MOMENTUM—Pemvidutide Phase 2 Obesity Trial

Week 24 Interim Analysis

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Forward-looking statements

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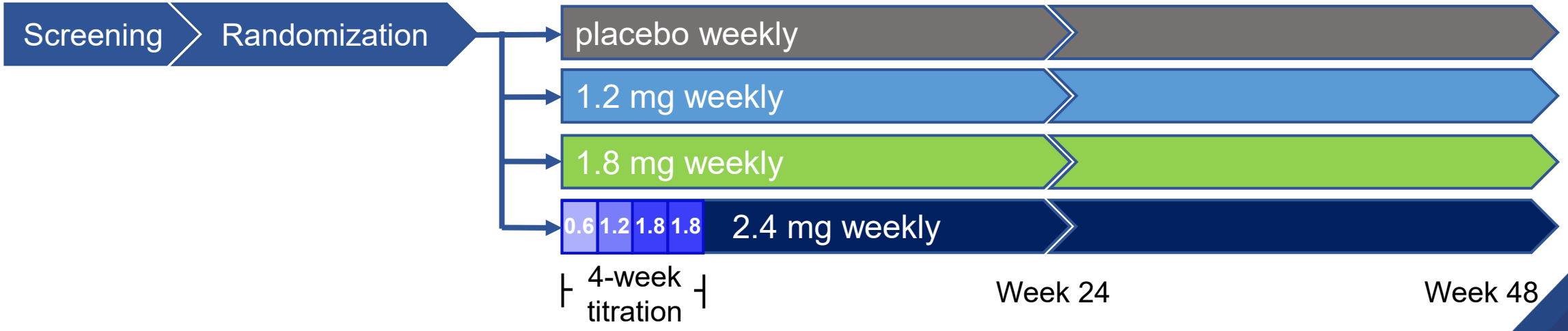
MOMENTUM Trial Design

- Phase 2, 48-week trial of pemvidutide in approx 320 subjects with overweight or obesity
- Randomized 1:1:1:1 to 1 of 4 treatment arms, stratified by sex and baseline BMI, with standard lifestyle interventions
- No or rapid (4 week) dose titration; dose reduction due to intolerability was not allowed
- A pre-specified 24-week interim analysis was performed on 160 subjects



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Study Population—Key Eligibility Criteria

- **Men and women ages 18-75 years**
- **BMI ≥ 30 kg/m^2 or BMI ≥ 27 kg/m^2 with at least one obesity-related comorbidity**
  - History of cardiovascular disease
  - Hypertension
  - Dyslipidemia
  - Pre-diabetes
  - Obstructive sleep apnea
- **Non-diabetes: HbA1c ≤ 6.5% and fasting glucose ≤ 125 mg/dL**
- **At least one unsuccessful weight loss attempt**
- **A minimum of approximately 25% of subjects were to be male**

Study Endpoints

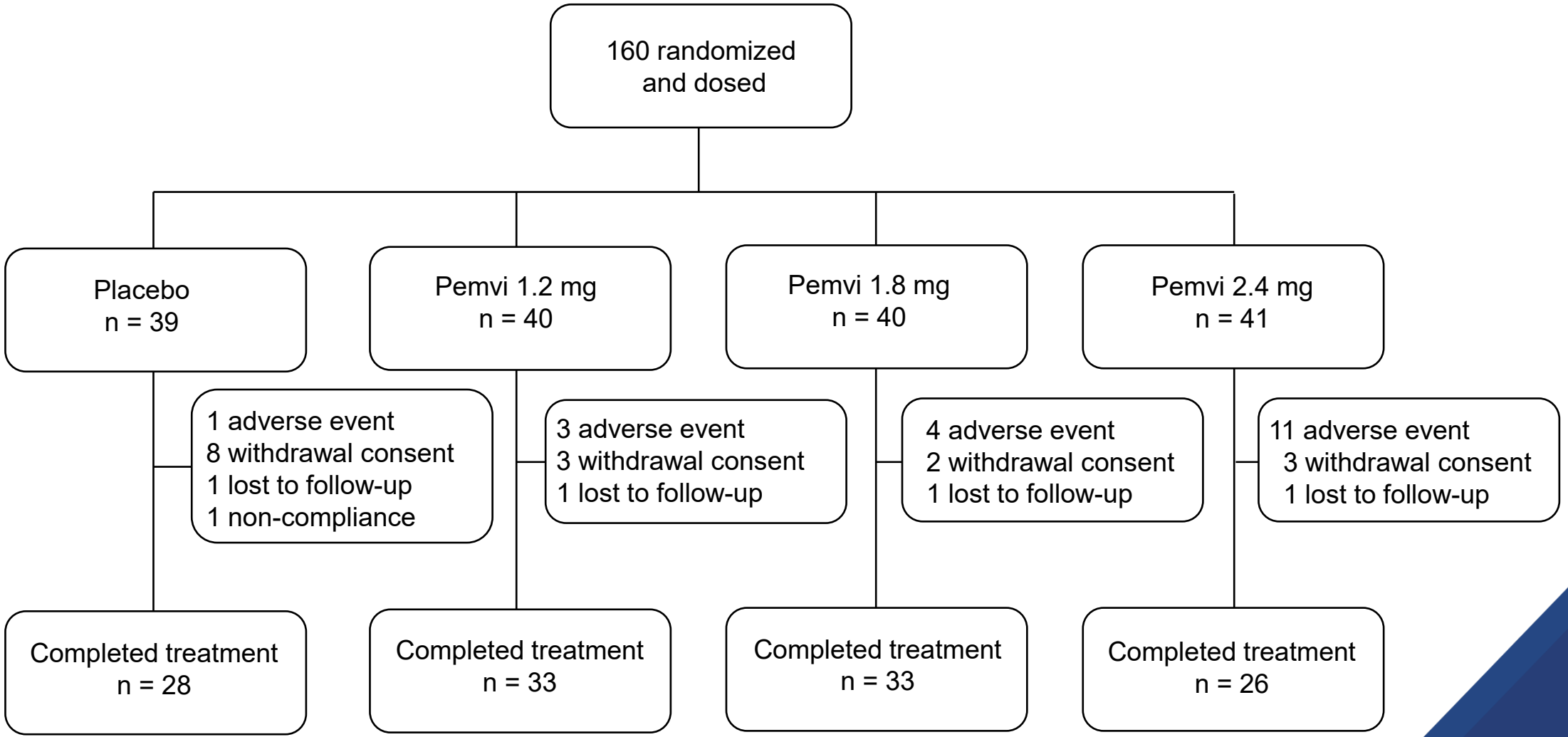
Efficacy

- **Primary Endpoint:**
  - Relative change from baseline in body weight (%)
- **Key Secondary Endpoints:**
  - Proportions (%) of subjects achieving weight loss of ≥ 5%, ≥ 10% and ≥ 15% body weight
  - Change from baseline in waist circumference, serum lipids, blood pressure

Safety

- **Adverse events (AEs)**
  - Serious and severe AEs
  - AEs leading to discontinuation
  - Gastrointestinal (GI) AEs
- **Heart Rate**
- **Glucose homeostasis**

Disposition of Subjects in Interim Analysis



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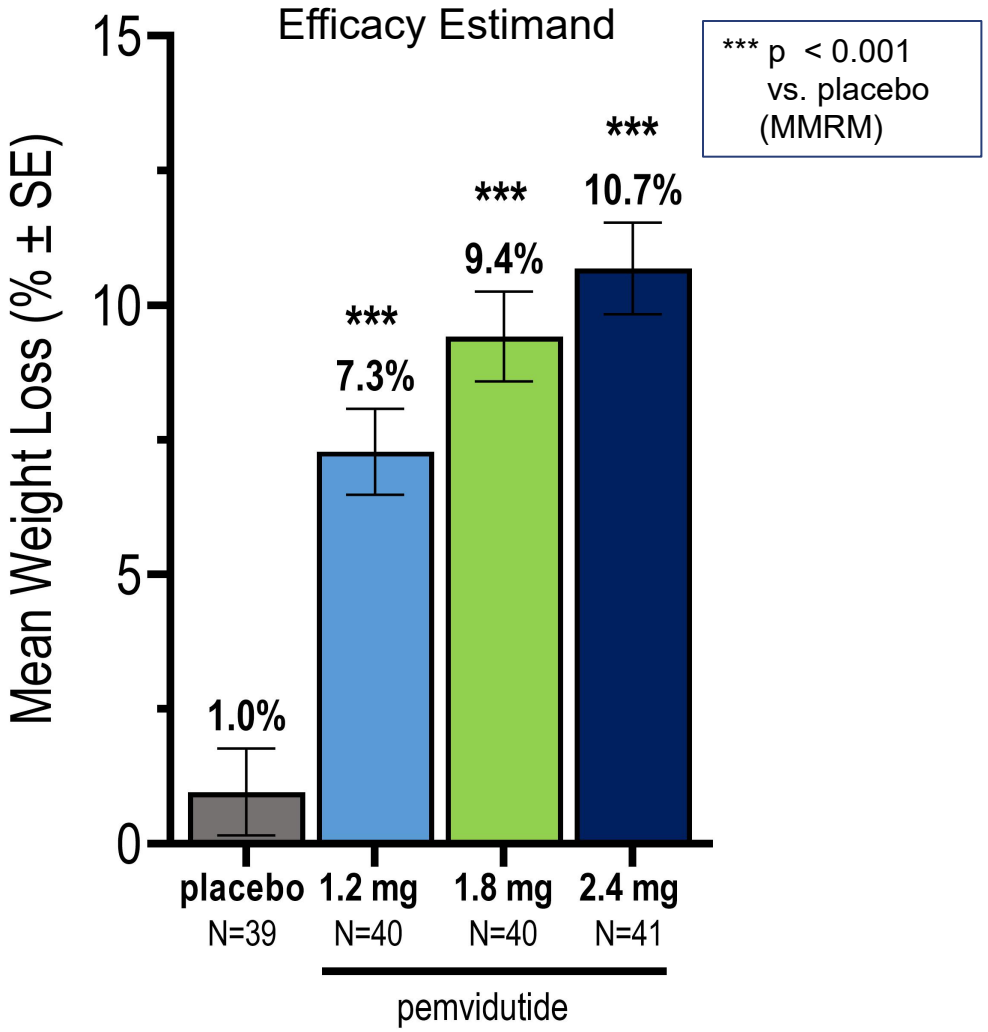
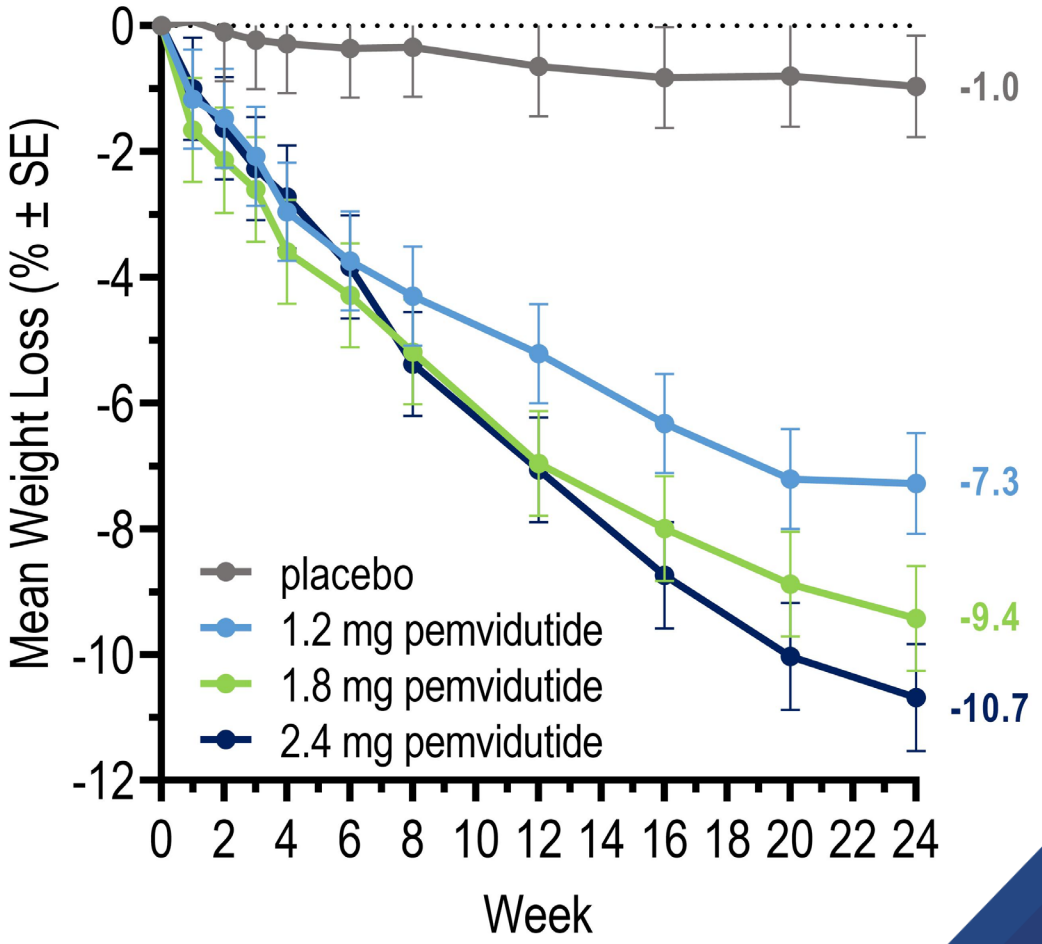
Baseline Characteristics of Subjects in Interim Analysis

Characteristic		Treatment			
		Placebo (n = 39)	1.2 mg (n=40)	1.8 mg (n=40)	2.4 mg (n=41)
Age, years	mean (SD)	46.7 (14.2)	46.5 (12.0)	49.5 (13.5)	48.2 (13.4)
Gender	female, n (%)	30 (76.9%)	31 (77.5%)	30 (75.0%)	31 (75.6%)
Race	white, n (%)	31 (79.5%)	36 (90.0%)	35 (87.5%)	34 (82.9%)
	Black or African-American	6 (15.4%)	2 (5.0%)	4 (10.0%)	7 (17.1%)
	Asian	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	other, n (%)	0 (0.0%)	2 (5.0%)	1 (2.5%)	0 (0.0%)
Ethnicity	Hispanic, n (%)	8 (20.5%)	10 (25.0%)	5 (12.5%)	9 (22.0%)
	not Hispanic, n (%)	31 (79.5%)	28 (70.0%)	34 (85.0%)	32 (78.0%)
	not reported, n (%)	0 (0.0%)	2 (5.0%)	1 (2.5%)	0 (0.0%)
BMI, kg/m^2	mean (SD)	37.8 (7.9)	37.1 (5.9)	36.0 (5.4)	36.0 (5.5)
Body weight, kg	mean (SD)	105.4 (24.8)	104.8 (24.0)	100.0 (20.4)	102.1 (17.7)
Blood pressure, mm Hg	systolic, mean (SD)	121.5 (13.0)	121.0 (12.2)	126.2 (12.6)	125.5 (13.7)
	diastolic, mean (SD)	75.4 (9.3)	77.4 (7.0)	79.2 (7.7)	80.3 (7.9)

Substantial Weight Loss Through Week 24

INTERIM DATA DEMONSTRATES PROMISING WEIGHT LOSS TRENDS





MMRM, mixed model for repeated measures

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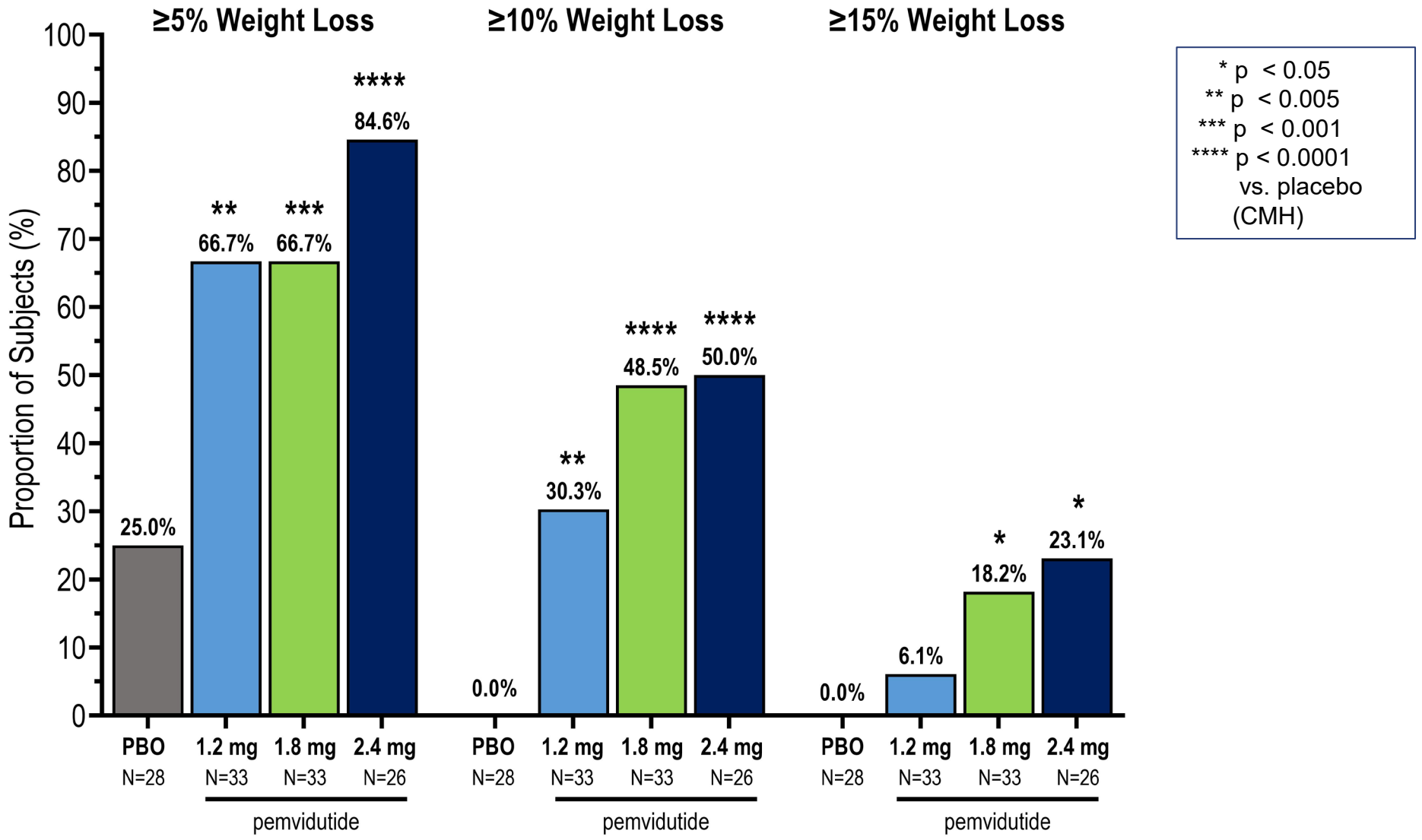
Weight Loss Responder Analysis at Week 24

50% OF SUBJECTS LOST 10% BODY WEIGHT AT 24 WEEKS



* p < 0.05
** p < 0.005
*** p < 0.001
**** p < 0.0001
vs. placebo
(CMH)

CMH, Cochran–Mantel–Haenszel

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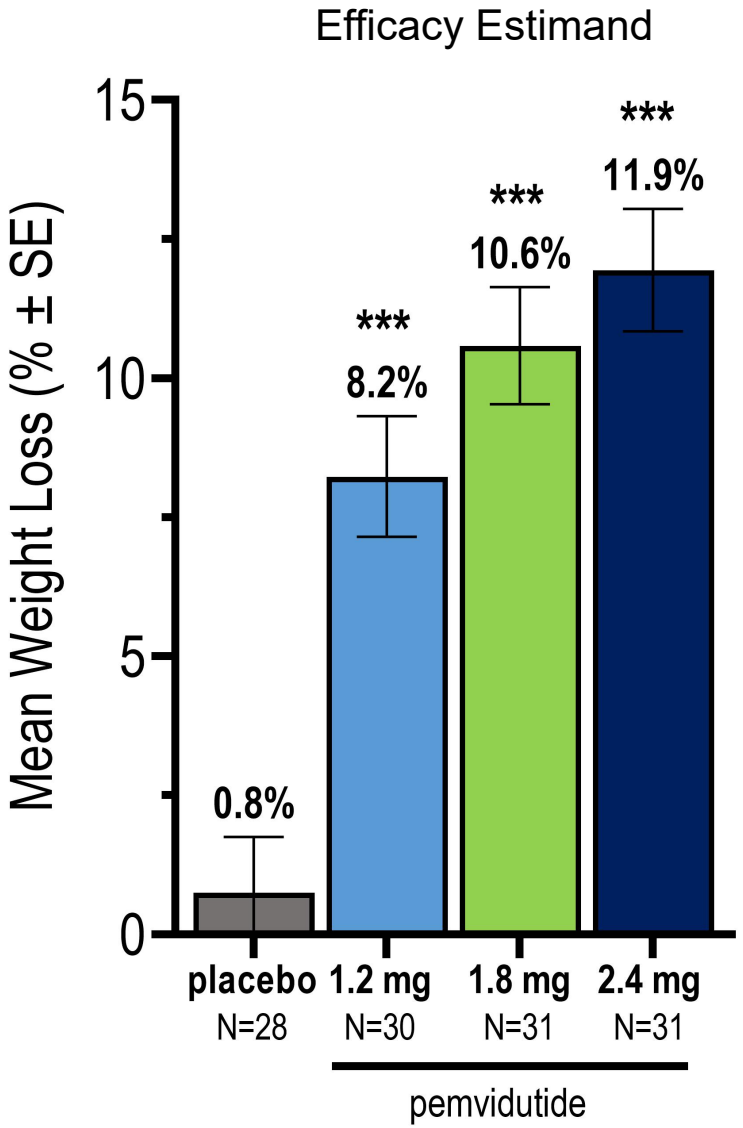
Impact of Baseline Body Weight on Efficacy

GREATER MEAN WEIGHT LOSS IN SUBJECTS WITH BASELINE BODY WEIGHT ≤115 kg



*** p < 0.001 vs. placebo (MMRM)

N =120 (75% of study population)

MMRM, mixed model for repeated measures

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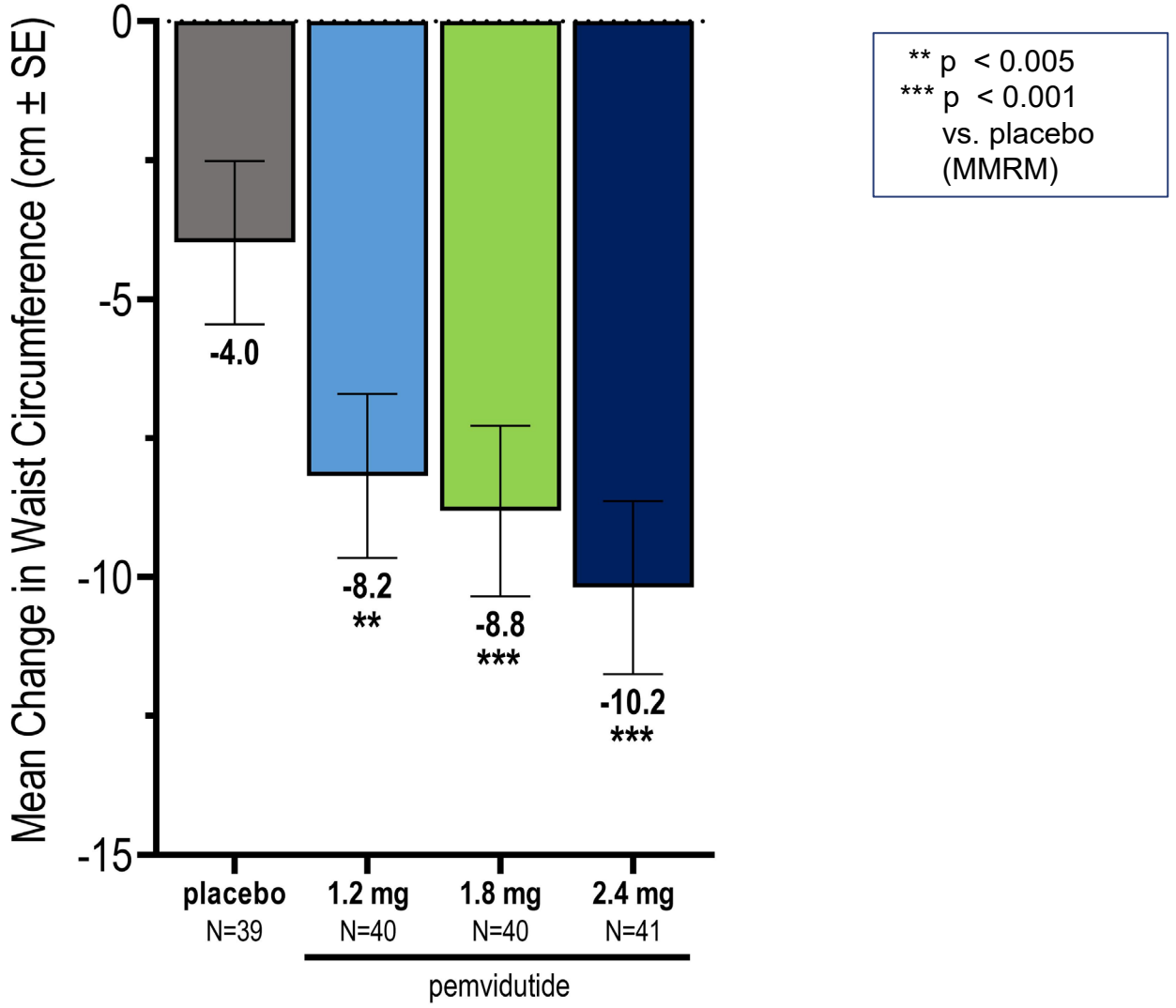
Significant Reductions in Waist Circumference at Week 24

REDUCTIONS IN CENTRAL OBESITY—A MARKER FOR VISCERAL FAT



** p < 0.005
*** p < 0.001
vs. placebo
(MMRM)

MMRM, mixed model for repeated measures

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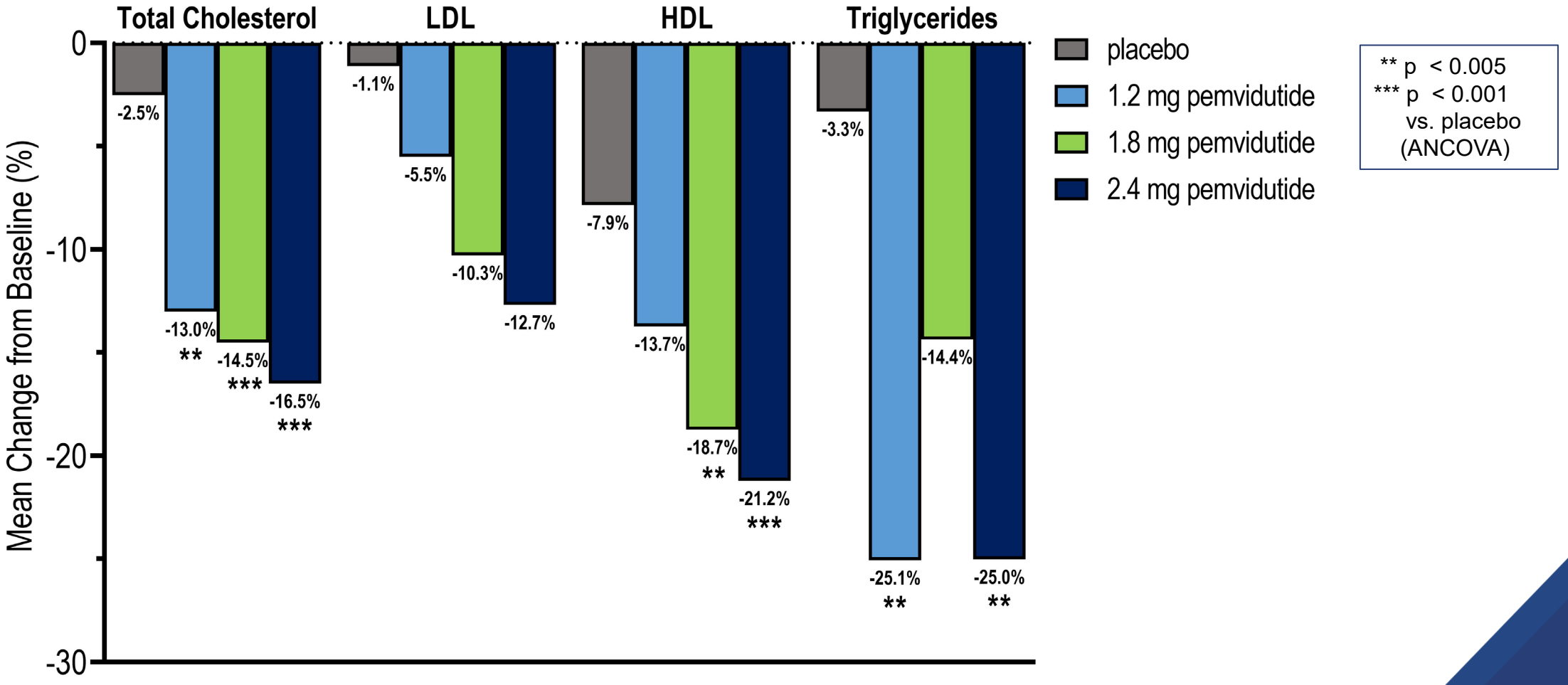
Robust Reduction in Serum Lipids at Week 24



ANCOVA, analysis of covariance

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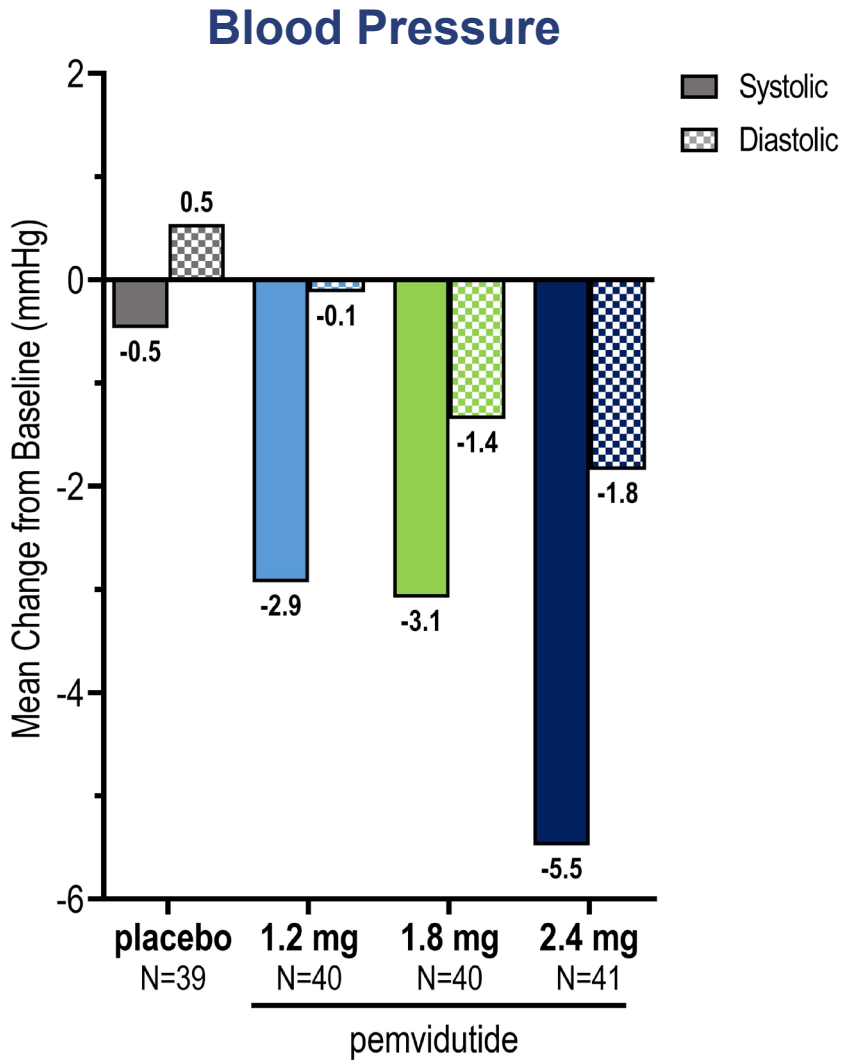
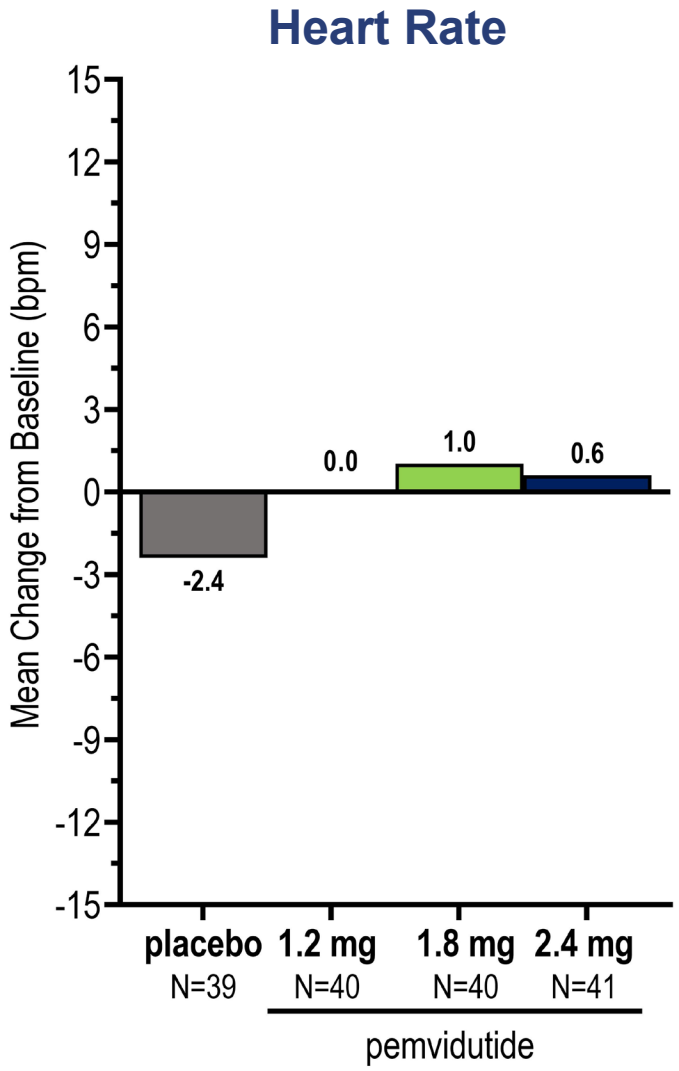
Improvements in Blood Pressure without Meaningful Changes in Heart Rate Through Week 24





MMRM, mixed model for repeated measures

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Safety Overview—AEs Through Week 24

Characteristic		Treatment			
		Placebo (n = 39)	1.2 mg (n=40)	1.8 mg (n=40)	2.4 mg (n=41)
Serious adverse events	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.4%)[1]
AEs leading to treatment discontinuation	n (%)	1 (2.6%)	3 (7.5%)	4 (10.0%)	11 (26.8%)
Gastrointestinal AEs					
Nausea					
Mild	n (%)	2 (5.1%)	5 (12.5%)	9 (22.5%)	12 (29.3%)
Moderate	n (%)	0 (0.0%)	3 (7.5%)	13 (32.5%)	9 (22.0%)
Severe	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.4%)
Vomiting					
Mild	n (%)	0 (0.0%)	0 (0.0%)	2 (5.0%)	5 (12.2%)
Moderate	n (%)	0 (0.0%)	2 (5.0%)	3 (7.5%)	4 (9.8%)
Severe	n (%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.4%)
Diarrhea					
Mild	n (%)	0 (0.0%)	3 (7.5%)	2 (5.0%)	4 (9.8%)
Moderate	n (%)	2 (5.1%)	0 (0.0%)	0 (0.0%)	2 (4.9%)
Constipation					
Mild	n (%)	0 (0.0%)	3 (7.5%)	1 (2.5%)	5 (12.2%)
Moderate	n (%)	2 (5.1%)	2 (5.0%)	1 (2.5%)	1 (2.4%)

[1]Rehydration for nausea and vomiting

Glucose Homeostasis Maintained Through Week 24

Characteristic		Treatment			
		Placebo (n = 39)	1.2 mg (n=40)	1.8 mg (n=40)	2.4 mg (n=41)
ALL SUBJECTS					
Fasting glucose					
Baseline, mg/dL	mean (SD)	96.1 (9.8)	97.0 (12.2)	103.1 (12.1)	100.3 (12.9)
Week 24, mg/dL	mean (SD)	97.7 (11.4)	96.0 (11.2)	103.9 (14.4)	102.5 (18.4)
HbA1c					
Baseline, %	mean (SD)	5.5 (0.4)	5.6 (0.3)	5.5 (0.4)	5.5 (0.4)
Week 24, %	mean (SD)	5.5 (0.3)	5.5 (0.3)	5.6 (0.5)	5.6 (0.5)

Summary and Conclusions

Efficacy

- 10.7% and 9.4% (placebo-adjusted: 9.7% and 8.4%) weight loss at 2.4 mg and 1.8 mg through Week 24
- 11.9% and 10.6% (placebo-adjusted:11.1% and 9.8%) weight loss at 2.4 mg and 1.8 mg through Week 24 in subjects with baseline body weight ≤ 115 kg
- Approximately 50% of subjects lost 10% or more of body weight and approximately 20% of subjects lost 15% or more body weight at 2.4 mg and 1.8 mg through Week 24
- Robust reductions in waist circumference, serum lipids and blood pressure

Safety and tolerability

- Gastrointestinal AE rates similar to earlier pemvidutide trials and to other incretin-based agents
- AE discontinuation rates at 2.4 mg dose - potentially mitigated by dose reduction and more extended dose titration
- No meaningful increases in heart rate
- Glucose homeostasis maintained

12-Week Phase 1b Trial of Pemvidutide in Subjects with Obesity or Overweight and Type 2 Diabetes

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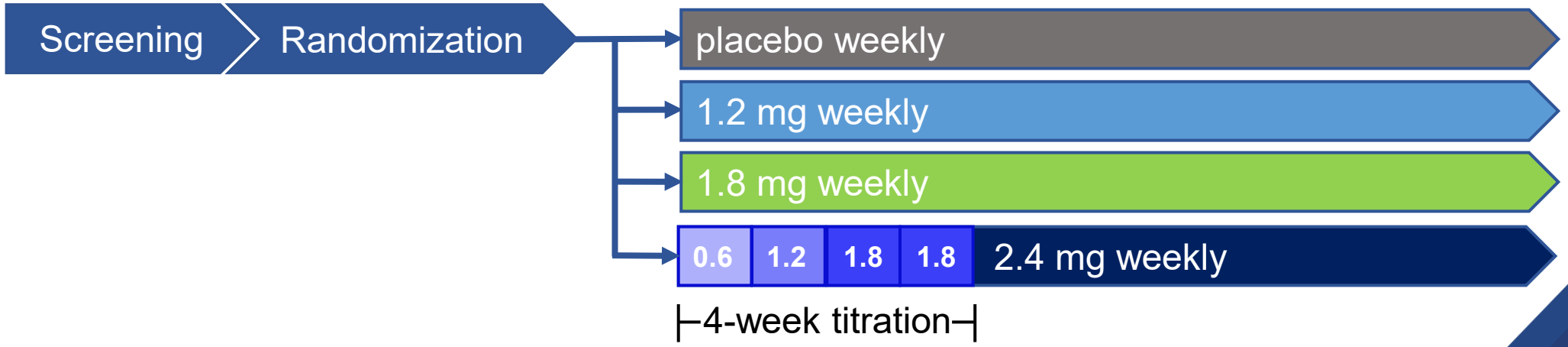
Pemvidutide Phase 1b Type 2 Diabetes Safety Trial

- 12-week, randomized, placebo-controlled study of pemvidutide in subjects with obesity or overweight and type 2 diabetes
- 54 subjects randomized 1:1:1:1 to 1 of 4 treatment arms, stratified by the presence or absence of metformin use at baseline
- No caloric restriction or lifestyle intervention



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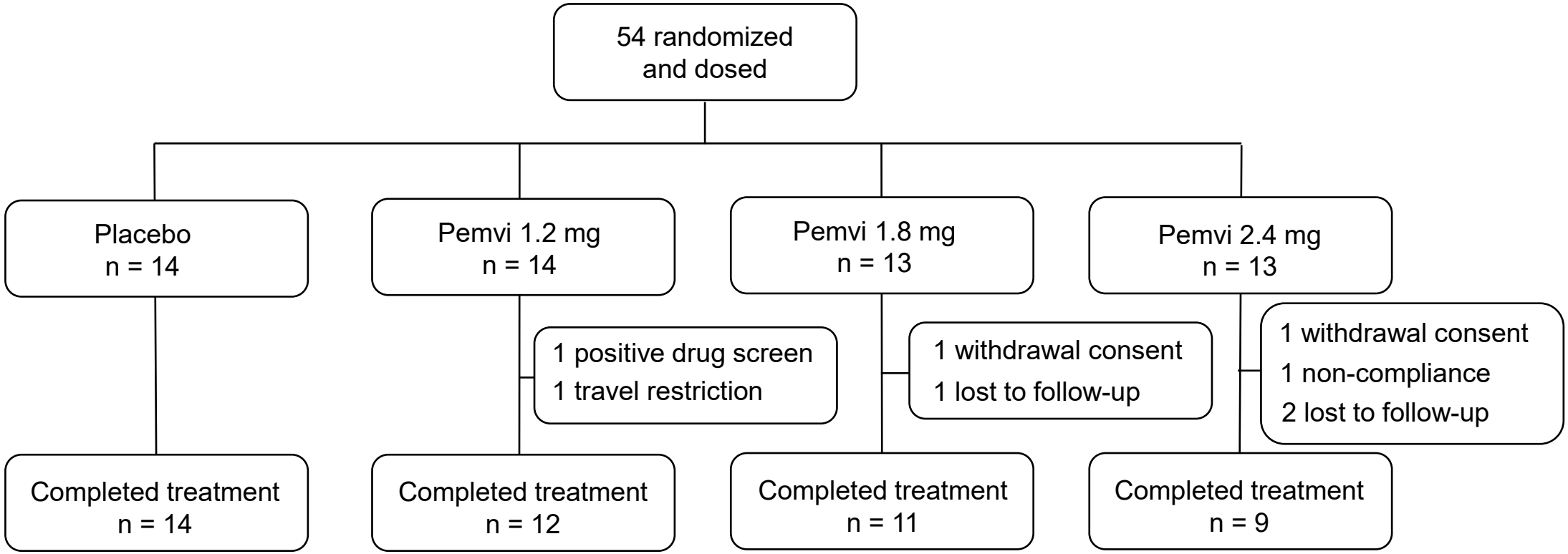
Study Population—Key Eligibility Criteria

- **Men and women, ages 18-65 years**
- **BMI ≥ 28 kg/m^2**
- **Type 2 diabetes on stable glucose control regimen for at least 3 months prior to screening**
- **Glucose control regimens included at least one of the following:**
  - Diet and exercise
  - Metformin with absent or mild gastrointestinal symptoms
  - SGLT-2 therapy

Disposition of Subjects



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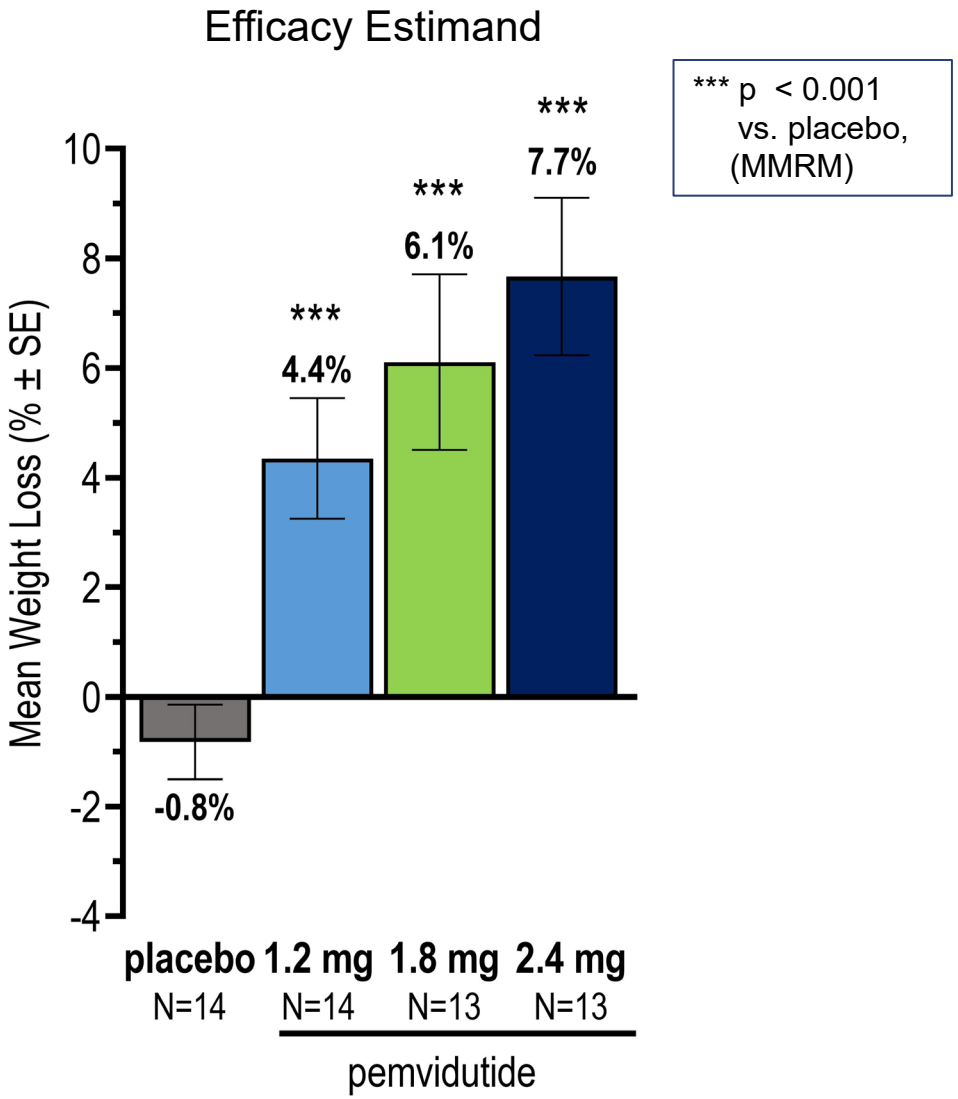
Substantial Weight Loss Through Week 12



MMRM, mixed model for repeated measures

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Glucose Homeostasis Maintained Through Week 12

Characteristic		Treatment			
		Placebo (n=14)	1.2 mg (n=14)	1.8 mg (n=13)	2.4 mg (n= 13)
ALL SUBJECTS					
Fasting glucose					
Baseline, mg/dL	mean (SD)	140.9 (41.6)	132.6 (25.0)	124.9 (31.0)	128.2 (22.8)
Week 12, mg/dL	mean (SD)	140.4 (45.4)	132.0 (32.8)	126.2 (15.7)	140.6 (28.7)
HbA1c					
Baseline, %	mean (SD)	6.6 (1.3)	6.5 (1.0)	6.6 (0.7)	6.9 (0.7)
Week 12, %	mean (SD)	7.0 (1.4)	6.5 (0.5)	6.7 (0.8)	7.0 (0.6)

Safety Overview—AEs Through 12 Weeks

Characteristic		Treatment			
		Placebo (n = 14)	1.2 mg (n=14)	1.8 mg (n=13)	2.4 mg (n=13)
Serious adverse events	n (%)	1 (7.1%)[1]	0 (0.0%)	0 (0.0%)	0 (0.0%)
AEs leading to treatment discontinuation	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hyperglycemia AEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gastrointestinal AEs					
Nausea					
Mild	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
Vomiting					
Mild	n (%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea					
Mild	n (%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Constipation					
Mild	n (%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[1] cervical radiculopathy

Summary and Conclusions

Weight loss

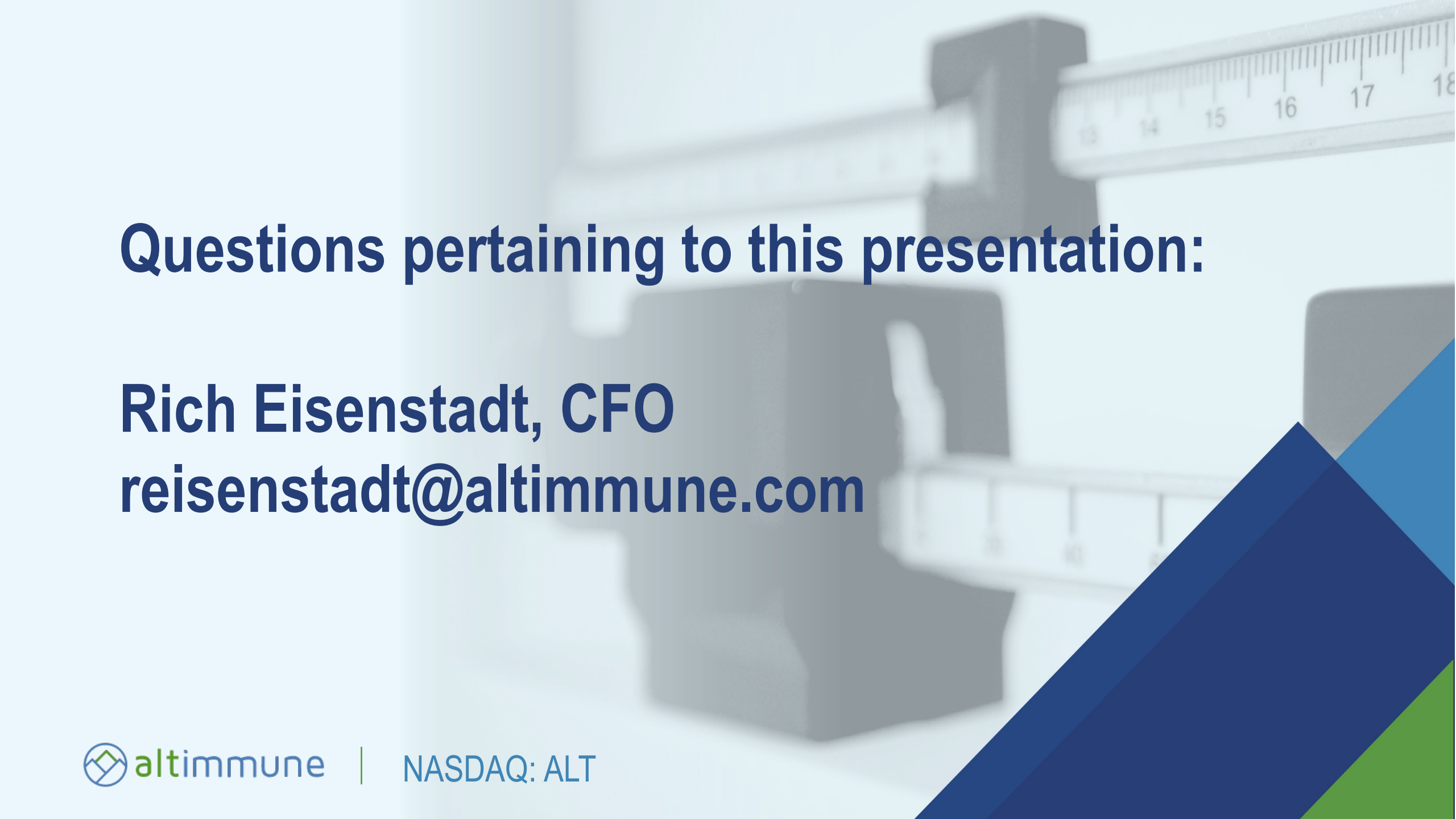
- 7.7% (placebo-adjusted 8.5%) weight loss at 2.4 mg through Week 12, with potential for robust weight loss at later timepoints

Glucose control

- Glucose homeostasis maintained, with no significant changes in fasting glucose or HbA1c through Week 12
- No hyperglycemia AEs

Safety and tolerability

- Excellent tolerability with low GI AE rates
- No discontinuations due to AEs



Questions pertaining to this presentation:

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