



Positive One-Year REVEAL-1 Open-Label Results Showing Sustained Post-GLP-1 Weight Maintenance

Participants retained ~78% of GLP-1 induced total body weight loss one year after discontinuation and a single Revita procedure

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

June 4, 2026

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.

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Weight Maintenance at 12 Months in Open Label Cohort

Single Revita procedure preserves GLP-1 induced weight loss through 1 year

Key Takeaways:

- **~78% of GLP-1-induced weight loss retained** at one year
- ~22% regained vs. 60-65% expected at 1 year¹ → ~1/3 the expected regain
- **33% (5/15) lost additional weight** through 52 weeks off GLP-1
- **Clean AEs and tolerability:** No device/procedure-related SAEs, no TEAE-related discontinuations through 12 months, no device/procedure-related late AEs.
- **FDA protocol amendment filed** to extend follow-up beyond 1 year
- **Supports thesis:** REMAIN-1 pivotal topline data expected early Q4 '26*

1. Budini et al., *eClinicalMedicine*, March 2026. *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: CTA, clinical trial application. FIH, first-in-human.

REVEAL-1 cohort study in weight maintenance

Ongoing, open-label cohort designed to provide early, real-world insights

Patient population

- Patients living with obesity (BMI ≥ 30) without T2D and achieving at least 15% TBW loss with tirzepatide or semaglutide
- $n \approx 20$ patients who need to or want to stop tirzepatide

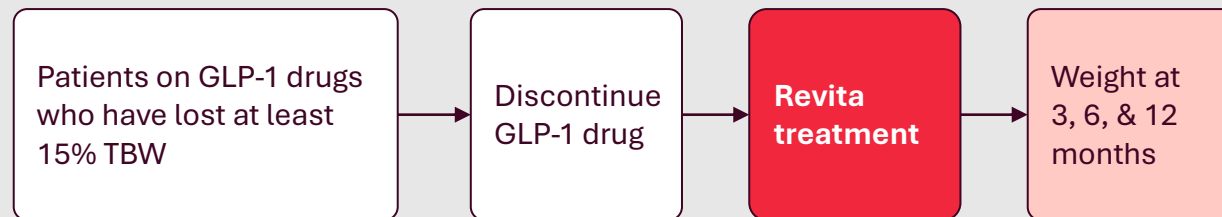
Primary endpoints

- Change from baseline in weight
- Comparison to historical controlled studies of GLP-1 withdrawal

Study design

- Single-arm, open-label, cohort study of Revita after GLP-1 drug discontinuation
- Diet and lifestyle counseling throughout

Study design



REVEAL-1 is an open label cohort as part of the REMAIN-1 pivotal IDE. Abbreviations: BMI, body mass index; GLP-1, glucagon-like peptide; LTFU, lost to follow-up; T2D, type 2 diabetes; TBW, total body weight

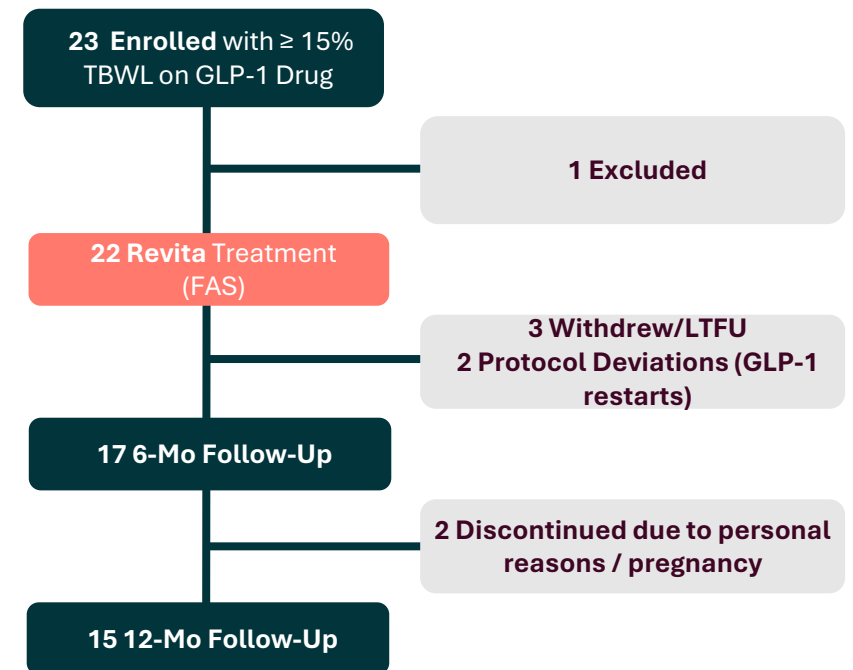
REVEAL-1 Open-Label Cohort Patient Disposition

Consistent procedure delivery; 12-mo retention in line with comparator trials

22 patients treated with Revita; 12-mo retention in line with comparator trials¹

- **Consistent procedure delivery:** average ablation length ~16 cm
- **Analysis populations:**
 - 22 in Full Analysis Set (FAS)
 - 22 in Safety Analysis
 - 15 in Completer Analysis

Patient Disposition



¹Aronne *et al.*, JAMA. 2023 Dec 11;331(1):38–48. FAS, full analysis set. GLP-1, glucagon-like peptide-1. LTFU, lost to follow-up,

REVEAL-1 Cohort Reflects REMAIN-1 Pivotal and Real-World Post-GLP-1 Demographics

Strong GLP-1 responders at high risk of post-discontinuation regain¹:

- **Substantial prior weight loss: -24% ± 7% TBW (> 50 lbs avg) on GLP-1s**
 - 17 of 22 participants ≥17.5% TBW loss on GLP-1s

Aligned with REMAIN-1 and real-world GLP-1 use:

- **21 of 22 (95%) on tirzepatide** — most relevant comparator to current real-world GLP-1 use
- Baseline characteristics align with REMAIN-1 Midpoint and Pivotal Cohorts^{2,3}

Table 1: Demographics and Baseline Characteristics

Baseline Characteristics	Baseline Post-GLP-1 (n=22)
Age, yrs, mean (SD)	50 (12)
Sex, no. (%)	
Male	3 (14)
Female	19 (86)
Pre-diabetes*, no. (%)	3 (14)
On Tirzepatide, no. (%)	21 (95)
Body Weight Pre-GLP-1, kg, mean (SD)	105 (19)
Body Weight Post-GLP-1, kg, mean (SD)	80 (15)
TBW Change on GLP-1, %, mean (SD)	-24 (7)
BMI Post-GLP-1, kg/m ² , mean (SD)	29 (4)
HbA1c Post-GLP-1, % mean (SD)	5.1 (0.4)

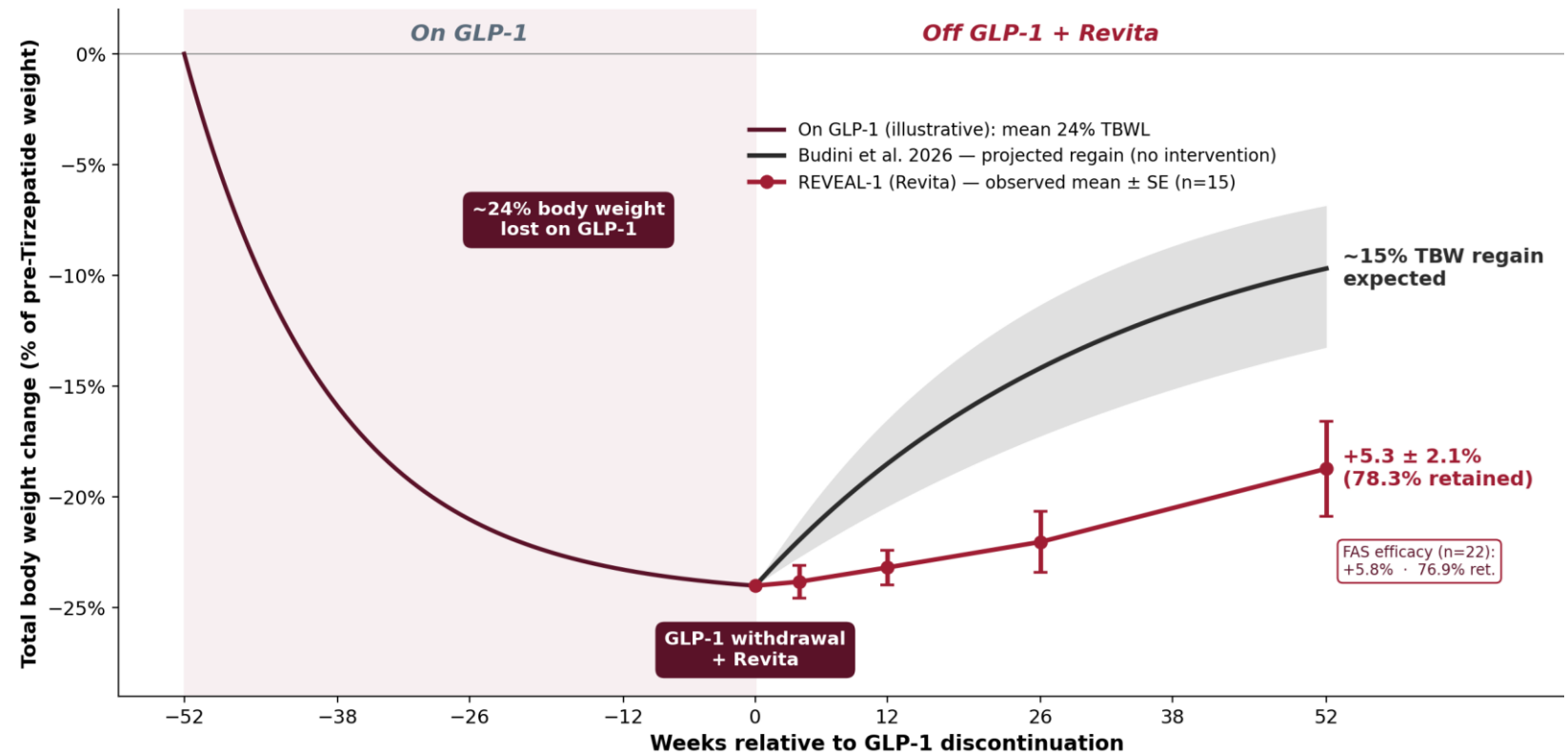
*prediabetes in participant medical history or per protocol definition: HbA1c 5.7-6.5 and/or fasting plasma glucose 100-125 mg/dL at baseline. 1. Budini et al., eClinicalMedicine 2026. 2. Fractyl Health press release and conference call dated September 26, 2025. 3. Fractyl Health data on file. BMI=body mass index, GLP-1=glucagon-like peptide-1, HbA1c=Hemoglobin A1c, SD=standard deviation, TBW=total body weight

~1/3 the Expected Weight Regain at 1 Year Post-GLP-1

REVEAL-1 open-label cohort: n=15 completers (n=22 FAS); single Revita treatment, no ongoing GLP-1

- **78.3% of pre-Revita weight loss retained** at 52 weeks (+5.3% ± 2.1% SE n=15; FAS sensitivity: +5.8%; 76.9% retained n=22)
- **~22% regained vs. ~60-65% literature-projected** regain at 1 year¹
- **33% (5 of 15) continued to lose weight** past GLP-1 discontinuation

Prevention of Weight Regain with Revita Post-GLP-1 Discontinuation



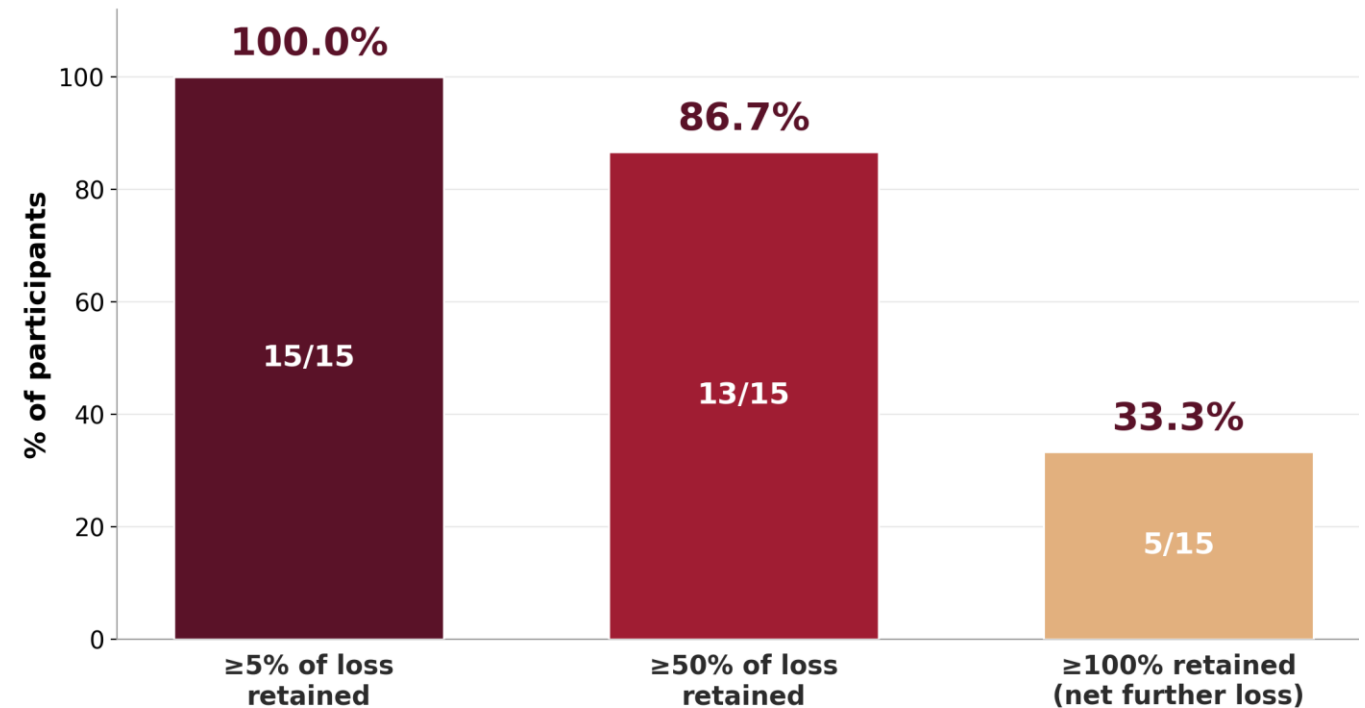
¹ Budini et al., eClinicalMedicine. 2026;93:103796

100% of REVEAL-1 Completers Hit the REMAIN-1 Pivotal Co-Primary Threshold at 52 Weeks

Responder Rates

- **100% retained at least 5% of GLP-1 induced weight loss** (co-primary endpoint in REMAIN-1 pivotal study)
- **87% retained at least 50% of GLP-1 induced weight loss** (industry clinical success threshold¹)
- **33% lost additional weight** at one year after discontinuing GLP-1 drugs
- Across this cohort, ablation length clustered narrowly around its median ablation length (16cm) and the study therefore does not have power to detect an ablation length dose response

100% Met Pivotal Co-Primary; 33% Lost Incremental Weight at 1 Year



1. Aronne LJ et al Nature Medicine 13 May 2026

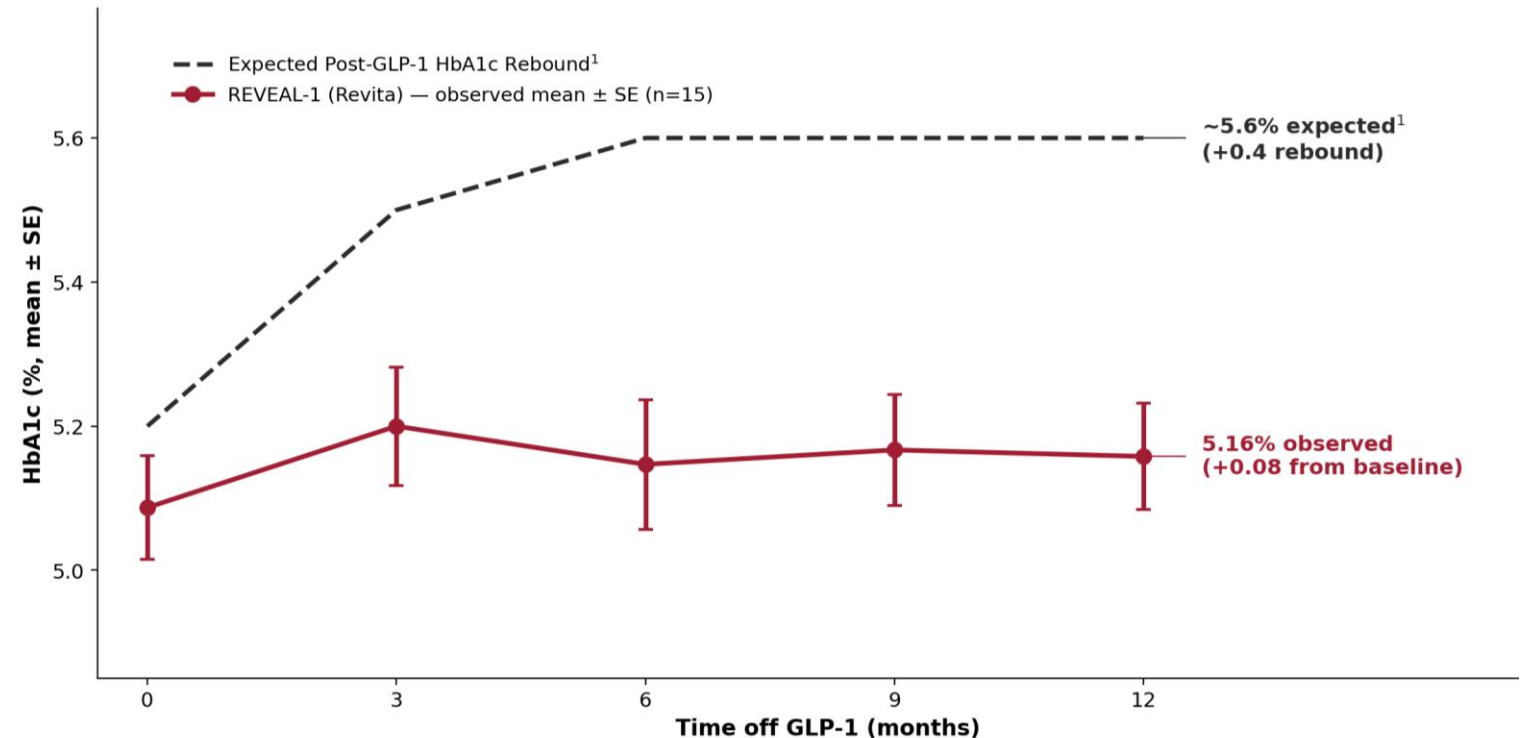
Sustained Glycemic Control Post-Revita

HbA1c held stable through one year off GLP-1

Glycemic Stability

- **HbA1c held flat at 5.16%** (+0.08 from baseline) through 52 weeks off GLP-1 which is within assay noise
- **No rebound observed** vs. ~0.4% increase expected post-GLP-1 trajectory¹
- **Absence of glycemic deterioration** despite discontinuation of GLP-1

HbA1c change (%)



1. Wilding et al. Diabetes Obes Metab. 2022 Aug;24(8):1553-1564. GLP-1=glucagon-like peptide-1, HbA1c= hemoglobin A1c, SEM=standard error of the mean

Excellent Safety and Tolerability Profile

No change to treatment emergent adverse events since last update

- No treatment-emergent serious adverse events related to device or procedure
- No TEAE-related study discontinuations
- No TEAE in long-term follow up
- Compelling safety and tolerability profile is consistent with prior Revita clinical experience

Table 2: Treatment-Emergent Adverse Events*

n=22	Patients, n (%)	Duration (days post-Revita)
Grade \geqIII TEAEs	0 (0)	N/A
Grade II TEAEs	0 (0)	N/A
Grade I TEAEs	8 (36)	1-5
Sore Throat	4 (18)	1-5
Bloating	2 (9)	2-3
Swollen, blistered lips	2 (9)	5
Nausea	2 (9)	1-4
Vomiting	1 (5)	1
Diarrhea	1 (5)	4
Abdominal pain and bloating	1 (5)	5
Inflammation to face lips and throat	1 (5)	5

Clavien-Dindo Classification¹: Standardized FDA recommended system for TEAE grading: Grade I: minor, any deviation from normal course without requiring treatment; Grade II: requiring treatment; Grade III: requiring surgical, endoscopic, radiologic intervention; Grade IV: Life-threatening, requiring ICU; Grade V: Death

*Related TEAEs are defined as definitely or probably related to the device and or procedure.
1. Dindo et al. Annals of Surgery 240(2):p 205-213, August 2004. TEAE= treatment-emergent adverse event.

Open-Label Durability Sets Up Two Key Randomized Readouts in the Next ~6 Months

What we know today

- **REVEAL-1 12-mo open-label** (today): ~22% regain vs. ~60-65% literature-projected¹
- **Midpoint Cohort 6-mo randomized** (Q1 '26): clear Revita-vs-sham separation; dose response established, large and growing effect size seen in high GLP-1 responders
- Independent datasets have shown consistent directional signal on durable post-GLP-1 weight maintenance
- Clean AE profile maintained through 12 months

What's next: randomized data

- **Anticipated Q3 2026***
 - **Midpoint Cohort 12-mo** randomized data
 - First randomized look at 1-year durability, direct controlled comparison to today's open-label signal
- **Anticipated Q4 2026 ***
 - **Pivotal Cohort 6-mo topline** expected in early Q4 2026
 - Registrational readout; supports De Novo submission planned late Q4 2026

¹ Budini *et al.*, *eClinicalMedicine*. 2026;93:103796. *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.

Near-term clinical catalysts and value-creation through to potential De Novo marketing application submission in Q4 2026

Revita *Outpatient endoscopic procedural therapy*

2026 Key Anticipated Milestones¹

Indication	Program	Recent accomplishments	Q2	Q3	Q4
Weight Maintenance	REVEAL-1 Cohort (Open Label)	✓ Durable 6-mo data shared (Dec '25)	✓ 1-year data		
	REMAIN-1 Midpoint Cohort	✓ Positive 6-month randomized data (Jan '26)		1-year data	
	REMAIN-1 Pivotal Cohort	✓ Completed randomization (Feb '26)			Topline 6-mo randomized data & potential De Novo marketing application submission

Rejuva *Local AAV-delivered pancreatic GLP-1 gene therapy*

Indication	Program	Research	Lead selection	IND/CTA enabling	Phase 1	2026 Key Anticipated Milestones ¹
Type 2 Diabetes	RJVA-001	CTA authorized in Netherlands				H2: FIH dosing, subject to site activation, and preliminary data
Obesity	RJVA-002	Candidate nominated				

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