested in feedback on whether we should establish a temporary process under which devices that have progressed beyond the IDE pre-submission stage and are currently being studied under an IDE could become eligible for the RAPID coverage pathway. [CMS-3487-NC](#)



Tailwind at Launch: Medicare's GLP-1 Bridge Program

CMS Administrator Dr. Mehmet Oz: “600,000 seniors have signed up to receive GLP-1 weight loss medications in the first two months of a new federal program created to expand access to the highly sought-after treatments.”

[Reuters 8/31/26](#)

Potential upside: CMS RAPID Coverage Pathway could establish a National Coverage Determination (NCD) 60-90 days after any potential FDA authorization for FFS/MA

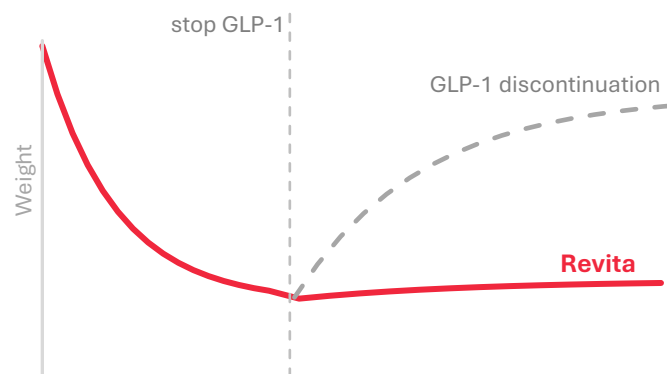
REMAIN-1 is an ongoing study; final data rely on database lock at 12 months. TPT, CPT coding, and coverage pathways are subject to CMS, AMA, and payer review cycles; outcomes are not assured. RAPID is a proposed CMS model. Statements assume FDA marketing authorization, which is not assured. Reuters 8/31/2026 [600,000 seniors have signed up for obesity drugs under new Medicare program](#)

One metabolic reset, three potential use cases in obesity

Step 1 · Prove it



Maintenance after GLP-1



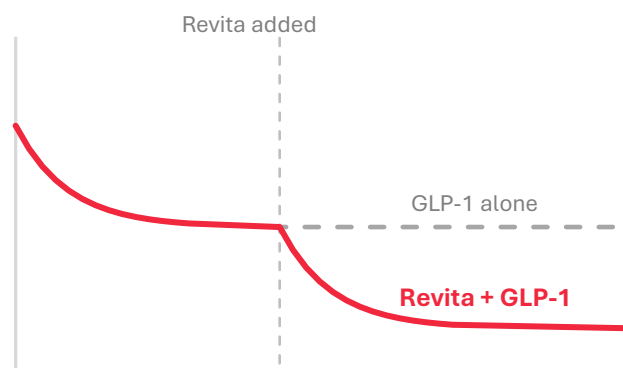
Illustrative and hypothetical; schematic, not clinical data; contingent on pivotal results

Off-ramp: preserve weight and metabolic benefit after discontinuation

Step 2 · Combine



Adjunct to orals, injectables, procedures



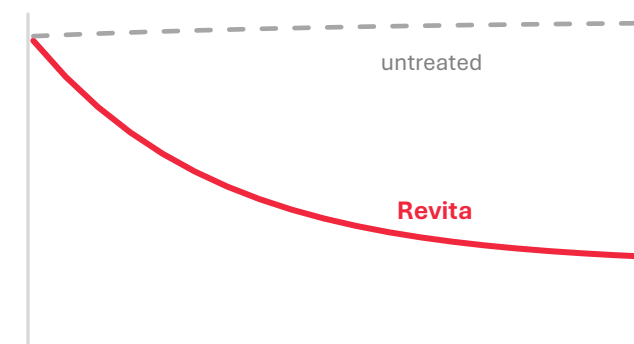
Illustrative and hypothetical; schematic, not clinical data; contingent on additional clinical evidence

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



Illustrative and hypothetical; schematic, not clinical data; contingent on additional clinical evidence

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

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months. 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.

Positive REMAIN-1 topline data strengthen the path to cash breakeven within 5-8 quarters of launch

Price per procedure

\$11–33K

Published benchmark range

ESG: \$11,600 Medicare
Bariatric: \$20,000 private payer
Bariatric: \$33,000 self-pay list

Gross margin at scale

~80%

Held constant across scenarios

Margin held flat across scenarios rather than modeled; higher-ASP cases would carry higher margin and earlier break-even than shown

Procedures to breakeven

80% gross margin, \$22M quarterly operating cash burn

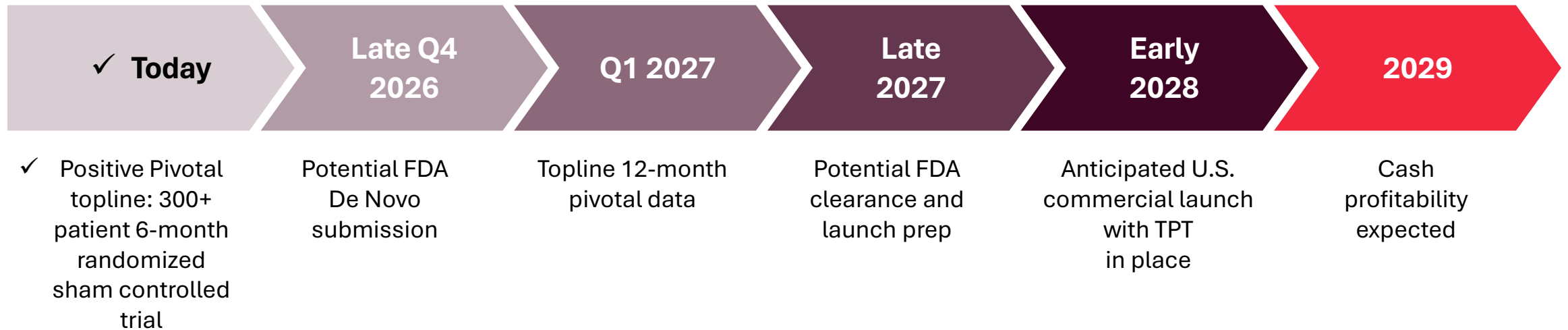
ASP	GP/proc	Procedures/qtr	Break-even
\$10,000	\$8,000	2,750	2H 2029
\$20,000	\$16,000	1,375	1H 2029
\$30,000	\$24,000	920	Q1 2029

Key Assumptions

Estimated De Novo grant in late 2027 — estimated CMS transitional pass-through early 2028

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.
Price benchmarks: CY2026 Medicare national averages (OPPS APC 5362; IPPS MS-DRG 621) and a derived private-payer estimate. Gross margin, operating cash run-rate and center productivity are Fractyl assumptions.
Break even quarters are contingent on De Novo authorization, coverage and financing, and are not guidance.

Positive REMAIN-1 topline advances Revita toward next expected regulatory and clinical milestones



REMAIN-1 is an ongoing study; final data rely on database lock at 12 months. Timelines are management estimates and forward-looking; actual events may differ. Revita is investigational — commercialization is subject to REMAIN-1 results and FDA marketing authorization, neither of which is assured.

REMAIN-1 pivotal study affirms Revita as a potential treatment for post-GLP-1 weight maintenance



Positive topline results: 6-month co-primary endpoint demonstrated that Revita was superior to sham in post-GLP-1 weight maintenance with 80% of weight loss retained in the Revita arm and a $p=0.0023$



Clinically meaningful: Exploratory analysis showed Revita patients with more complete ablation achieved statistically significant and clinically meaningful weight loss



Favorable side effect and tolerability: AE profile was consistent with prior Revita clinical experience



FDA De Novo pathway: We believe the results support a potential regulatory submission with Breakthrough Device Designation for Revita in post-GLP-1 weight maintenance



Category leadership: Strong reimbursement tailwinds and targeted Center of Excellence commercial model enable a potentially substantial commercial opportunity for a new category in obesity care

REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.



**Adrian Dan, MD, FACS,
FASMBS, DABS-MBS, DABOM**

Medical Director, Weight Management Institute, Summa Health
Professor of Surgery, Northeast Ohio Medical University

A clinician's perspective: what REMAIN-1 means for patients and practice



Q&A

NASDAQ:GUTS



Appendix

NASDAQ:GUTS

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Weight maintenance is the most important problem to solve in obesity

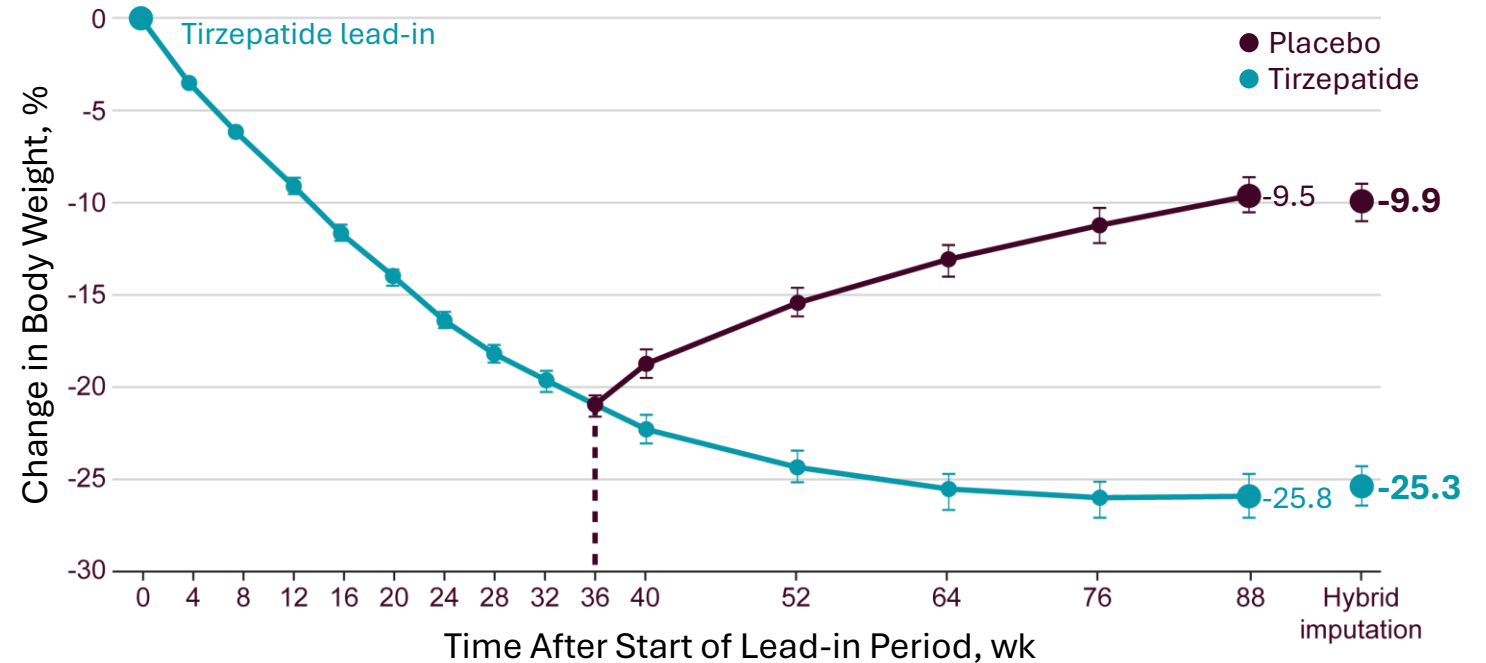
~29M Estimated U.S. patients on GLP-1s¹

85% Of patients regain lost weight after GLP-1 discontinuation³

No FDA-approved therapies for post-GLP-1 weight maintenance

Percent change in body weight (week 0-88) from the SURMOUNT-4 Study³

Overall mean baseline body weight = 107.3 kg



The next phase of obesity care will be defined by weight maintenance, not weight loss

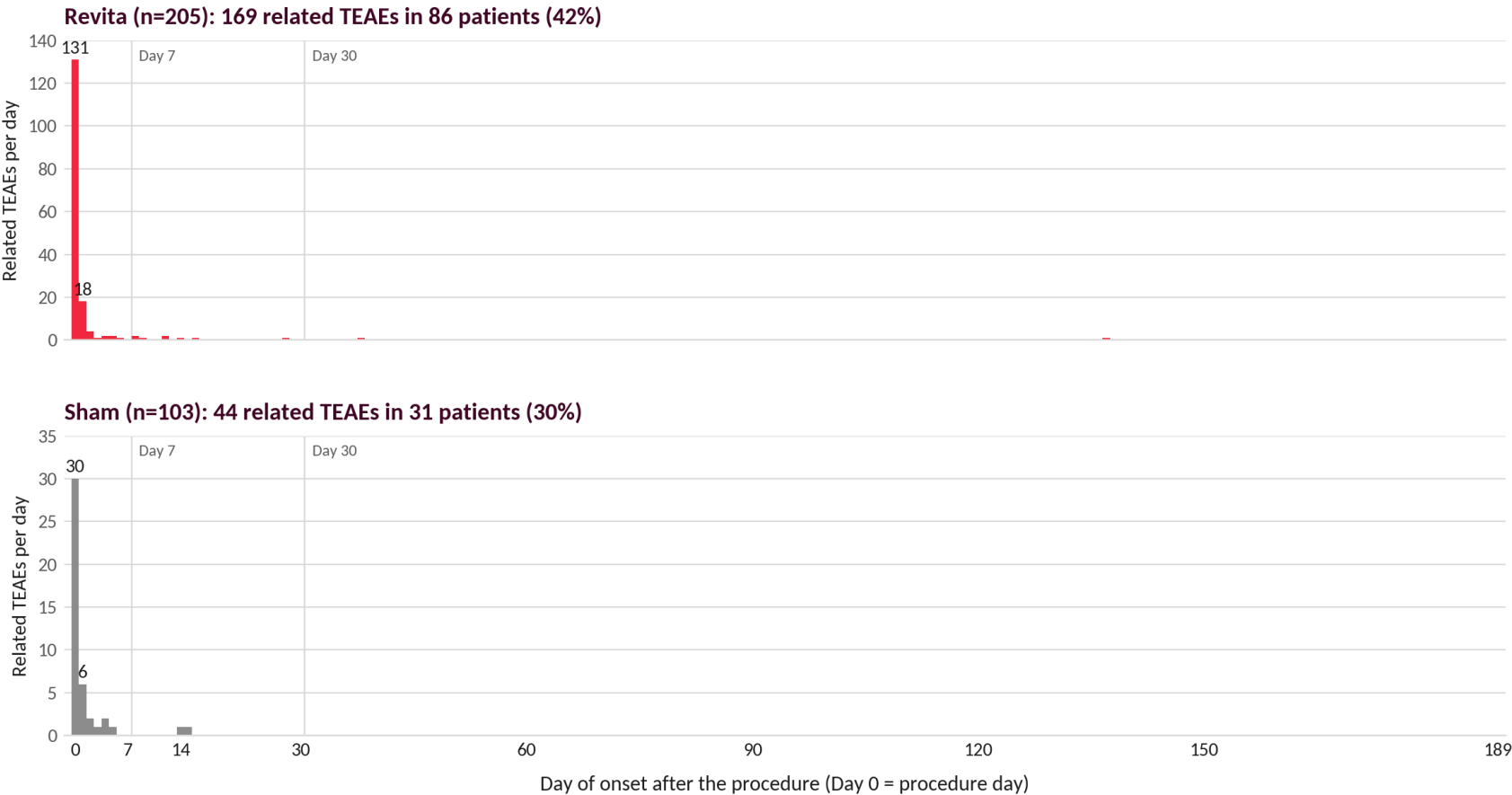
¹KFF Health Tracking Poll, Nov 2025: ~1 in 8 adults currently on a GLP-1 ²Rodriguez, Patricia J., et al. JAMA Network Open 8.1 (2025): e2457349-e2457349. ³Aronne et al. JAMA. 2023 Dec 11;331(1):38–48.

⁴Revita is currently being studied under an open Investigational Device Exemption (IDE) in the U.S. and holds FDA Breakthrough Device designation for weight maintenance in patients discontinuing GLP-1 therapy. Abbreviations: GLP-1, glucagon-like peptide-1; wk, week.

TEAEs were generally mild and peri-procedural¹

Timing of related TEAEs relative to randomization, through Week 26

REMAIN-1 Pivotal Cohort, mITT.



REMAIN-1 is an ongoing study; final data rely on database lock at 12 months. 1 As of the September 24th, 2026 data cutoff