Redefining Durable Weight Loss Maintenance in the Post-GLP-1 Era

Corporate Presentation | October 2026

NASDAQ:GUTS

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

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GLP-1s unlocked weight loss, but durability remains unsolved

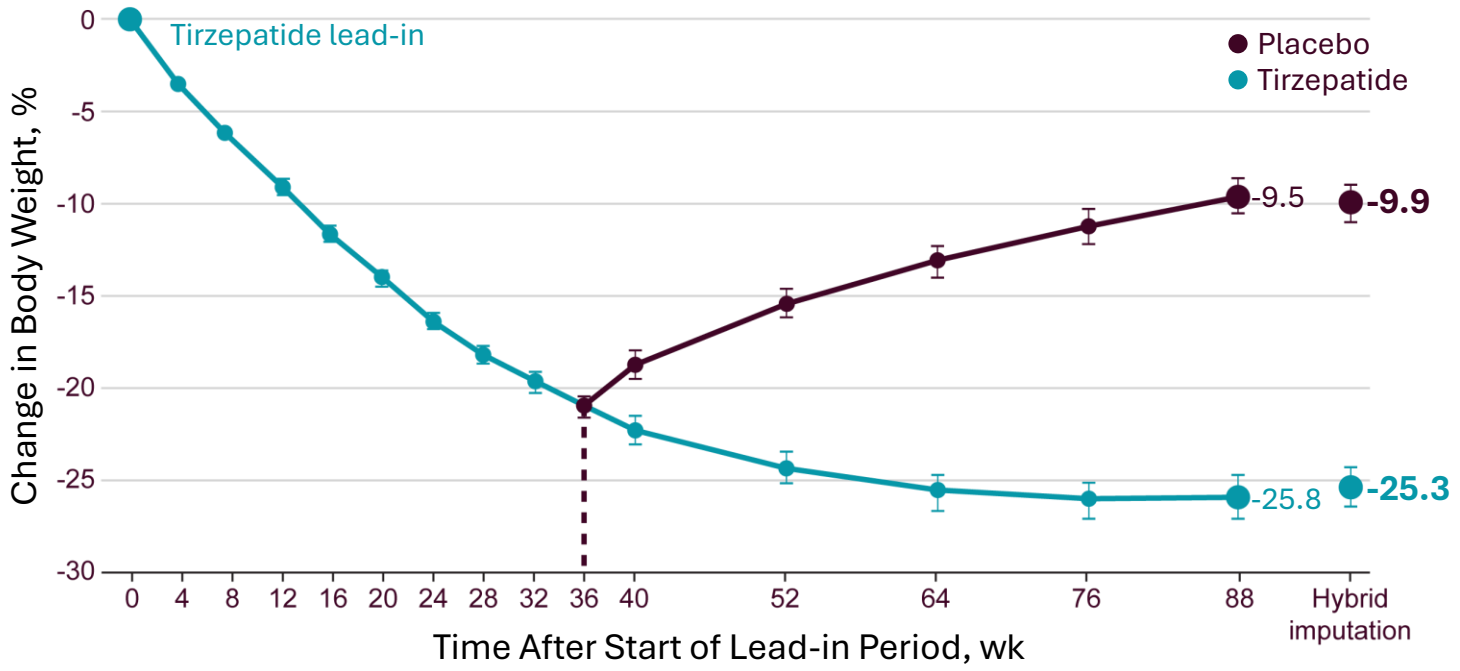
~29M Estimated U.S. patients on GLP-1s[1]

85% Patients regain lost weight after GLP-1 discontinuation[3]

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

Percent change in body weight (week 0-88) from the SURMOUNT-4 Study[3]

Overall mean baseline body weight = 107.3 kg



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

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

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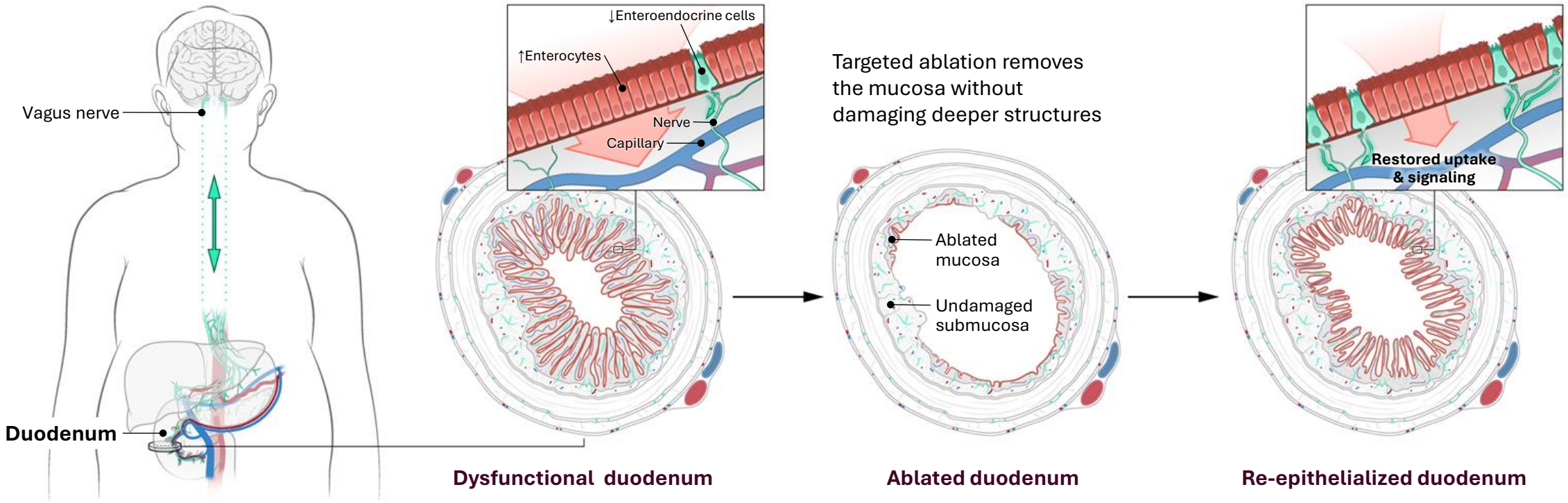
Gut dysfunction is a root cause of obesity

and mucosal ablation is a compelling modality 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]

Regenerated mucosa has potential to restore signaling and metabolic control



[1]Kentish, Stephen J., and Amanda J. Page. "The role of gastrointestinal vagal afferent fibres in obesity." *The Journal of Physiology* 593.4 (2015): 775-786.
[2]Aliluev, Alexandra, et al.'Diet-induced alteration of intestinal stem cell function underlies obesity and prediabetes in mice." *Nature Metabolism* 3.9 (2021): 1202-1216.

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Revita®

One procedure – lasting results



CONSOLE

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

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.

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Revita Duodenal Mucosal Resurfacing (DMR) procedure

Utilizes familiar skills, does not alter patient's anatomy, complements other approaches

Entire length of the post-papillar duodenum is treated through two primary actions:

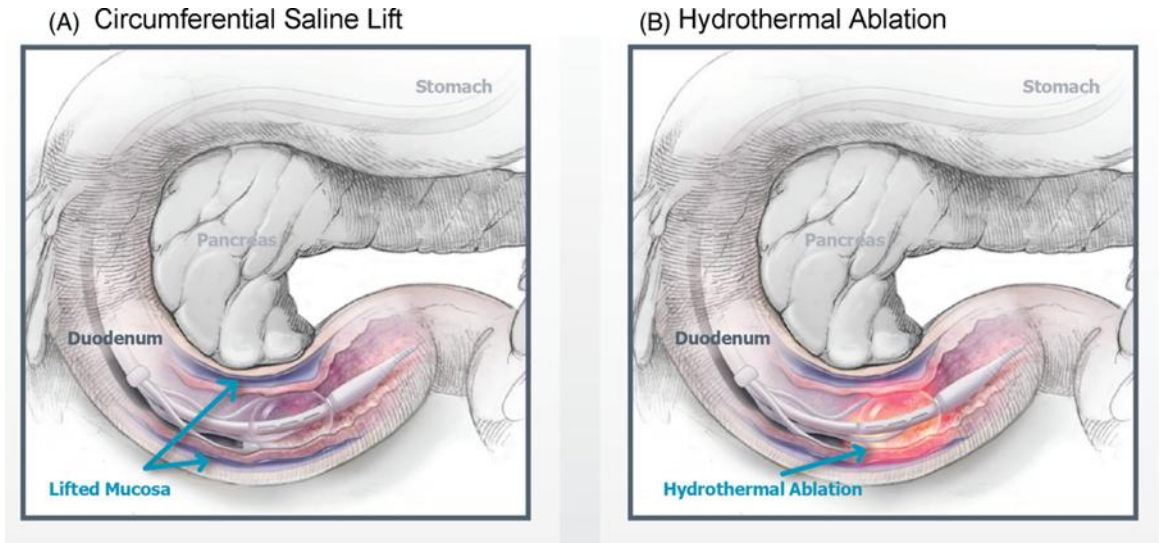
(A) **Circumferential saline lift**

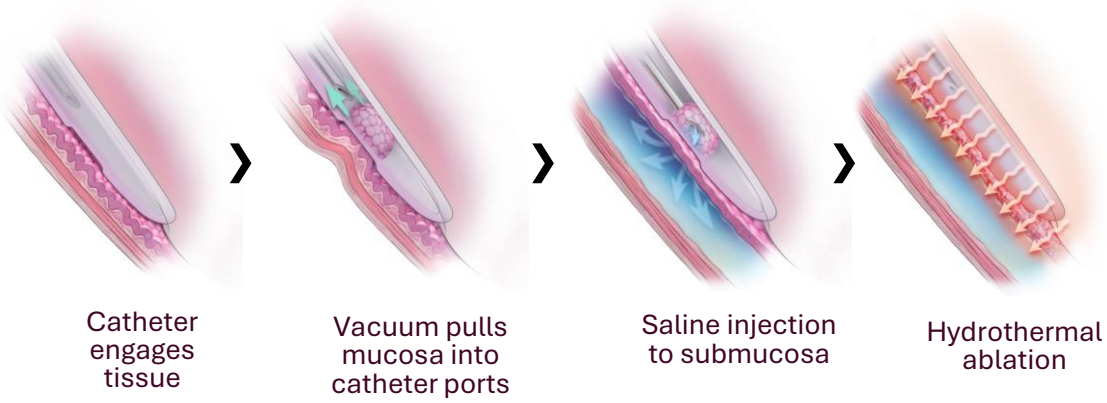
- Balloon engages tissue
- Vacuum pulls mucosa into ports
- Needle injects saline into submucosa

(B) **Hydrothermal ablation**

- Controlled hot water creates precise ablation at each lift site
- Steps repeated along full duodenal length (>14cm)

Utilizes familiar skills.
No implant or anatomy alteration.
Does not preclude any other therapeutic option.





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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

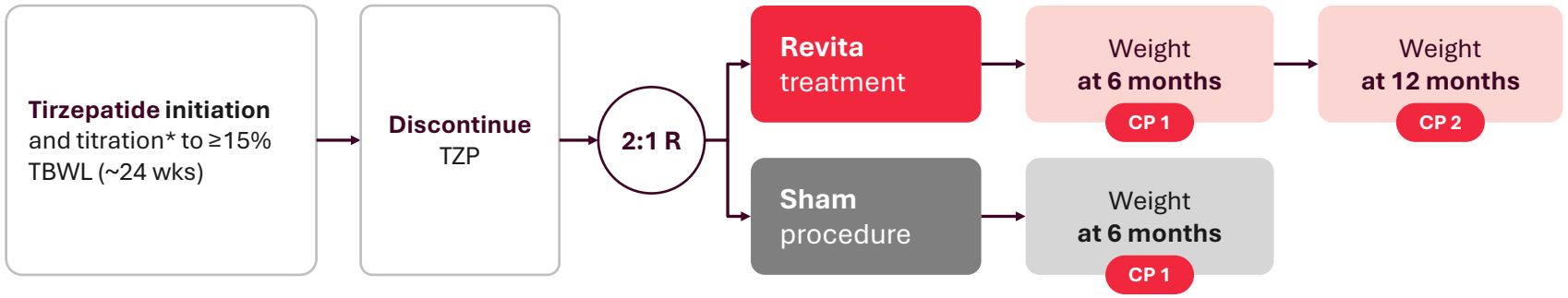
n=308

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 milestones[1]

- ✓ **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.

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Revita is for Investigational Use Only under US Law

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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	**MET** p = 0.0023 80% of GLP-1 weight loss retained with Revita vs 67% with sham (mITT; n=176 vs 76)
2 Greater efficacy with more complete treatment	**MET** 53% less regain 3.8% vs 8.2% at 20 cm or more (n=47) *Post hoc, nominal p=0.003*
3 Safety consistent with prior Revita experience	**MET** 0 related serious AEs 0 device- or procedure-related serious adverse events[1]

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

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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).
[1]Medical history of hypertension, dyslipidemia, prediabetes, type 2 diabetes, sleep apnea, cardiovascular disease or MASLD/NAFLD. [2] Efficacy estimand population.

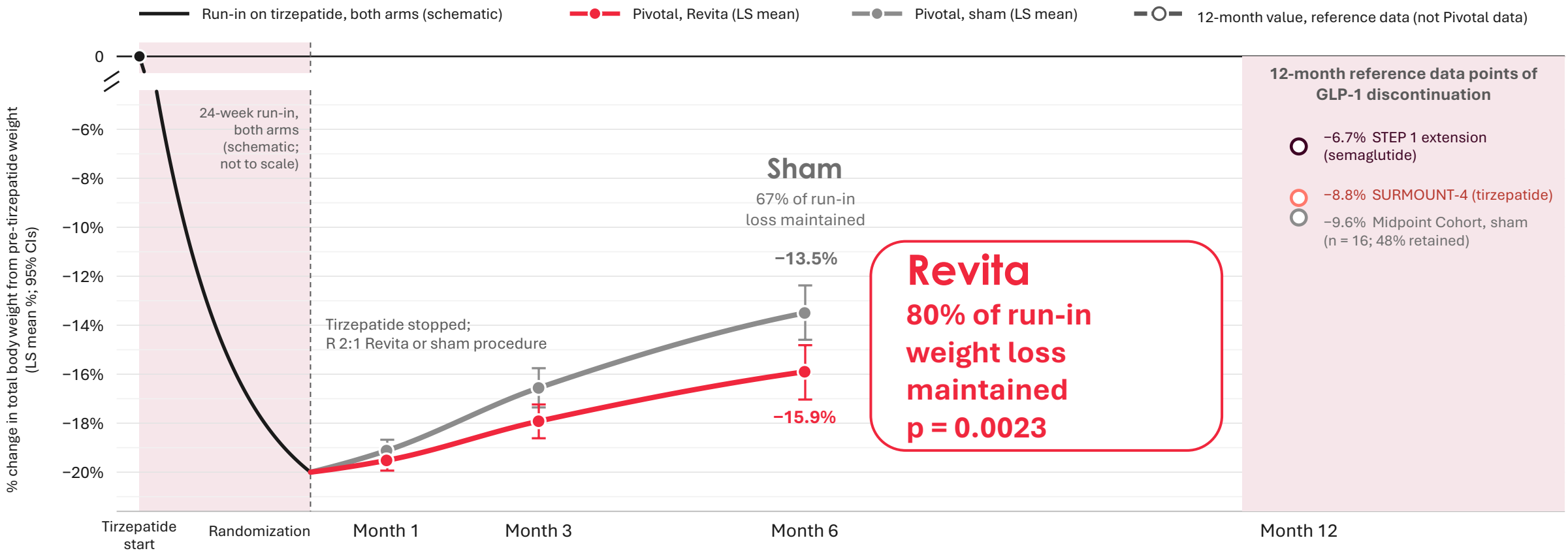
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Goal 1: REMAIN-1 pivotal 6-month co-primary endpoint

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)



	Randomization	Month 1	Month 3	Month 6
Revita, n	205	197	187	176
Sham, n	103	81	76	74

mITT, SAP MMRM, LS means at the 20% run-in-loss reference through Week 26.

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

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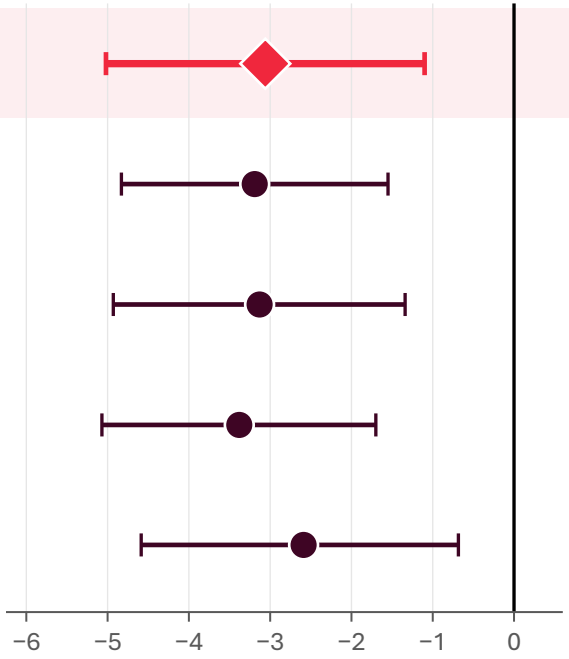
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Revita's effect on post-GLP-1 weight maintenance was robust across prespecified analyses

Weight regain at 6 months

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

Analysis	Sham vs Revita mean regain	Revita – sham, %TBW (95% CI)	p-value	Relative reduction
Primary analysis MMRM, RWL = 20%	**8.2% vs 5.1%**	**-3.06 (-5.02, -1.10)**	**p = 0.0023**	**38%**
Primary sensitivity MMRM, RWL = 18.3%	8.3% vs 5.1%	-3.19 (-4.83, -1.55)	p = 0.0001	39%
ANCOVA sensitivity at population mean MI, RWL = 18.3%	8.3% vs 5.1%	-3.13 (-4.93, -1.34)	p = 0.0007	38%
Observed means Unadjusted, participants with a Week 26 weight	8.1% vs 4.8%	-3.38 (-5.07, -1.70)	p = 0.0001	42%
Regression sensitivity MMRM, RWL = 20%, ARH(1)	7.9% vs 5.2%	-2.6 (-4.6, -0.7)	p = 0.0084	34%



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

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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 ≤2% above randomization weight, vs 18% with sham (post hoc p = 0.020)

48%
of Revita participants

Kept ≥80% of GLP-1 weight loss

Regained ≤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.

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Goal 2: Demonstrated meaningful efficacy with more complete Revita treatment

Exploratory ablation length dose analysis

43%
less regain vs sham

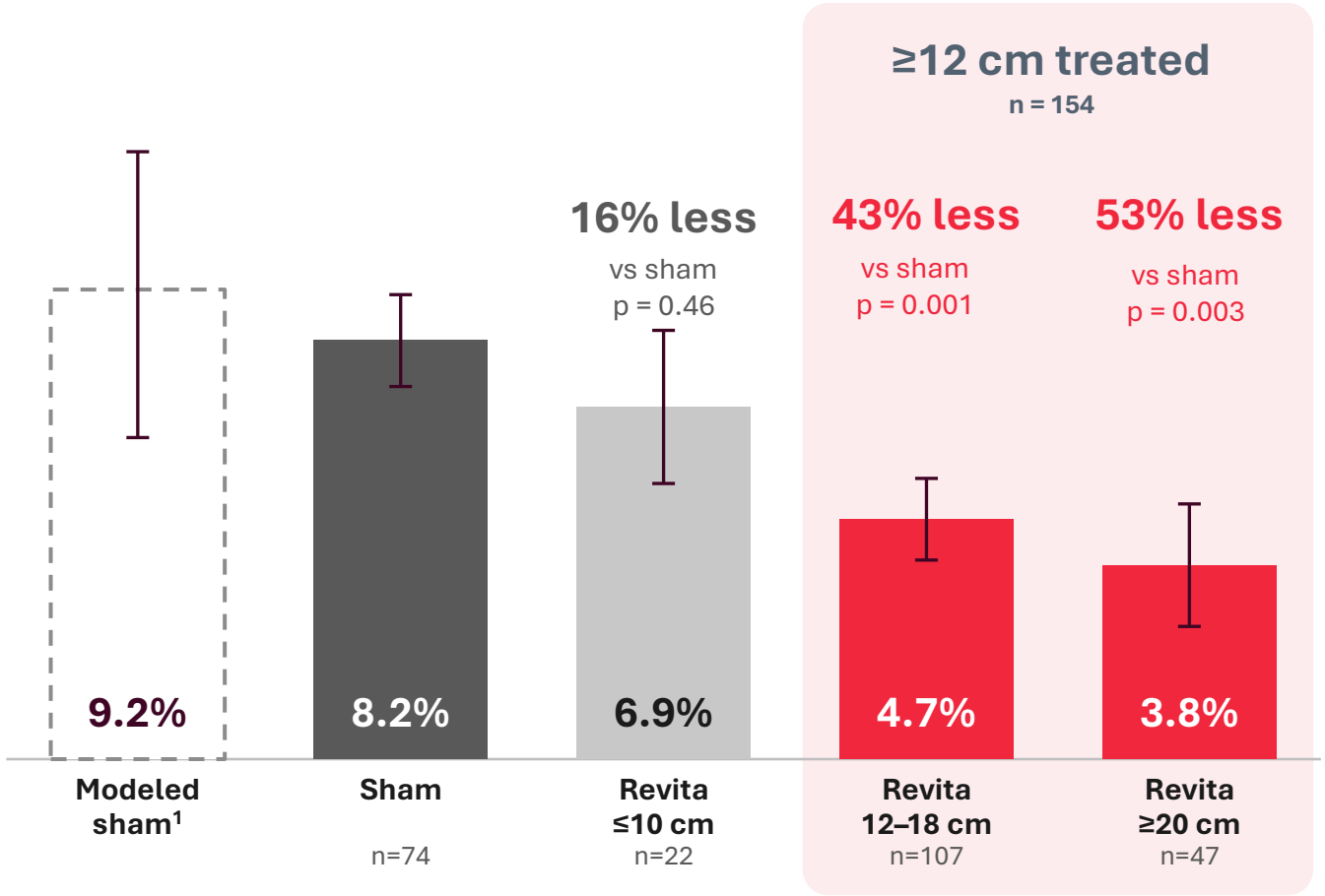
≥12 cm: potential efficacy threshold

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 (± 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.

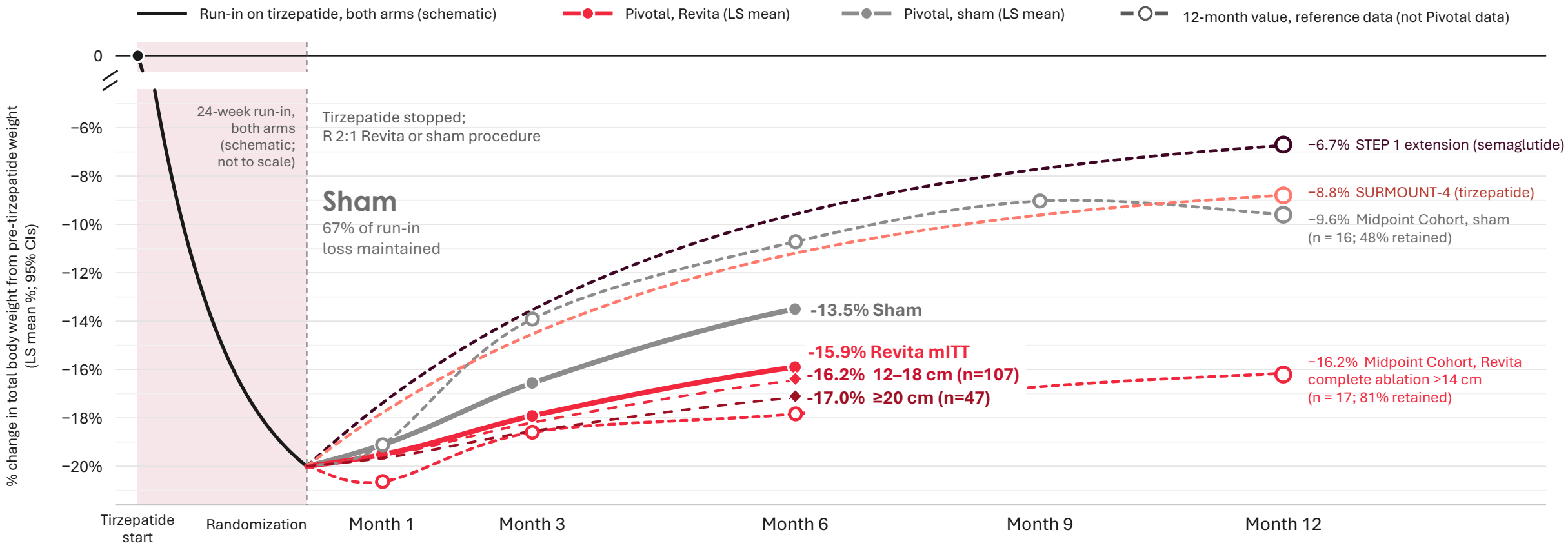
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Goal 2: REMAIN-1 pivotal 6-month co-primary endpoint

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% + LS mean × 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% + regain × 0.8. SURMOUNT-4 and STEP 1 dotted lines are modeled curves from randomization to each reported 12-month value (assumed exponential regain, τ ≈ 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% × 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.

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

Predominantly mild peri-procedural related events[1]

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

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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.

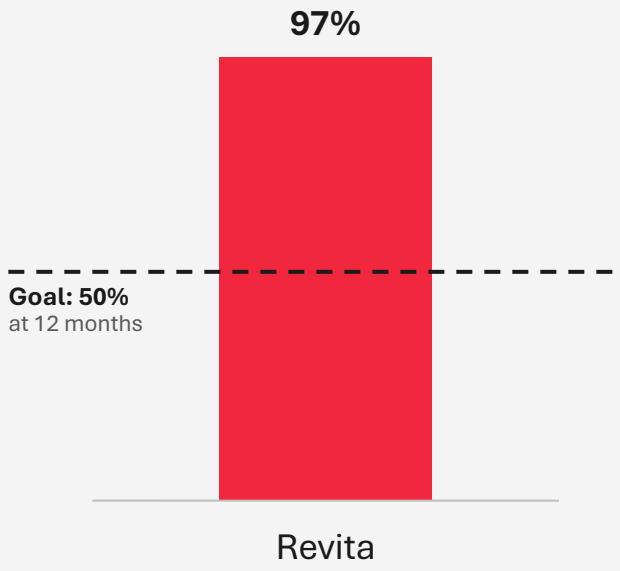
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Second co-primary endpoint well-powered with data expected Q1 2027

SECOND CO-PRIMARY ENDPOINT | READS OUT Q1 2027

Patients maintaining ≥5% TBW at 6 months



97%

p < 0.0001

of Revita patients in exploratory analysis at 6 months with nominal p-value shown (mITT)

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

Key secondary endpoints (complete ablation >14 cm, run-in weight loss ≥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.

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Second co-primary endpoint on track

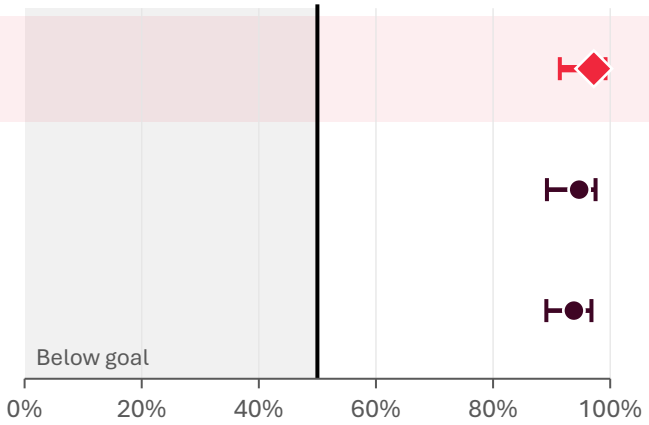
> 97% of Revita patients maintained clinically meaningful weight loss at 6 months

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

Analysis	Responders / participants	Responder rate (95% CI)	Lower bound above goal	p-value (one-sided)
Primary analysis MI + logistic regression, RWL = 20%	**n = 205**	**97.2% (91.4, 99.2)**	**+41 pts**	**p < 0.0001**
Primary sensitivity MI + logistic regression, RWL = 18.3%	n = 205	94.7% (89.2, 97.5)	+39 pts	p < 0.0001
Observed responder rate Participants with a Week 26 weight, exact binomial	165/176	93.8% (89.1, 96.8)	+39 pts	p < 0.0001



Revita participants maintaining ≥ 5% total body weight loss at Week 26

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), HC0 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.

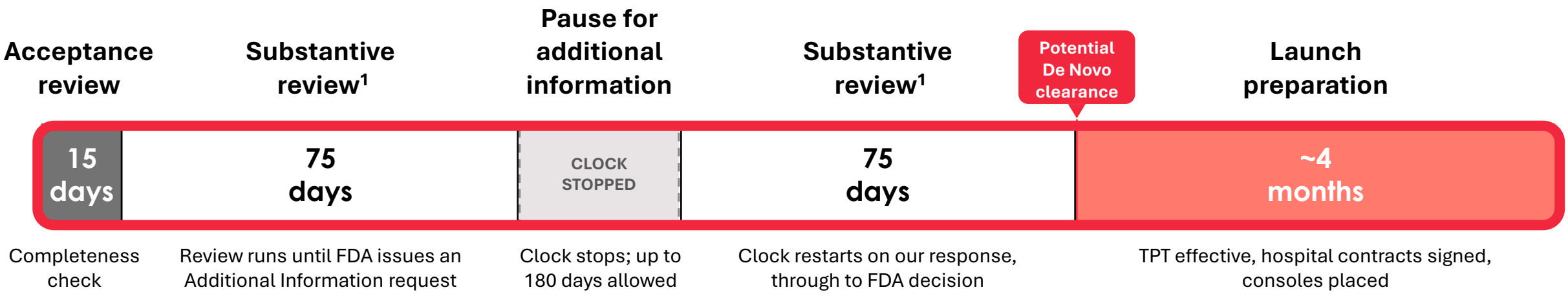
REMAIN-1 is an ongoing study; final data rely on database lock at 12 months.

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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

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~4M eligible patients for Revita translates to $40-120B opportunity*

US GLP-1 users → patients clinically eligible for Revita (post-GLP-1 weight maintenance)



Bars: ● share of prior step retained (point estimate)

~4M

eligible patients

* TAM is an internal figure developed by management based on certain assumptions that management believes to be reasonable as of the date hereof. Please refer to the disclaimer titled "Market Data, Estimates and Industry Information" set forth on Slide 2 of this presentation.[1]Gallup 2026 — ~11% of ~262M US adults currently on a GLP-1 for weight loss. [2] 65% discontinuation rate is for individuals without T2D - Rodriguez et al., JAMA Netw Open 2025;8(1):e2457349. [3]30% base · Monte Carlo median 29.3% based on Fractyl market estimates. [4]On-label BMI 30–45 (~70%; RWE / Fractyl est.) Abbreviations: TAM, total addressable market

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Ready centers already have necessary infrastructure — only missing the GLP-1 off-ramp

Already in place

- Comprehensive metabolic program
- Metabolic interventionalists who already manage GLP-1 patients
- Nutrition and lifestyle counseling
- Prior-authorization machinery
- Endoscopy and fluoroscopy suite time
- The interventional skillset
- Registry participation

›

Still missing
An approved, reimbursed, durable off-ramp procedure

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Targeted and efficient COE launch strategy

Focused on top 10-20% high volume comprehensive metabolic centers across the U.S.



~1,000

Accredited centers, U.S. and Canada[1]

100–200

Early launch starts with top 10–20% of potential COEs

First wave includes Revita clinical centers and established ASMBS COEs

Locations approximated from the ASMBS center locator. Illustrative. 1 https://www.facs.org/quality-programs/accreditation-and-verification/metabolic-and-bariatric-surgery-accreditation-and-quality-improvement-program/

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Site-level volume potential is material and credible

Initial target centers

100–200

High-volume systems

GLP-1 patients/center/year

>2000

Patients at ready COEs[1]

Potential procedures /center/year

250–500

Procedures during ramp[1]

1. Company estimates

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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

2 Payment

Potential Transitional Pass-Through (TPT)

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

3 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*

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Major payers already cover obesity procedures

Bariatric surgery + GLP-1 coverage provide tailwinds for potential Revita coverage

Payer	2025 commercial lives[1]	GLP-1s for obesity[2]	Bariatric surgery[3]
United Healthcare	~35M	Prior Auth + opt-in	Covered
Elevance Health	~30M	Prior Auth + opt-in	Covered
aetna™	~20M	Prior Auth + opt-in	Covered
Cigna	~18M	Prior Auth + opt-in	Covered
HCSC Health Care Service Corporation	~14M	Prior Auth + opt-in	Covered
CMS (Medicare)	~68M[4]	GLP-1 Bridge	Covered

~190M lives sit with the six payers already reimbursing bariatric surgery

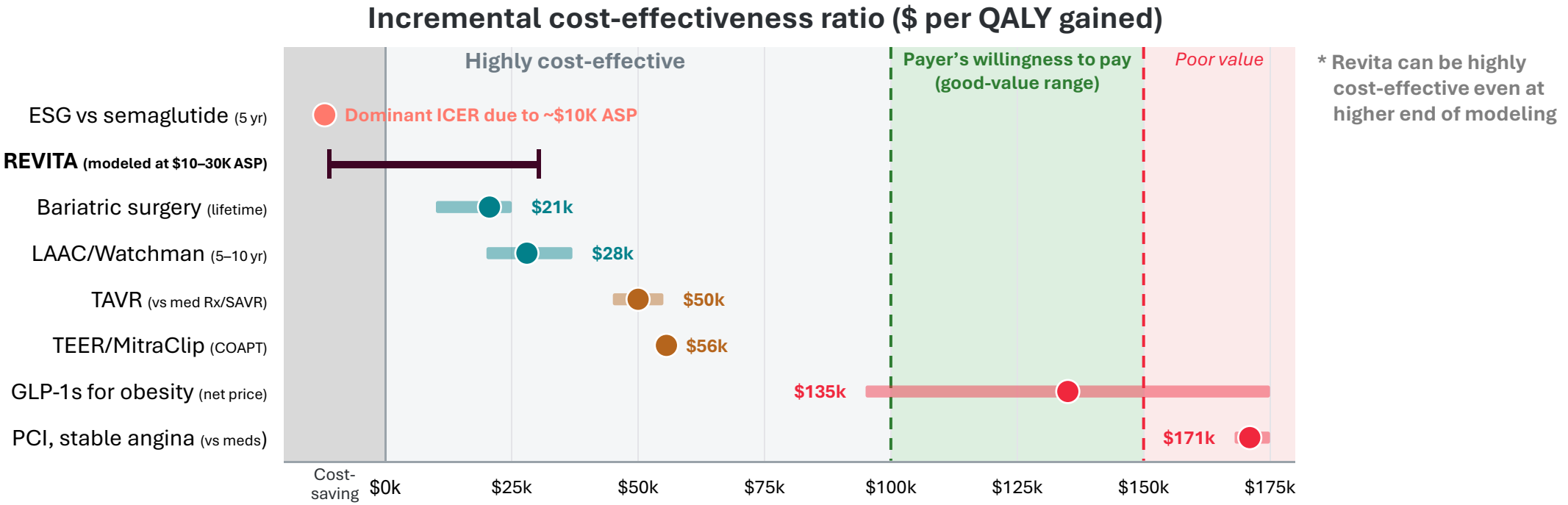
[1]Total U.S. medical enrollment, all lines — Mark Farrah Associates / Peterson–KFF, 2025; CMS row is Medicare Part D enrollment, not commercial. [2]Obesity indication; PA + employer election typically required (CVS Caremark 7/25; Evernorth 5/25). [3]Payer commercial medical policies; typical criteria BMI ≥40 or ≥35 + comorbidity (UnitedHealthcare policy, 2026). [4]Medicare GLP-1 Bridge: CMS §402 demonstration, Jul 1 2026–Dec 31 2027, outside Part D payment flow; $50/mo copay, central processor for PA (CMS, 2026). BALANCE Model indefinitely delayed. Bariatric surgery per NCD 100-1.1.

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A one-time procedure that maintains post-GLP-1 weight loss can be highly cost-effective

We believe Revita's modeled cost-effectiveness is highly favorable: Better cost per QALY than widely covered CV procedures, bariatric surgery, and comparable to ESG-vs-GLP-1 at lower ASP



Based on published cost to payers and cost-effectiveness benchmarks for obesity therapies and other device-based interventions

Sources: JAMA Netw Open 2024 (ESG vs semaglutide, dominant at ~$10K ASP); ACS Clinical Congress 2024 & lifetime CE literature (bariatric surgery $10k–$25k/QALY); Stroke 2018 / PROTECT AF (LAAC); PARTNER economic substudies (TAVR); COAPT (TEER); ICER 2025 net-price review (GLP-1s); COURAGE (PCI). Revita value is internal model, not peer-reviewed. IVL omitted — no published ICER. Cross-study comparisons are directional: populations, comparators, & horizons differ.

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Revita pricing corridor

Bracketed by the endoscopic and surgical benchmarks that payers already pay



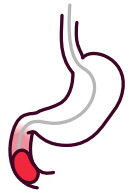
Endoscopic sleeve gastroplasty

~$11,600[1]+

CPT 43889 – APC 5362
Category I code effective Jan 1, 2026

Medicare, hospital outpatient
$10,860 facility + $720 physician

Self-pay market
$8,000 – $15,000, bundled



Revita DMR

Pricing to be determined

Outpatient endoscopic
Under one hour, same-day discharge

No resection or anatomic change
Repeatable; no permanent implant

Duodenal target
Distinct mechanism from restriction



Bariatric surgery

Up to $33,000[2]

Sleeve gastrectomy, CPT 43775
Inpatient only under Medicare

Commercial/uninsured
$20,000 – $33,000

[1] ESG Lower bound is the CY2026 Medicare national average in the hospital outpatient setting: $10,860 facility (OPPS APC 5362, a Comprehensive APC — device cost is bundled, not separately paid; CMS-1834-FC) plus $720 physician (PFS at a $33.40 conversion factor; CMS-1832-F), before the 2% sequestration reduction. Upper bound is the published US self-pay range for ESG, typically $8,000–$15,000 as a bundled package.
[2] Bariatric surgery Lower bound is CY2026 Medicare for an uncomplicated laparoscopic sleeve gastrectomy: MS-DRG 621 at $10,976 (IPPS) plus $1,000 physician (CPT 43775); MS-DRG 619 with a major complication or comorbidity pays $21,011. Upper bound is self-pay and uninsured list pricing from published market surveys — a charge, not a payer-allowed amount. Published commercial episode payments sit materially below it.

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Potentially attractive unit economics at the center and at the company

Unit economics potentially favorable for hospital and Fractyl

The hospital's view

- Endoscopy and bariatrics are major drivers of hospital contribution margin
- TPT enables positive contribution margin by passing disposable costs through to CMS
- No new capital footprint to justify

Fractyl's view

- High gross margin of ~80%
- Capital-light: no high cost, long lead-time sales cycle per site
- Commercial cost scales with sites, not linearly with volume

Recurring, high-margin procedure revenue concentrated in high-throughput centers

Hospital economics assume pass-through plus facility payment.

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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**

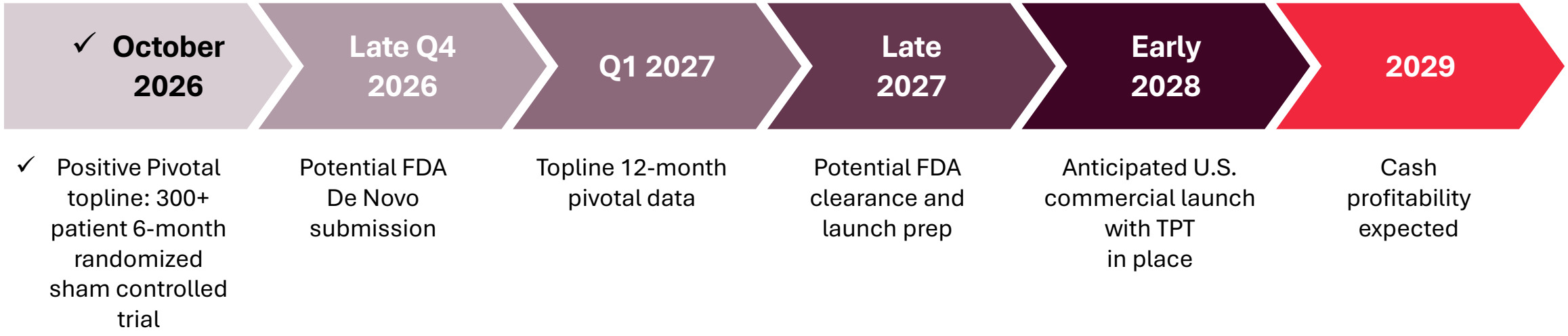
Key Assumptions | Estimated De Novo grant in late 2027 — estimated CMS transitional pass-through early 2028

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.

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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.

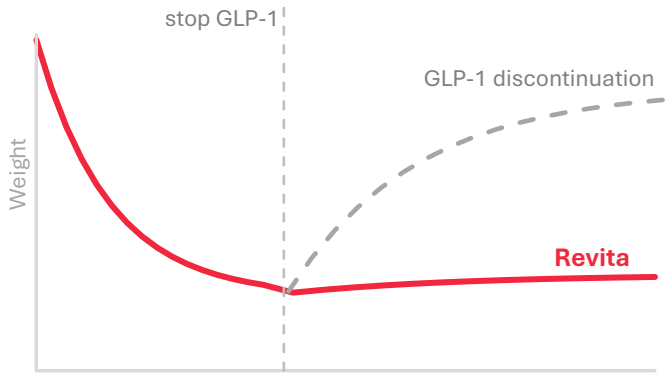
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One metabolic reset, three potential use cases in obesity

Step 1 · Prove it

Maintenance after GLP-1

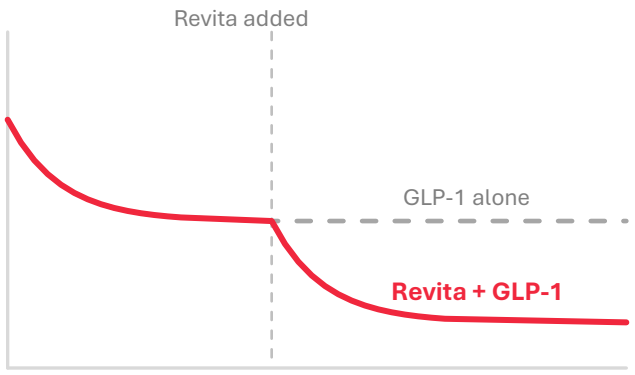


Illustrative and hypothetical; schematic, not clinical data; contingent on pivotal results

Off-ramp: preserve weight and metabolic benefit after discontinuation

Step 2 · Combine

Adjunct to orals, injectables, procedures

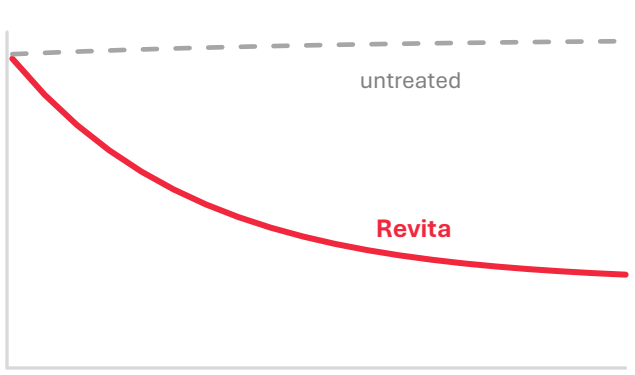


Illustrative and hypothetical; schematic, not clinical data; contingent on additional clinical evidence

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.

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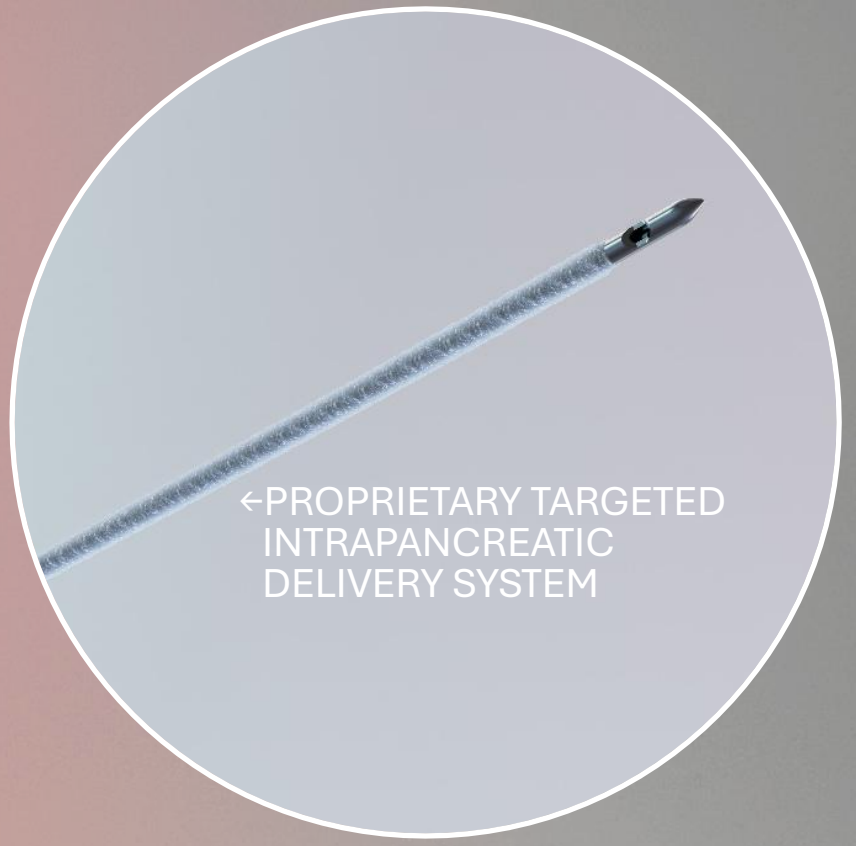
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Rejuva®

Rejuva®: Advancing targeted pancreatic gene therapy for durable metabolic control





←PROPRIETARY TARGETED INTRAPANCREATIC DELIVERY SYSTEM

←"SMART GLP-1" GENE THERAPY

Rejuva is an investigational preclinical asset which has received Clinical Trial Authorization in the Netherlands. Rejuva is currently under review for clinical research in additional countries in the EU and AUS. It has yet to be assessed by the FDA.

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Reimagining gene therapy economics for metabolic disease

Large patient population



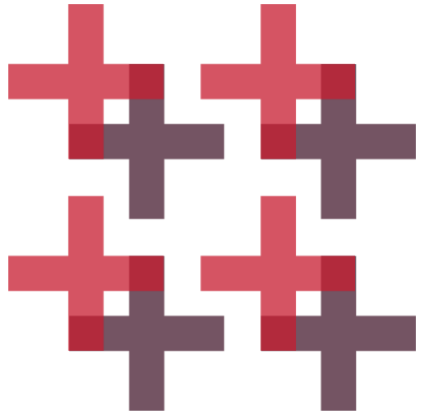
~27M with T2D in US[1]
~100M with Obesity in US[2]

Low cost of goods



< $10K COGs per patient enabled by local delivery

High economic value



~$10K price per year ICER price benchmark[3]

[1]CDC National Diabetes Statistics Report 2026, [2]CDC NCHS Data Brief No. 508. Obesity and Severe Obesity Prevalence in Adults: United States, August 2021– 2023, [3]ICER Medications for Obesity Mgmt 2022.

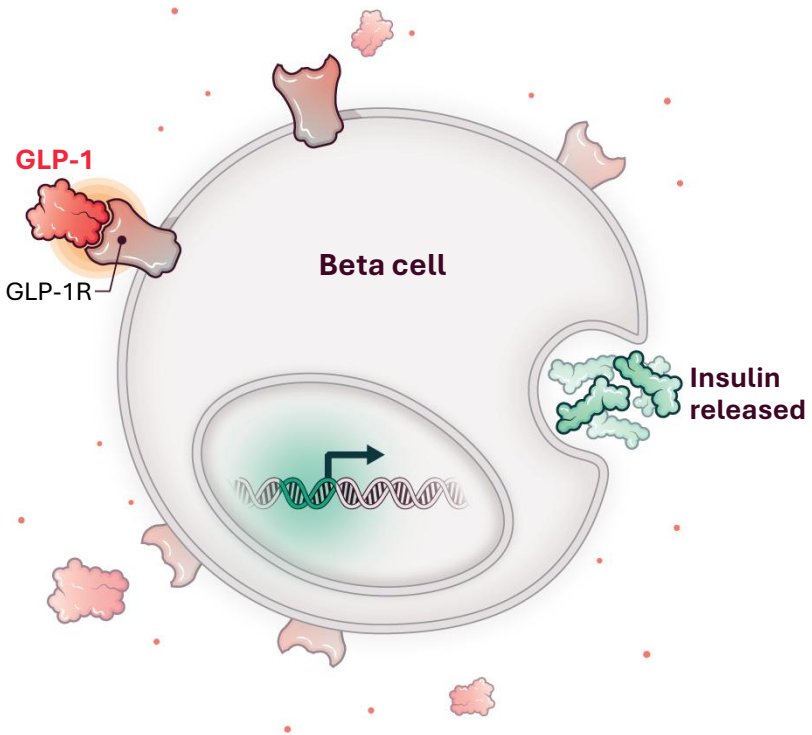
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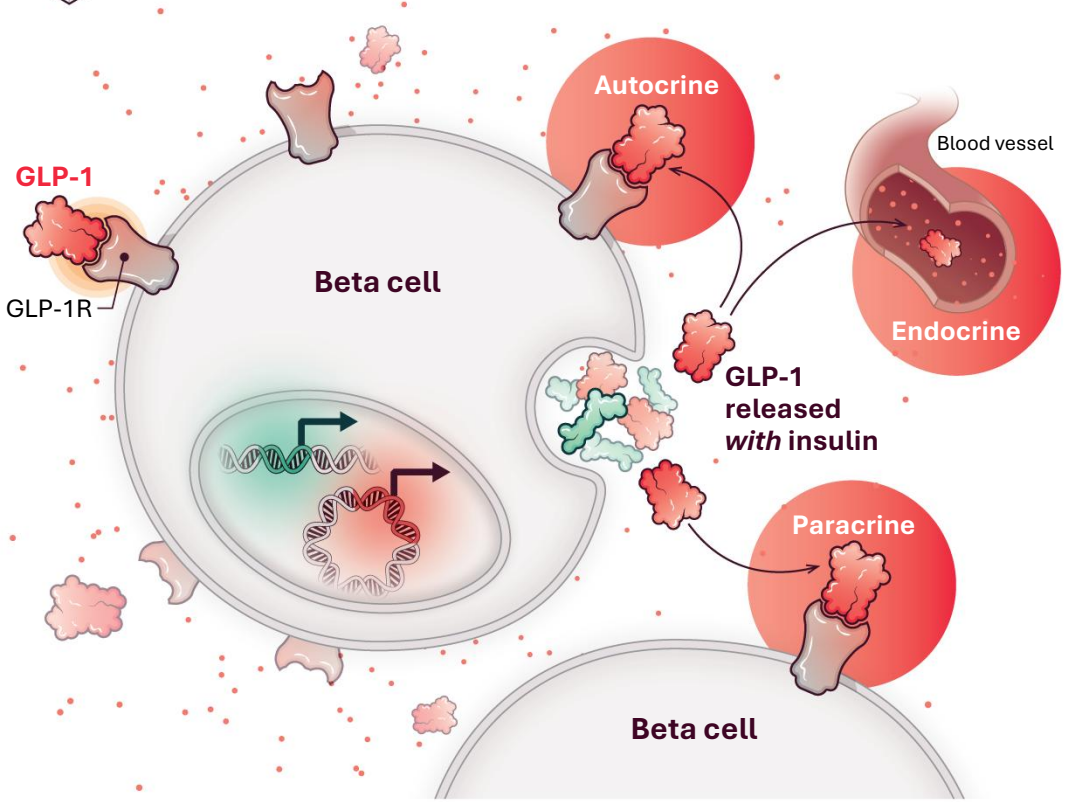
RJVA-001 for T2D

Nutrient-responsive “Smart” GLP-1 via intrapancreatic gene therapy

Type 2 Diabetes
Insufficient pancreatic GLP-1 signaling[1]



Rejuva
Nutrient-responsive GLP-1 expression



Product design

- Proprietary targeted endoscopic delivery
- AAV9 vector
- Insulin promoter
- Human GLP-1 transgene

Smart GLP-1 differentiation

- Single intrapancreatic administration
- Designed to transduce pancreatic islets
- Expression regulated by the insulin promoter
- Enables nutrient-responsive GLP-1 expression

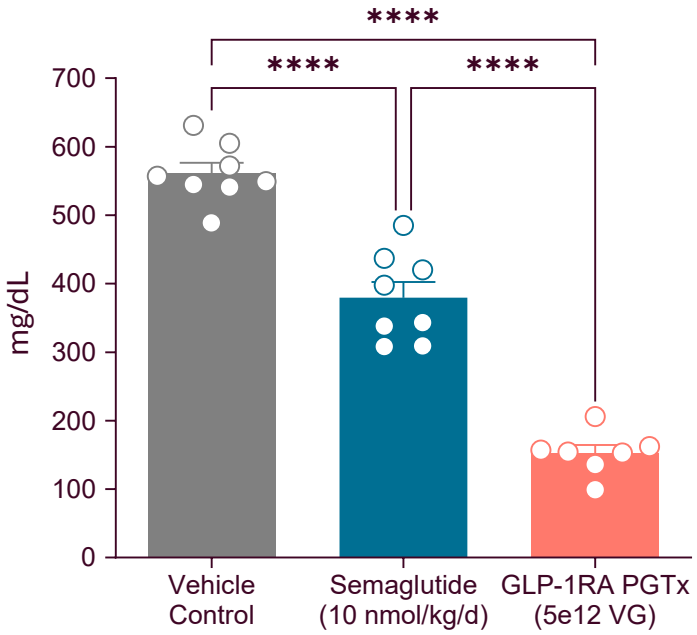
Abbreviations: GLP-1, glucagon-like peptide 1.

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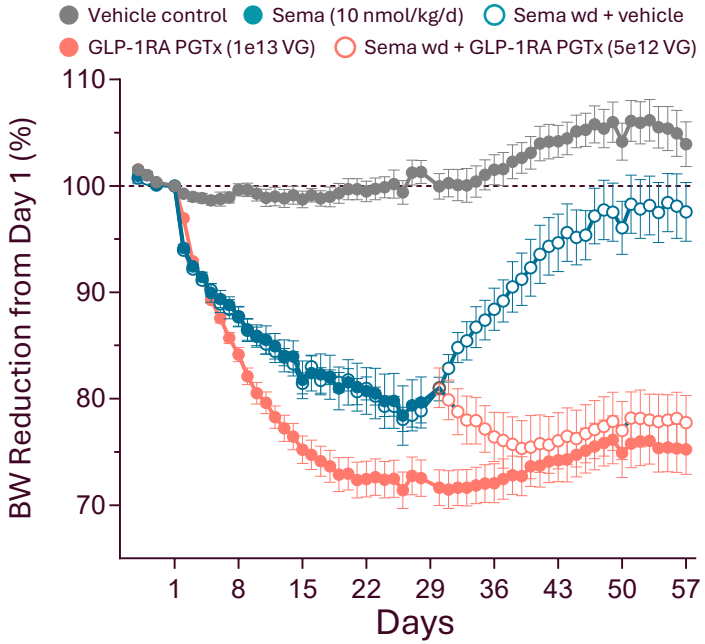
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Potent efficacy in T2D & obesity mouse models with no toxicity observed in large animal model

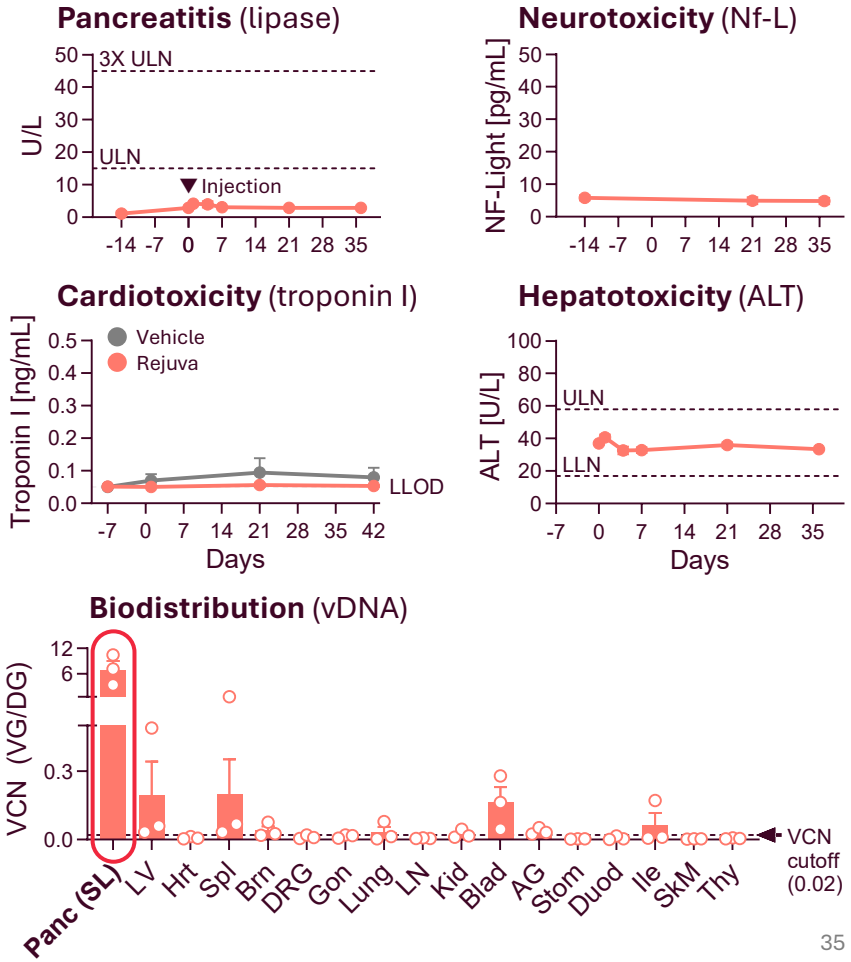
Glucose-lowering activity in *db/db* mouse model[1]



Sustained weight loss in DIO mouse model[2]



No toxicity observed in Yucatan pig model[3]



One-Way ANOVA, post-hoc Tukey Test: ****: P<0.0001. [1]Mean ± SEM shown; n=7-8 per group, day 29 shown, Rajagopalan et al. DDW 2024 oral presentation. Abstract no. 4029196. [2]Mean ± SEM shown; n=5-10 per group. Fitzpatrick et al. WCIRDC 2023 oral presentation. Abstract no. 0077. [3]Fitzpatrick et al., ASGCT 2025 oral presentation. Data are mean ± SEM, n=2-6 pigs per group. Abbreviations: AG, adrenal gland; ALT, alanine transaminase; Blad, bladder; BW, body weight; Brn, brain; DIO, diet-induced obesity; DRG, dorsal root ganglion; GLP-1RA, glucagon-like peptide 1 receptor agonist; Gon, gonad; Hrt, heart; Ile, ileum; Kid, kidney; LLN, lower limit of normal; LN, lymph node; LV, liver; NF-L, neurofilament light chain; Panc, pancreas; PGTx, pancreatic gene therapy; SkM, skeletal muscle; SL, single-lobe; Spl, spleen; Stom, stomach; Thy, thyroid; ULN, upper limit of normal; VCN, vector copy number; VG/DG, vector genome/diploid genome; wd, withdrawal.

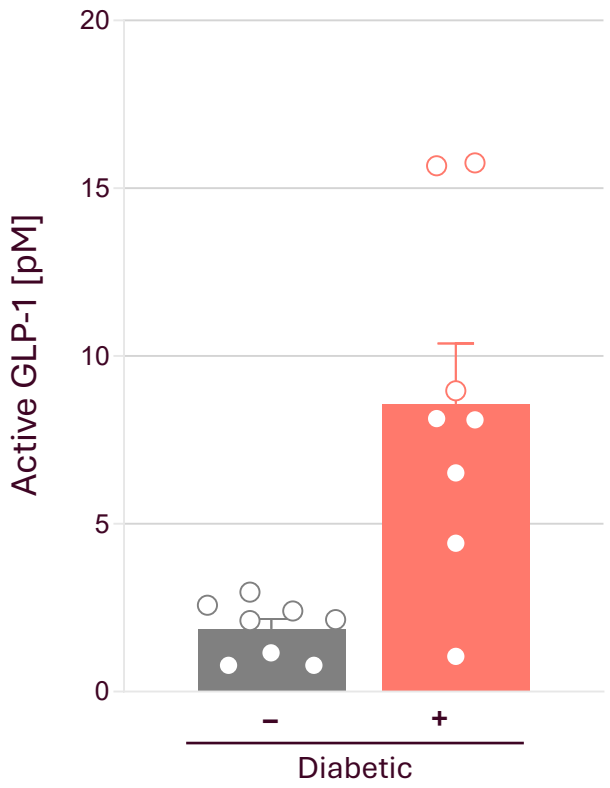
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Robust efficacy without high systemic GLP-1 exposure

May be less likely to cause tolerability issues

Rejuva active GLP-1 (circulating)[1]



Circulating active GLP-1 Levels[2]

Modality	Levels	Tolerability
Physiological	<5 pM	✓
DPP4 inhibition	~10 pM	✓
Rejuva GLP-1	**10-20* pM**	**TBD in FIH clinical study**
Roux-en-Y gastric bypass	~20 pM	✓
GLP-1RA drugs	50-150 pM	✗

[1]Fitzpatrick et al., ASGCT 2025 oral presentation. Data are mean ± SEM, n=8 per mice group from day 44 post IP AAV injection [2]Smits and Holst et al. Diabetes Metab Res Rev. 2023 Nov;39(8):e3699. *Levels detected at highest Rejuva dose tested in db/db mice. Circulating GLP-1 levels in db/db mice were more than twice those of healthy controls (db/+) (data on file). Abbreviations: DPP4, dipeptidyl peptidase-4; FIH, first-in-human; GLP-1, glucagon-like peptide 1; GLP-1RA, GLP-1 receptor agonist; TBD, to be determined.

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RJVA-001 planned FIH dose escalation study design

Aligned with regulators to assess safety, tolerability, PK, preliminary PD

Patient population

- Adults with T2D and obesity and preserved pancreatic function on GLP-1RA therapy
- HbA1c 7-10%; BMI 30-40 kg/m^2
- Not yet on insulin therapy
- No prior AAV9 exposure

Endpoints

- Primary: Safety and tolerability across dose levels
- Secondary: PK profiling, exploratory PD biomarkers (blood glucose, metabolic markers)

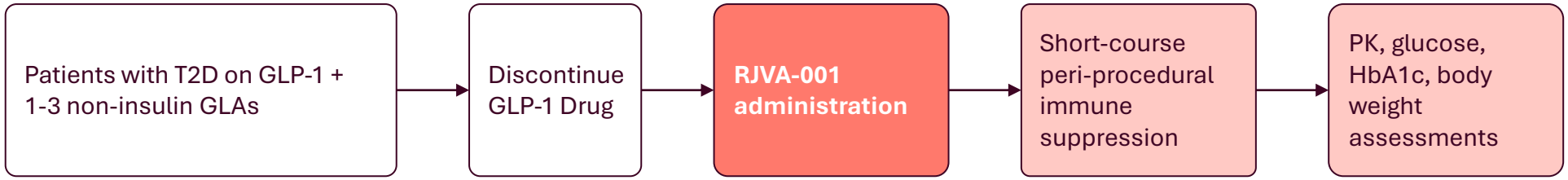
Study design

- GLP-1 drug therapy washout prior to therapy
- Sequential dose cohorts receiving escalating single doses of RJVA-001

Anticipated milestones[1]

- **FIH dosing, subject to site activation, and preliminary data:** H2 2026

Study design: Ph 1/2 open-label, dose escalation



[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: AAV, adeno-associated virus; CTA, clinical trial application; FIH, first-in-human; GLP-1, glucagon-like peptide 1; PD, pharmacodynamics; PK, pharmacokinetics; T2D, type 2 diabetes.

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Robust IP estate covering Revita & Rejuva

Strategic platform for long-term value and optionality

Global footprint[1]

36	Active patent families
100+	Patents issued globally
39	Patents issued in the US
80+	Pending patent applications

- **Protection across key jurisdictions** including: U.S., EU, China, Japan, Canada, Korea
- Foundational patents with **priority dates from 2011**
- IP is home-grown; **no in-licensing**

Diverse Protection

Issued claims cover devices, systems, methods of treatment

IP Portfolio focus includes:

- **Methods** of treating critical region of duodenum
- **Devices** for treating target tissue in the duodenum
- **Gene therapy** infusion devices, methods, constructs

Leadership in thermal & non-thermal DMR ablation

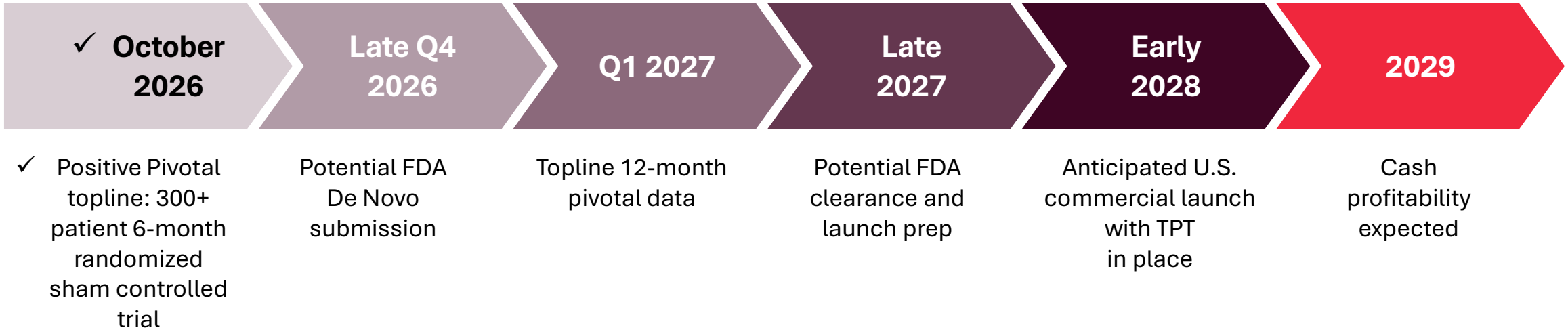
Proactive continuation strategy extends protection to improvements & **emerging technologies**

[1]As of August 2026.

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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.

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Leadership team & BOD

Experience spanning biotechnology and medical technology



Harith Rajagopalan, MD, PhD
Co-Founder & CEO



Jay Caplan
Co-Founder, President, & CPO



Lara Smith Weber
CFO



Sarah Toomey
General Counsel & Corp. Secretary



Mike Zumdahl
Sr VP of Market Access & Commercial Strategy



Jon Fitzgerald
Sr VP of Regulatory, Quality, & Clinical



Len Rosberg
VP of Manufacturing

Board of Directors

Ajay Royan (Chair) Co-founder & Managing General Partner, Mithril Capital	**William Bradley** Former U.S. Senator	**Harith Rajagopalan** Co-founder & CEO, Fractyl Health	**Marc Elia** Founder of M28 Capital	**Kelly Barnes** Former Partner, PwC	**Samuel Conaway** President of Boston Scientific U.S. Cardiology Sales & Chair of Close the Gap	**Clive Meanwell** Executive Chairman & Founder of Population Health Partners	**Christopher Thompson** Prof of Medicine, Harvard Medical School & Dir of Endoscopy, Brigham & Women's Hospital	**Ian Sheffield** Managing Partner, North Country Holdings, LLC

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Thank you

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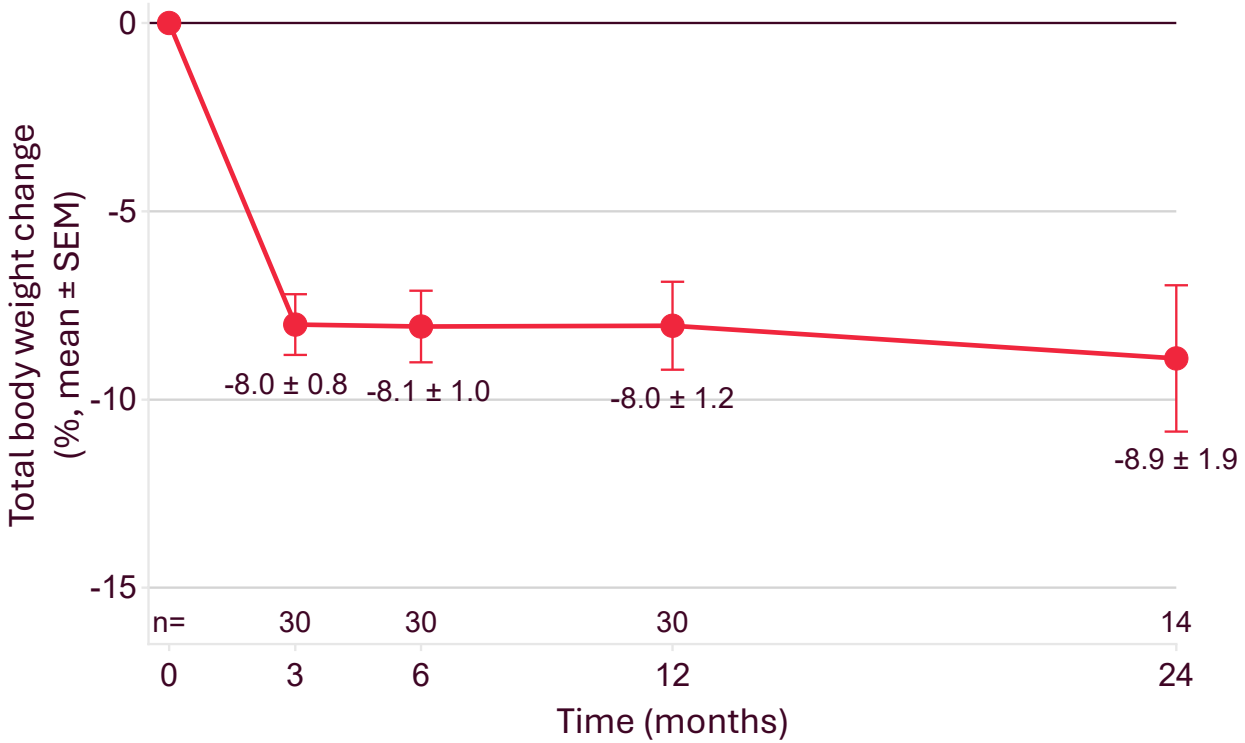
Appendix

NASDAQ:GUTS

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Real-world data show sustained 2-year metabolic benefits after a single Revita treatment

~9% total body weight loss sustained through 2 years after a single Revita treatment



- **Metabolic control:** Mean HbA1c ↓1.7% from baseline (9.1% → 7.4%)
- **Reduced medicines:** 86% of patients on stable or fewer glucose-lowering drugs
- **Patient satisfaction:** At 2 yrs, 93% would repeat or recommend Revita
- **Real-world data:** Outcomes maintained despite reduced clinical surveillance
- **Safety:** No device- or procedure-related SAEs reported

The Germany Real-World Registry study is a prospective, post-market, clinical follow-up study to evaluate the Revita procedure in patients with inadequately controlled T2D. Entry criteria included a baseline HbA1c between 7-10% (inclusive), a BMI of ≤45 kg/m2, and use of at least one glucose-lowering agent (GLA). Baseline demographics: mean age of 60 years, a mean weight of 102 kg (225 lbs; BMI 33 kg/m^2), a mean HbA1c of 8.8%, despite being on up to three GLAs. Fractyl Health internal data, October 2025.
Abbreviations: QOL, quality of life; SAE, serious adverse event.

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Medicare alone is a multi-billion dollar opportunity

GLP-1 Bridge program may create a massive discontinuation pool Revita is designed to help

~4M

Medicare beneficiaries expected to access GLP-1s through the Bridge[1]

2–3M

expected to discontinue within a year | Bridge expires 12/31/2027[2]

600–970K

an estimated will achieve a deep response before stopping[3]

510K – 830K CMS beneficiaries eligible for Revita & TPT[3]

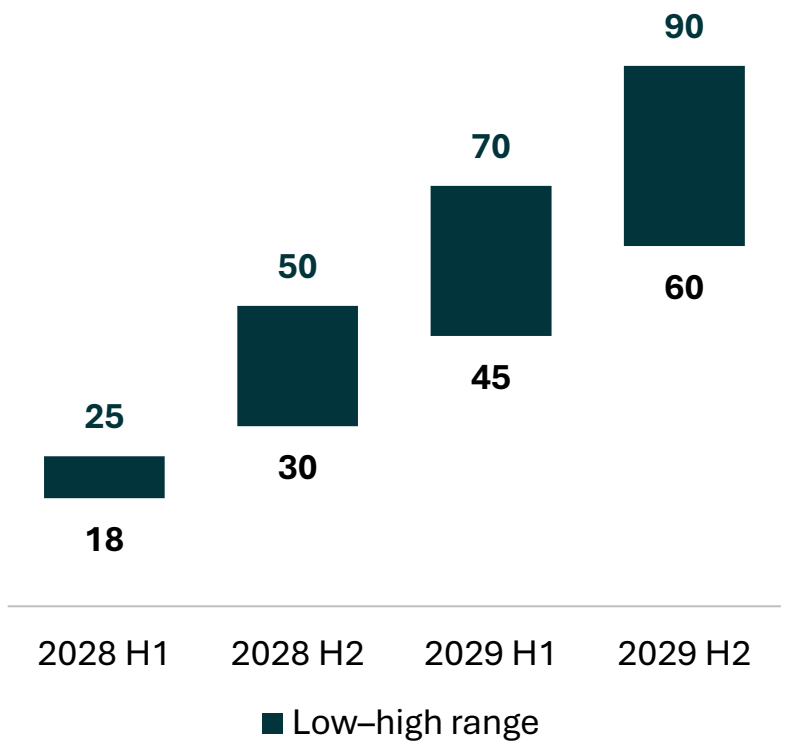
[1]https://www.kff.org/medicare/nearly-four-million-medicare-beneficiaries-met-the-eligibility-criteria-in-2023-for-the-medicare-glp-1-bridge . [2]CBO estimates 65% discontinuation - Publication 60441. [3]Company estimates

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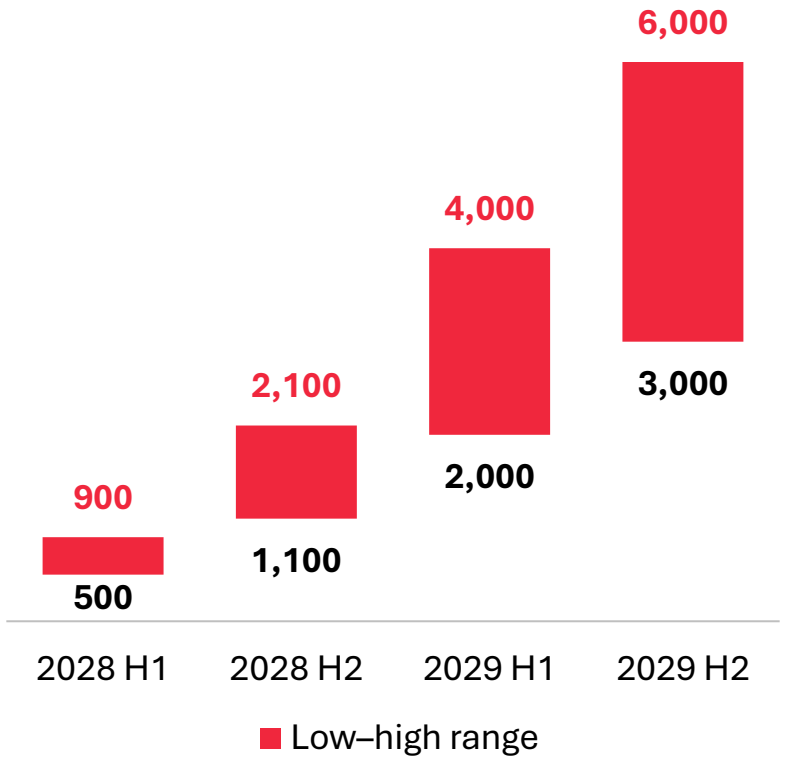
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Potential launch expected early 2028: Center-led ramp with ~1,600–3,000 procedures by EOY 2028 and 5,000–10,000 procedures in 2029

Centers live (cumulative)[1]



Procedures (per half-year)[1]



Centers of excellence[1]

30-50
live at the end of 2028

60-90
live at the end of 2029

Procedure volume[1]

1,600 to 3,000
procedures in 2028

5,000 to 10,000
procedures in 2029

1. Figures presented are management estimates contingent on pivotal results and on FDA marketing authorization, neither of which is assured, and they are not guidance

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