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Results of the First Phase 3 Study of Retatrutide in Participants With Type 2 Diabetes (TRANSCEND-T2D-1)

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Disclosures

SPEAKING/CONSULTING HONORARIA:

- **Novo Nordisk**
- **Eli Lilly and Company**

TRIAL/RESEARCH SUPPORT:

- **Amgen**
- **AstraZeneca**
- **Boehringer Ingelheim**
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- **Madrigal Pharmaceuticals**
- **Merck KGaA**
- **Novo Nordisk**
- **Pfizer**
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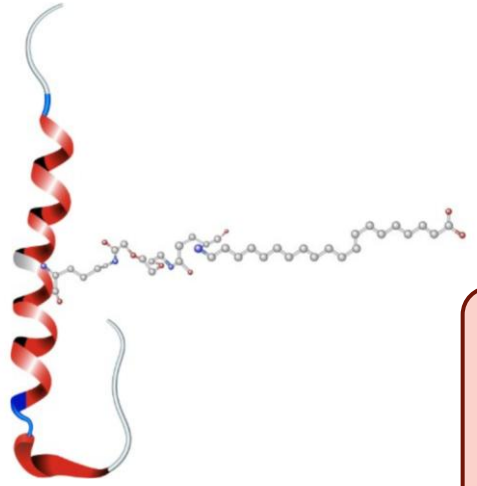
Retatrutide: Novel Triple Receptor Agonist

GLP-1R

2.5-fold lower potency vs. endogenous GLP-1[1]



GCGR

2.9-fold lower potency vs. endogenous glucagon[1]

GIPR

8.9-fold greater potency vs. endogenous GIP[1]

Molecular Design[1]

- **Novel** synthetic molecule
- **C-20 fatty diacid moiety** enables albumin binding and prolongs half-life

Mechanism of Action[1]

- Agonist of **3 receptors**:
  - **GLP-1R**, **GIPR**, and **GCGR**

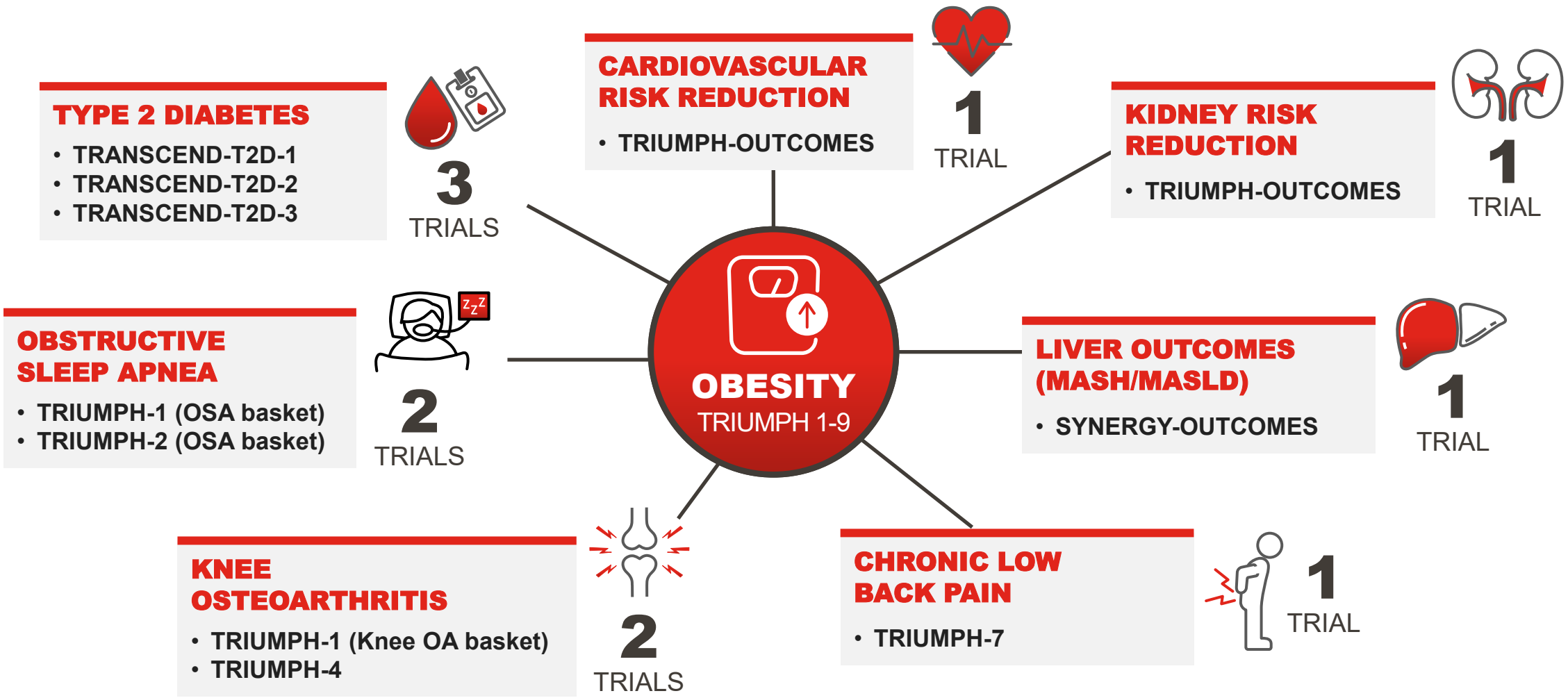
Pharmacokinetics[1,2]

- Mean half-life: **~6 days**
- Enables **weekly** SC dosing

1. Coskun T, et al. *Cell Metab*. 2022;34:1234-1247.e9. 2. Urva S, et al. *Lancet*. 2022;400:1869-1881.
GCGR=glucagon receptor; GIP=glucose-dependent insulinotropic polypeptide; GIPR=GIP receptor; GLP-1R=glucagon-like peptide-1 receptor; SC=subcutaneous.

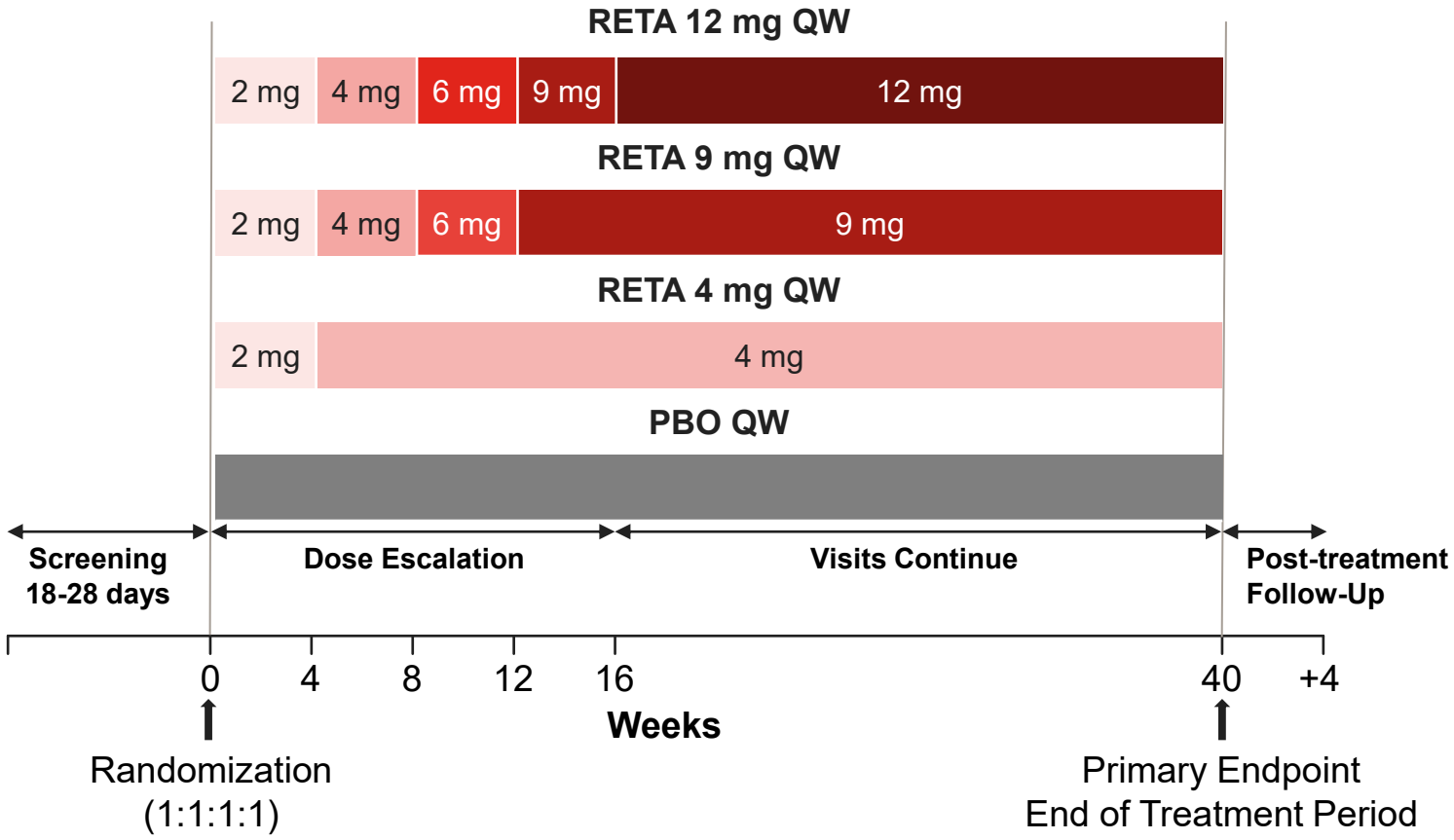
Retatrutide Phase 3 Program Across Obesity & Complications

Retatrutide Phase 3 Program Across Obesity & Complications



TRANSCEND-T2D-1 Study Design

Double-Blind Trial Assessing Retatrutide 4 mg, 9 mg, and 12 mg vs. PBO



Participants (N=537)

Key Inclusion Criteria

- Adults with T2D
- HbA1c ≥7.0% to ≤9.5%[a] at screening
- BMI ≥23 kg/m^2
- Stable weight (≤5-kg change) for ≥90 days prior to screening
- Naïve to insulin therapy
- No anti-hyperglycemic agents for ≥90 days prior to screening

[a]Inadequate glycemic control with diet and exercise alone.
Note: Temporary dose reduction for intolerable GI symptoms can be initiated for a 4-week period only during dose escalation (the first 20 weeks of the study) and should be followed by a dose re-escalation attempt.
https://clinicaltrials.gov/study/NCT06354660 (Accessed May 19, 2026).
BMI=body mass index; GI=gastrointestinal; HbA1c=glycated hemoglobin; PBO=placebo; QW=once weekly; RETA=retatrutide; T2D=type 2 diabetes.

Primary and Key Secondary Endpoints

Primary objective: To demonstrate the superiority of retatrutide (4 mg, 9 mg, 12 mg) vs. placebo in glycemic control at Week 40

Primary Endpoint

Change from baseline in HbA1c at Week 40

Key Secondary Endpoints[a] (at Week 40)

- Incidence of participant with **HbA1c of <7.0%, ≤6.5%, and <5.7%**[b]
- Change from baseline in **fasting serum glucose**[b]
- Change from baseline in **body weight**
- Incidence of participant reaching **weight reduction of ≥5%; ≥10%; and ≥15%**[b]
- Incidence of participant with **HbA1c ≤6.5%** and **reaching ≥10% body weight reduction** from baseline
- Percent change from baseline in lipid parameters (**non–HDL-C and triglycerides**)[b]
- Change **in systolic blood pressure**[b]

[a]Strongly controlled for type I error. [b]For retatrutide 9 and 12 mg ONLY.
HbA1c=glycated hemoglobin; HDL-C=high-density lipoprotein cholesterol.

Statistical Methods and Estimands

What is the treatment difference in mean change in HbA1c from baseline at Week 40 between retatrutide 4 mg, 9 mg, and/or 12 mg doses vs. placebo in individuals who meet eligibility criteria…

Efficacy Estimand

…assuming the following intercurrent events did not occur

- **Permanent discontinuation** of study intervention
- Initiation of additional **anti-hyperglycemic medications**[a]

All randomized participants (ITT)
MMRM or ANCOVA with missing endpoints imputed

Treatment Regimen Estimand

…regardless of adherence to study intervention or initiation of additional anti-hyperglycemic medications

All randomized participants (ITT)
ANCOVA with missing endpoints imputed

[a]Additional AHMs refers to any AHM used for >14 days.
ANCOVA=analysis of covariance; HbA1c=glycated hemoglobin; ITT=intent-to-treat; MMRM=mixed model for repeated measures.

Baseline Demographics

Characteristic	PBO (N=134)	RETA 4 mg (N=134)	RETA 9 mg (N=133)	RETA 12 mg (N=136)	Total (N=537)
Age, years	48.0 (12.2)	47.9 (12.2)	50.2 (12.1)	49.2 (12.1)	**48.8** (12.1)
Female, %	49.3	53.0	59.4	58.8	**55.1**
Race, %					
American Indian or Alaska Native	33.6	37.3	37.9	36.0	36.2
Asian	33.6	30.6	31.1	31.6	31.7
Black or African American	6.7	3.7	3.8	5.9	5.0
White	26.1	26.9	25.0	25.7	25.9
Ethnicity, %					
Hispanic or Latino	51.5	53.7	53.4	52.2	52.7
Duration of T2D, years	2.4 (4.1)	2.3 (4.3)	2.9 (5.3)	2.5 (4.0)	**2.5** (4.4)
Prior use of anti-hyperglycemic medication,[a] %	14.2	17.2	15.0	14.7	15.3
HbA1c, %	7.9 (1.1)	7.9 (1.1)	8.0 (1.0)	7.9 (1.0)	**7.9** (1.1)
FSG, mg/dL	131.8 (51.8)	137.8 (52.6)	144.7 (59.6)	129.9 (53.3)	136.1 (54.6)
Weight, kg	93.3 (18.6)	99.6 (23.3)	95.1 (21.9)	99.6 (25.1)	96.9 (22.5)
BMI, kg/m^2	34.7 (6.5)	36.6 (7.4)	35.6 (6.7)	36.4 (7.1)	**35.8** (7.0)

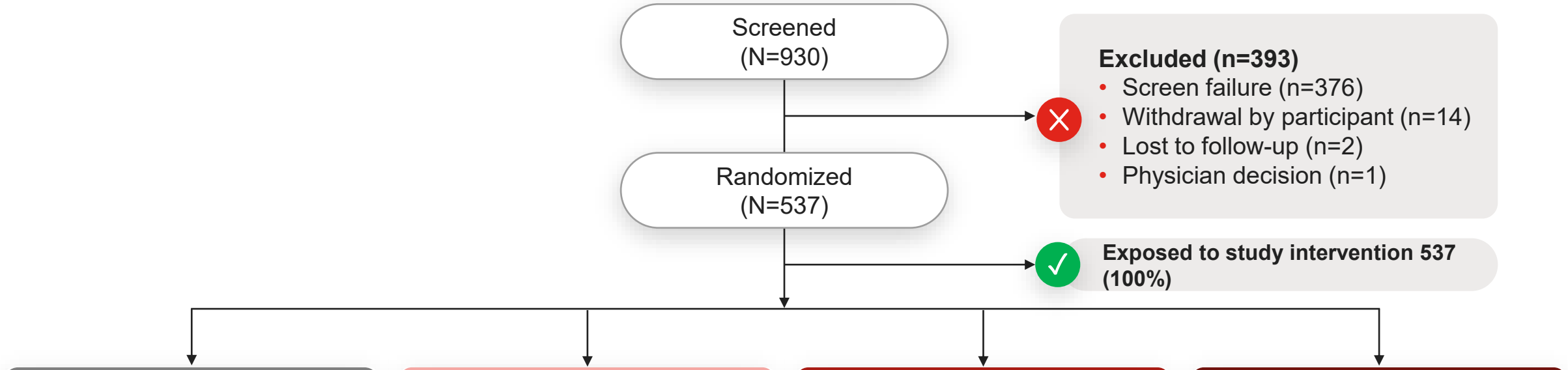
Recent T2D diagnosis, with mean HbA1c and BMI at baseline of 7.9% and 35.8 kg/m^2, respectively

[a]>90 days prior to Visit 1.

Notes: Data are shown as mean (SD) unless stated otherwise. Data from all randomized participants with non-missing data.

BMI=body mass index; FSG=fasting serum glucose; HbA1c=glycated hemoglobin; N=number of participants; PBO=placebo; RETA=retatrutide; SD=standard deviation; T2D=type 2 diabetes.

Participant Disposition



PBO (N=134)	RETA 4 mg (N=134)	RETA 9 mg (N=133)	RETA 12 mg (N=136)
124 (92.5%) completed treatment	**127 (94.8%)** completed treatment	**120 (90.2%)** completed treatment	**119 (87.5%)** completed treatment
123 (91.8%) completed study	**128 (95.5%)** completed study	**124 (93.2%)** completed study	**129 (94.9%)** completed study

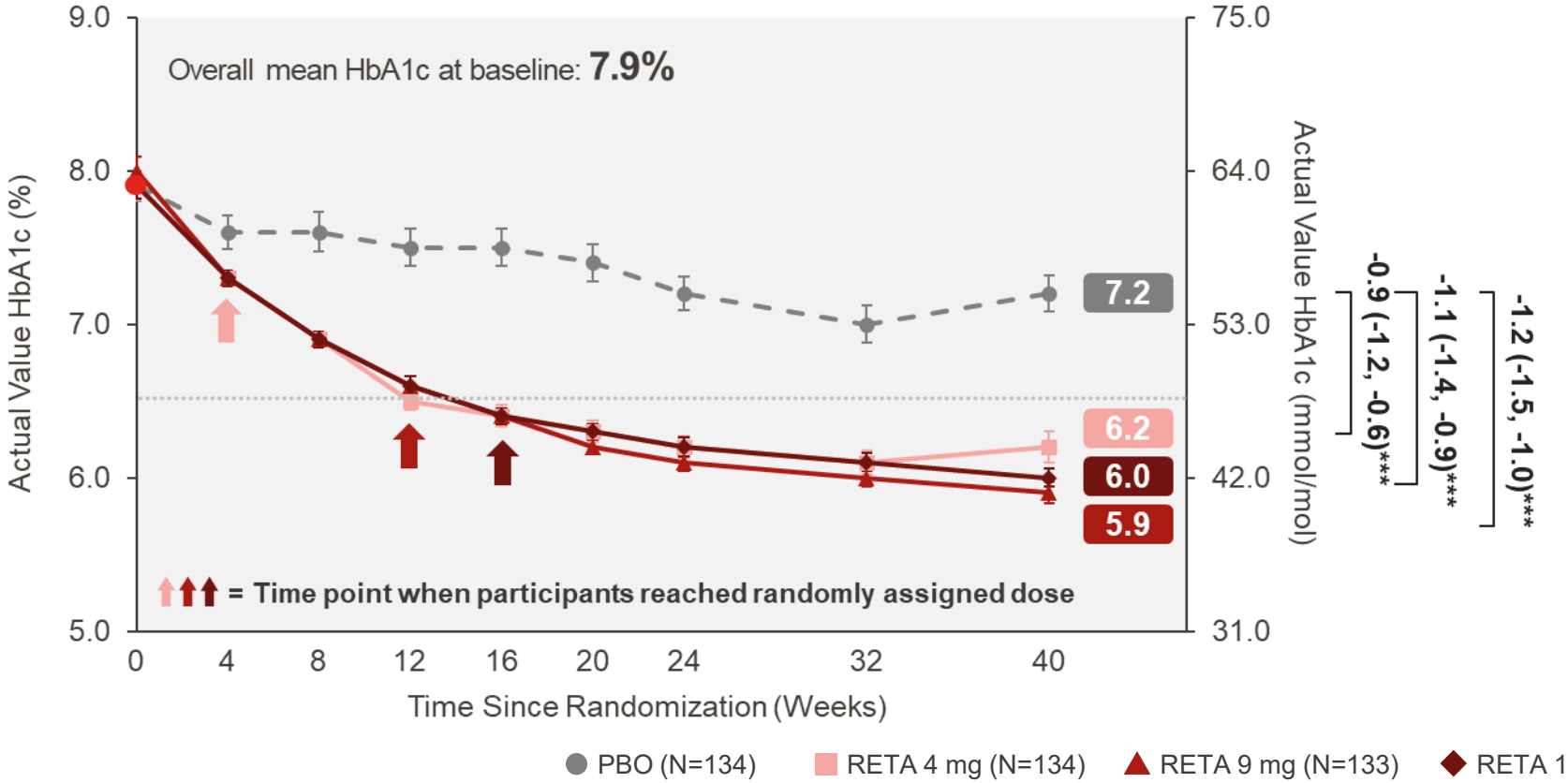
PBO: ~93% completed treatment and ~92% completed the study
RETA: ~88%-95% completed treatment, with ~93%-96% completed the study

Notes: Study completion is defined as completing both the 40-week treatment period and the safety follow-up period, regardless of completion of study intervention. If participants discontinue the study during the treatment period, they also discontinue the study intervention, either earlier or at the same time.
PBO=placebo; RETA=retatrutide.

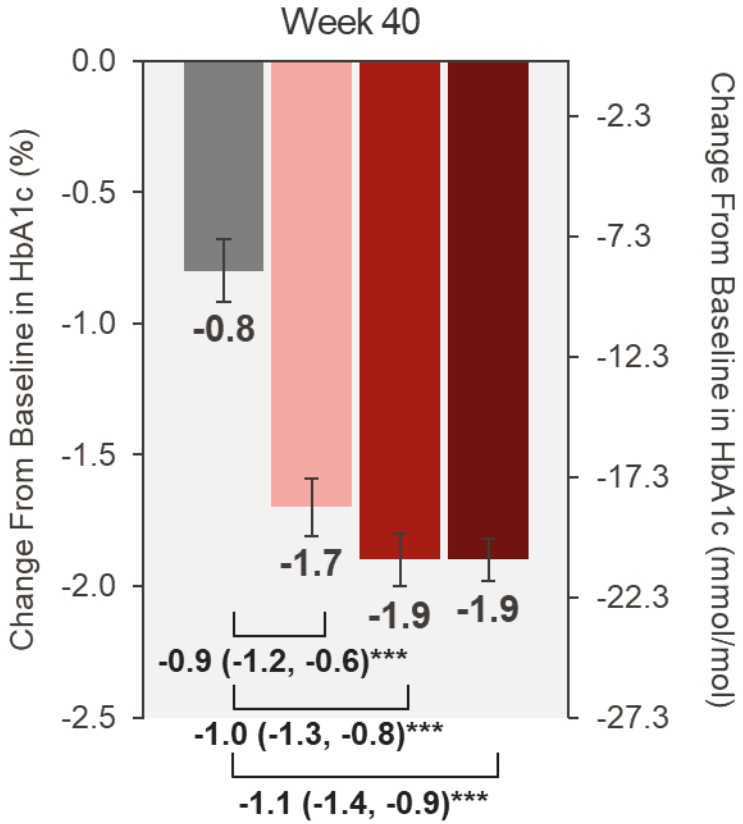
Primary Endpoint: HbA1c Over 40 Weeks With Retatrutide

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Efficacy Estimand



Treatment Regimen Estimand



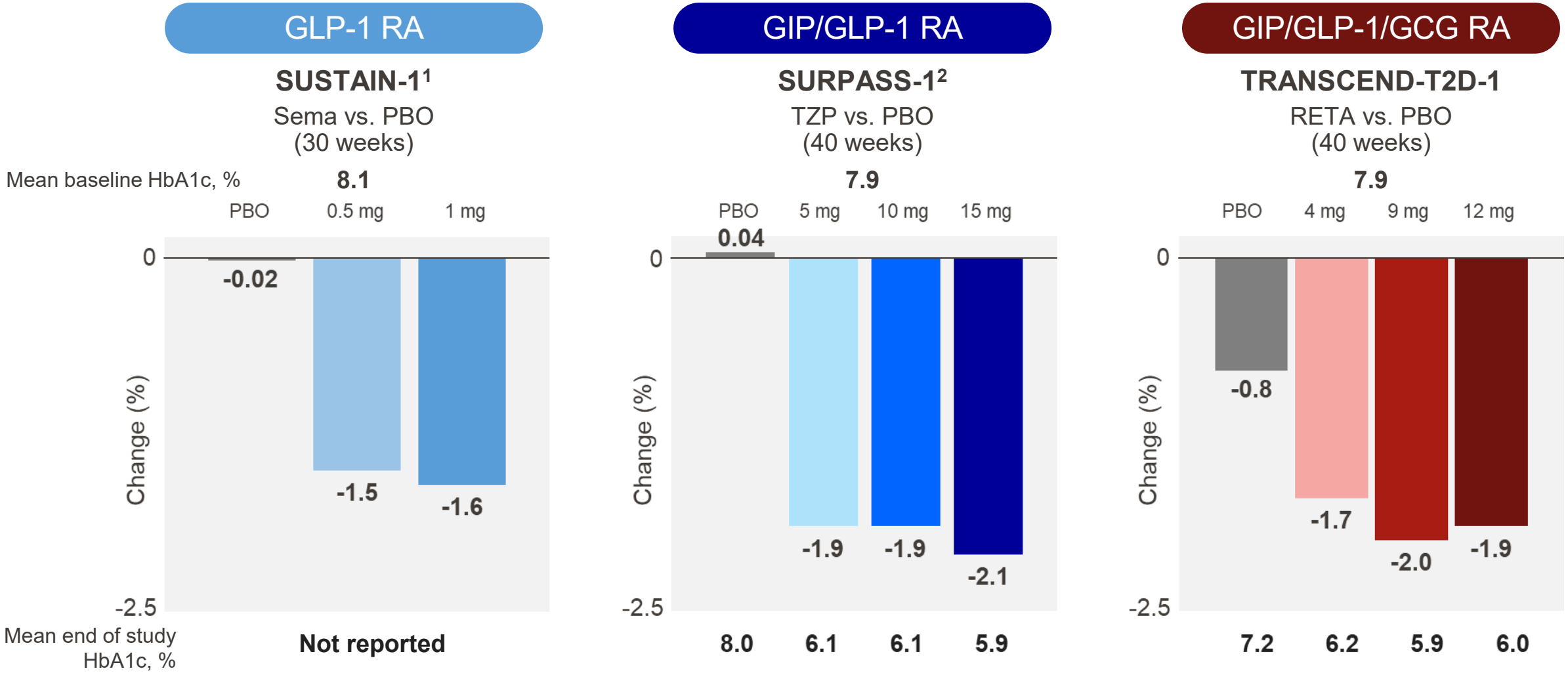
PBO (N=134) RETA 4 mg (N=134) RETA 9 mg (N=133) RETA 12 mg (N=136)

The HbA1c values at Week 40 were 5.9-6.2% in participants treated with RETA vs. ~7.2% in the PBO group

***p<0.001. p-values are for MBE change difference vs. PBO.
Notes: Data presented are MBE ± SE, and MBE difference (95% CI). EE analysis was conducted using MMRM. TRE analysis was conducted using ANCOVA. Data are from all randomized participants.
ANCOVA=analysis of covariance; CI=confidence interval; EE=efficacy estimand; HbA1c=glycated hemoglobin; MBE=model-based estimate; MMRM=mixed model for repeated measures; N=number of participants; PBO=placebo; RETA=retatrutide; SE=standard error; TRE=treatment regimen estimand.

Indirect Comparison of Change in HbA1c From Baseline in Similar Phase 3 Studies (Efficacy Estimand)

RETATRUTIDE T2D
TRANSCEND-T2D-1



Notes: This indirect comparison is for illustrative purposes and is not intended to draw conclusions based on the results of different studies. In SUSTAIN-1, semaglutide was a once-weekly subcutaneous injection.

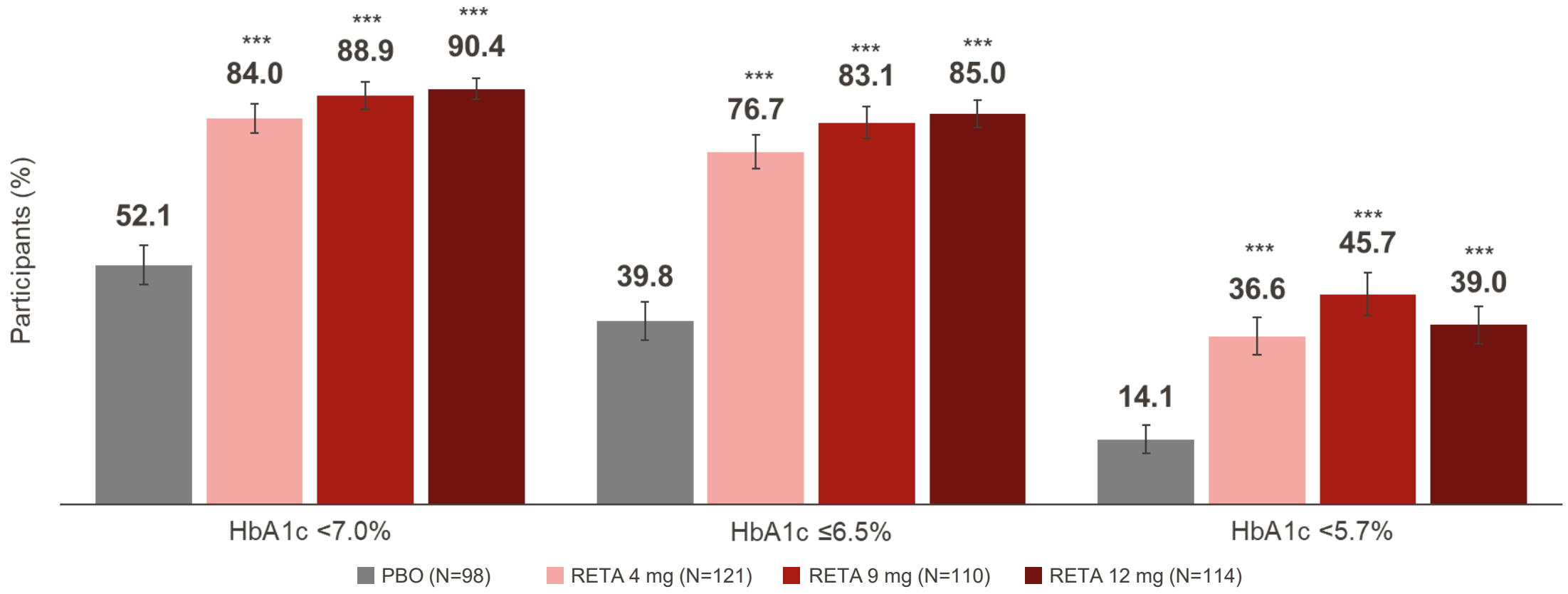
1. Sorli C, et al. *Lancet Diabetes Endocrinol*. 2017;5:251-260. 2. Rosenstock J, et al. *Lancet*. 2021;398:143-155.

GCG=glucagon; GIP=glucose-dependent insulinotropic polypeptide; GLP-1=glucagon-like peptide-1; HbA1c=glycated hemoglobin; PBO=placebo; RA=receptor agonist; RETA=retatrutide; Sema=semaglutide; TZP=tirzepatide.

Proportion of Participants Reaching HbA1c Targets at Week 40 With Retatrutide

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Efficacy Estimand



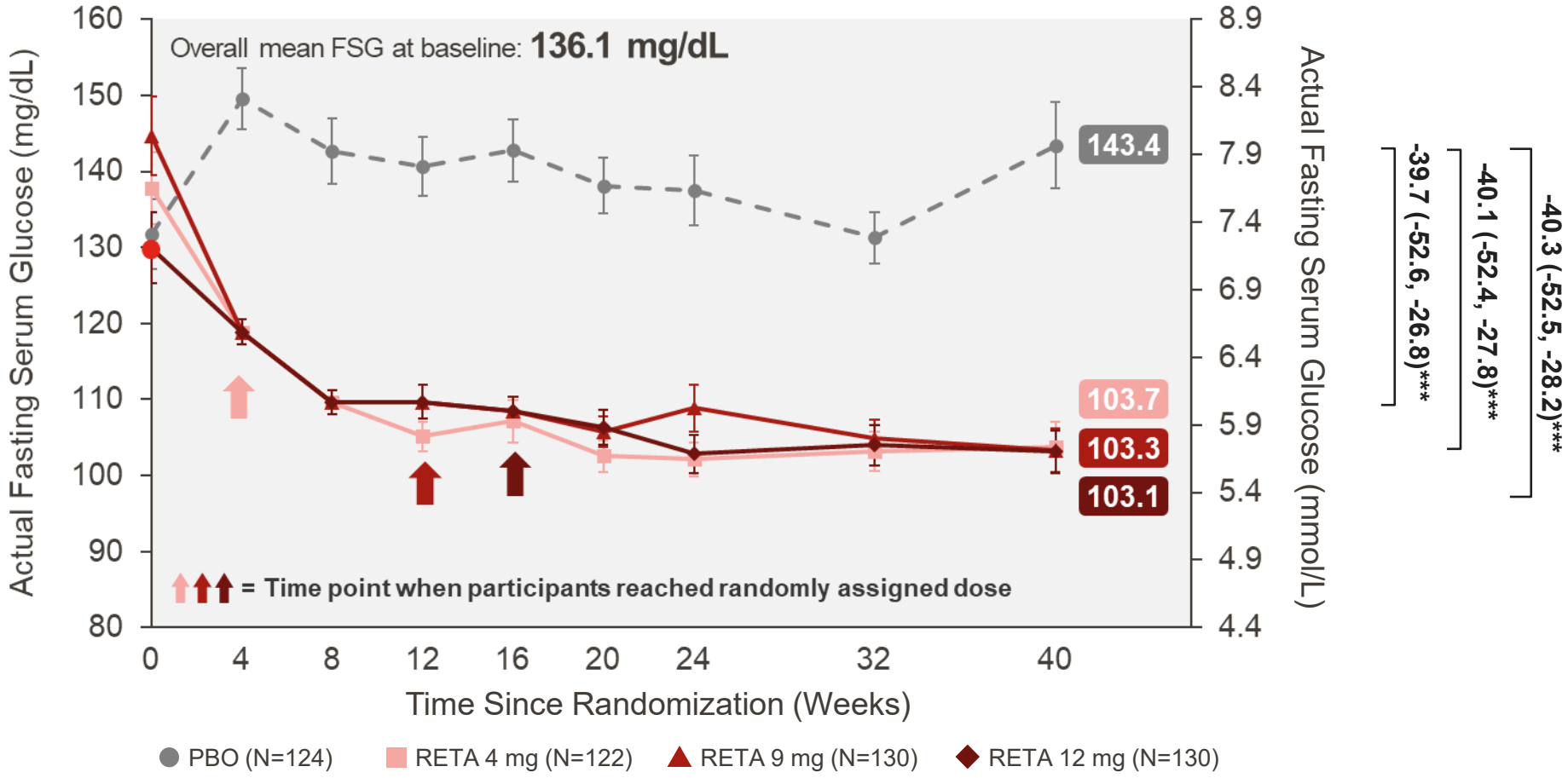
Up to 85% of participants treated with RETA reached the HbA1c target of ≤6.5% and 46% had HbA1c <5.7% (normoglycemia)

RETA vs. PBO: ***p<0.001. p-values are for risk difference vs. PBO. Data are from all randomized participants.
Notes: Data presented are MBE ± SE. HbA1c target <5.7% was not controlled for type I error for the RETA 4 mg arm.
HbA1c=glycated hemoglobin; MBE=model-based estimate; N=number of participants with non-missing value at the specified time point; PBO=placebo; RETA=retatrutide; SE=standard error.

Fasting Serum Glucose Over Time With Retatrutide vs. PBO

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Efficacy Estimand



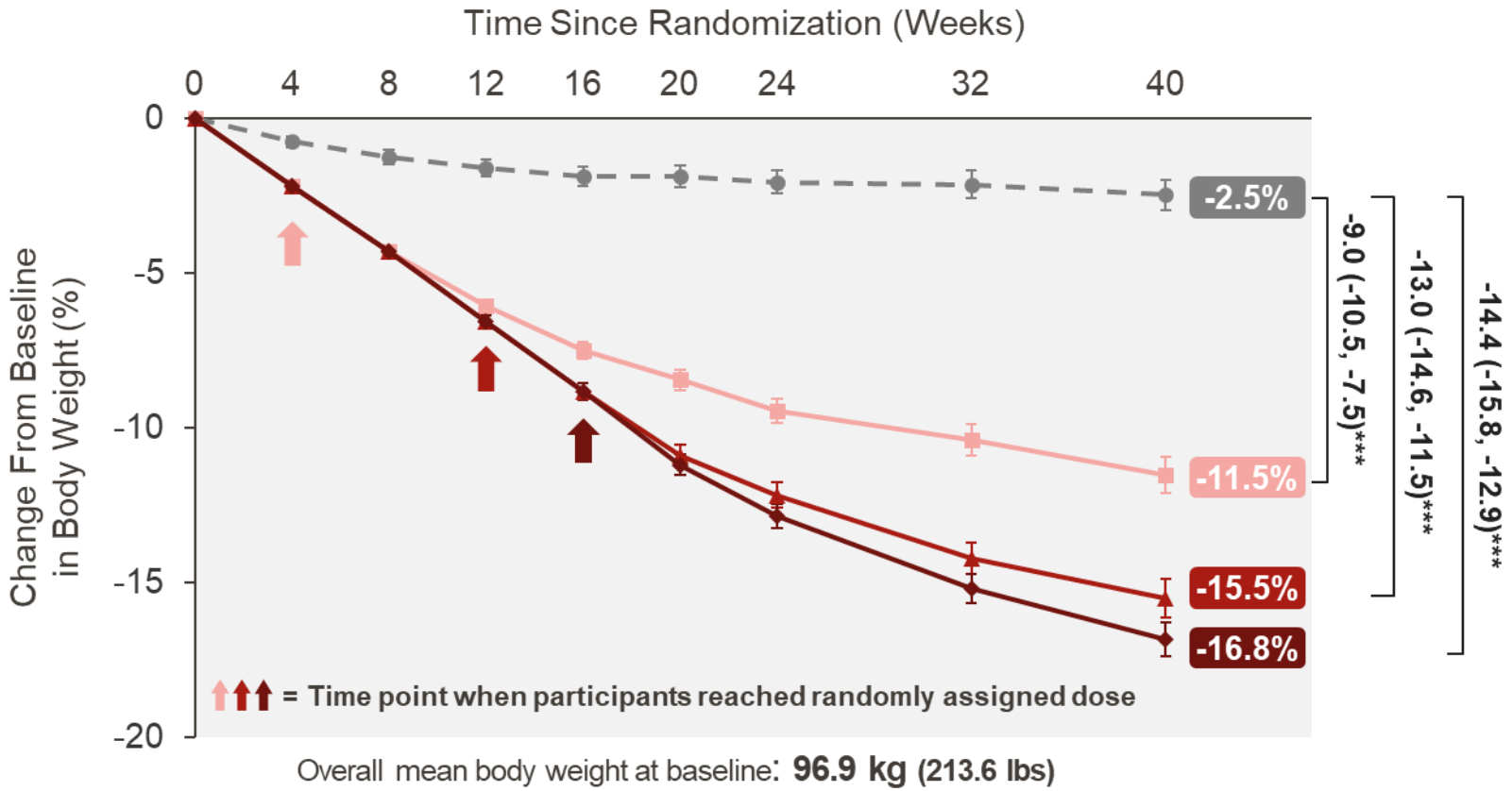
Clinically meaningful reduction in fasting serum glucose was maintained in the setting of glucagon activity of RETA

RETA vs. PBO: ***p<0.001. p-values are for MBE change difference vs. PBO.
Notes: Data presented are MBE ± SE, and MBE difference (95% CI). EE analysis was conducted using MMRM. The comparison of RETA 4 mg vs. PBO was not controlled for type I error.
CI=confidence interval; EE=efficacy estimand; MBE=model-based estimate; MMRM=mixed model for repeated measures; N=number of participants; PBO=placebo; RETA=retatrutide; SE=standard error.

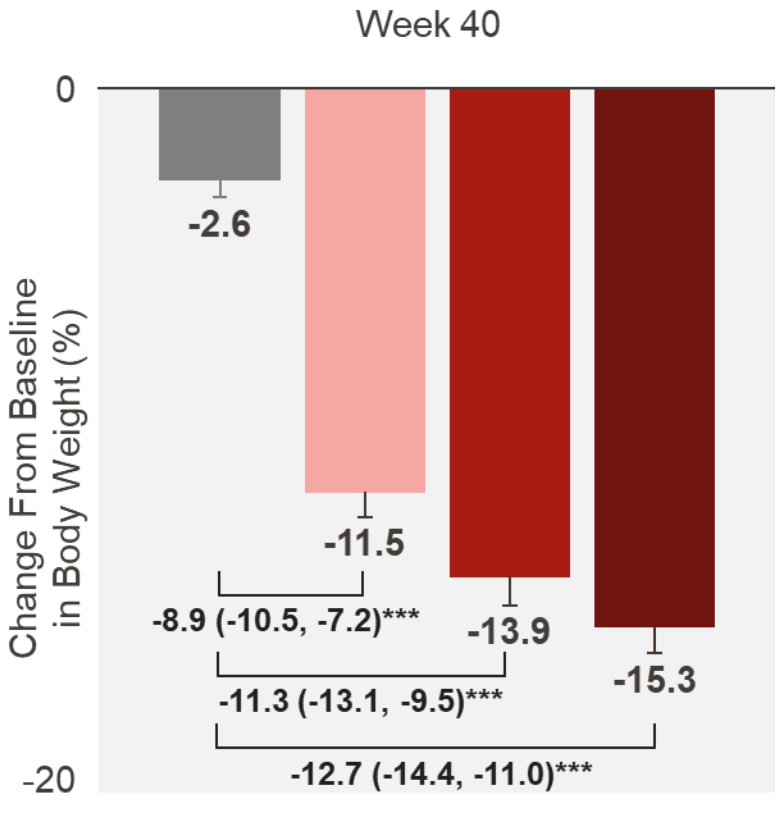
Percent Change From Baseline in Body Weight With Retatrutide

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Efficacy Estimand



Treatment Regimen Estimand



PBO (N=134) RETA 4 mg (N=134) RETA 9 mg (N=133) RETA 12 mg (N=136)

Participants receiving RETA lost up to an average of 16.6 kg (36.6 lbs), or 16.8% of their body weight at 40 weeks

RETA vs. PBO: ***p<0.001. p-values are for MBE change difference vs. PBO.
Notes: Data presented are MBE ± SE, and MBE difference (95% CI). EE analysis was conducted using MMRM. TRE analysis was conducted using ANCOVA. Data are from all randomized participants.
ANCOVA=analysis of covariance; CI=confidence interval; EE=efficacy estimand; MBE=model-based estimate; MMRM=mixed model for repeated measures; N=number of participants; PBO=placebo; RETA=retatrutide; SE=standard error; TRE=treatment regimen estimand.

Indirect Comparison of Percent Change in Body Weight From Baseline in Similar Phase 3 Studies (Efficacy Estimand)

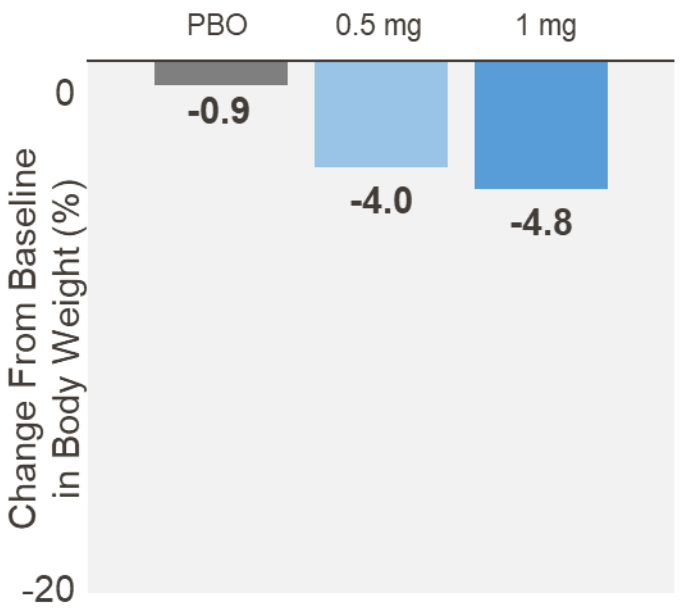
RETATRUTIDE
T2D
TRANSCEND-T2D-1

GLP-1 RA

SUSTAIN-1[1]

Sema vs. PBO
(30 weeks)

Mean baseline weight **91.9 kg**
Mean baseline BMI 32.9 kg/m^2

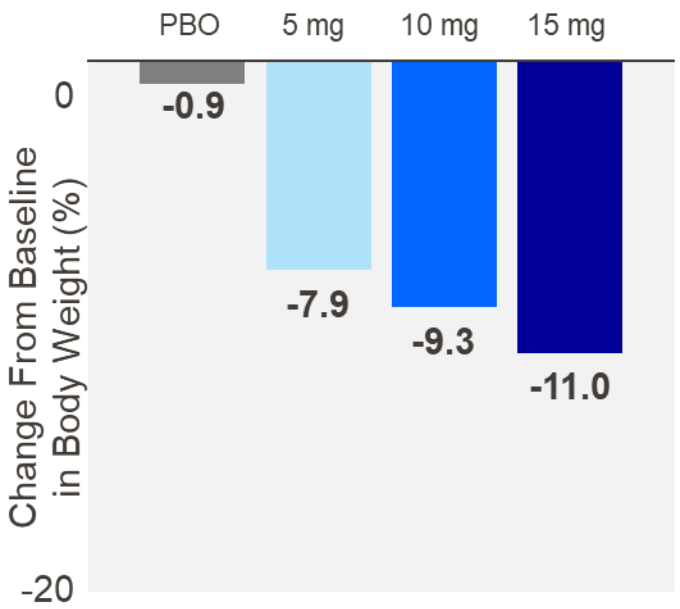


GIP/GLP-1 RA

SURPASS-1[2]

TZP vs. PBO
(40 weeks)

85.9 kg
31.9 kg/m^2

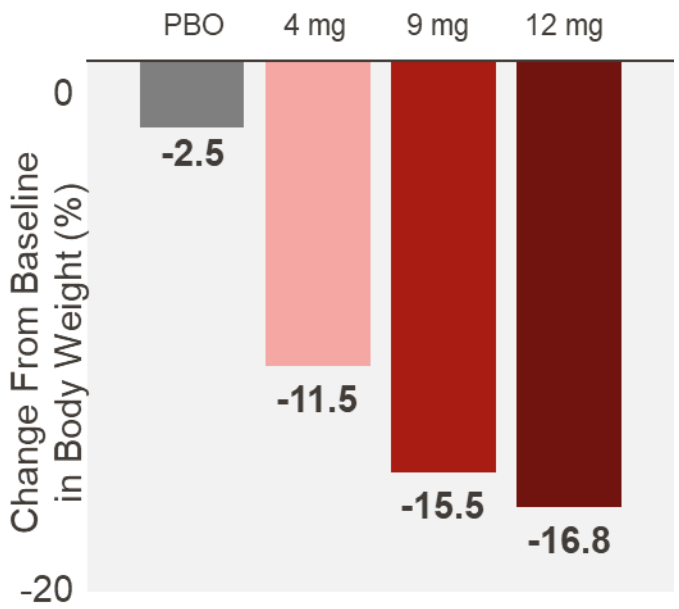


GIP/GLP-1/GCG RA

TRANSCEND-T2D-1

RETA vs. PBO
(40 weeks)

96.9 kg
35.8 kg/m^2



Notes: This indirect comparison is for illustrative purposes and is not intended to draw conclusions based on the results of different studies. Percent weight change data for SUSTAIN-1 were estimated from literature-reported weight change (kg). In SUSTAIN-1, semaglutide was a once-weekly subcutaneous injection.

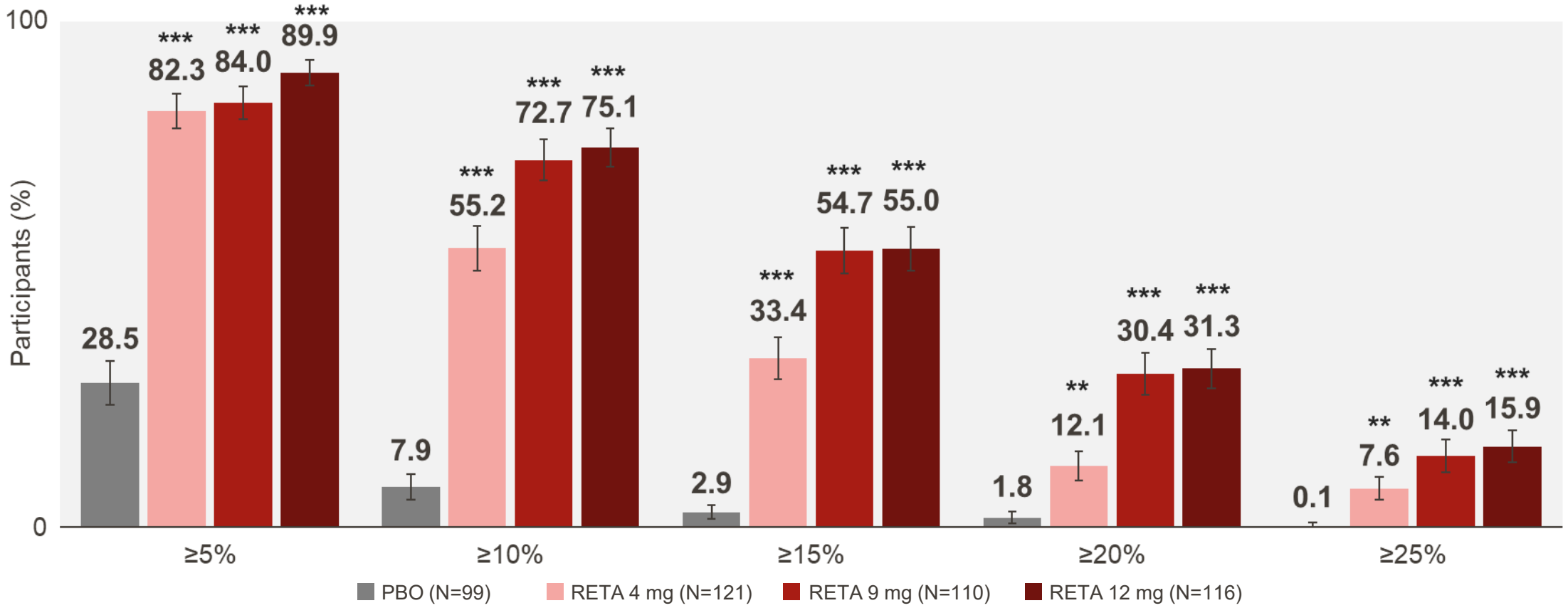
1. Sorli C, et al. *Lancet Diabetes Endocrinol*. 2017;5:251-260. 2. Rosenstock J, et al. *Lancet*. 2021;398:143-155.

BMI=body mass index; GCG=glucagon; GIP=glucose-dependent insulinotropic polypeptide; GLP-1=glucagon-like peptide-1; PBO=placebo; RA=receptor agonist; RETA=retatrutide; Sema=semaglutide; TZP=tirzepatide.

Proportion of Participants Reaching Weight Reduction Thresholds at Week 40 With Retatrutide

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Efficacy Estimand

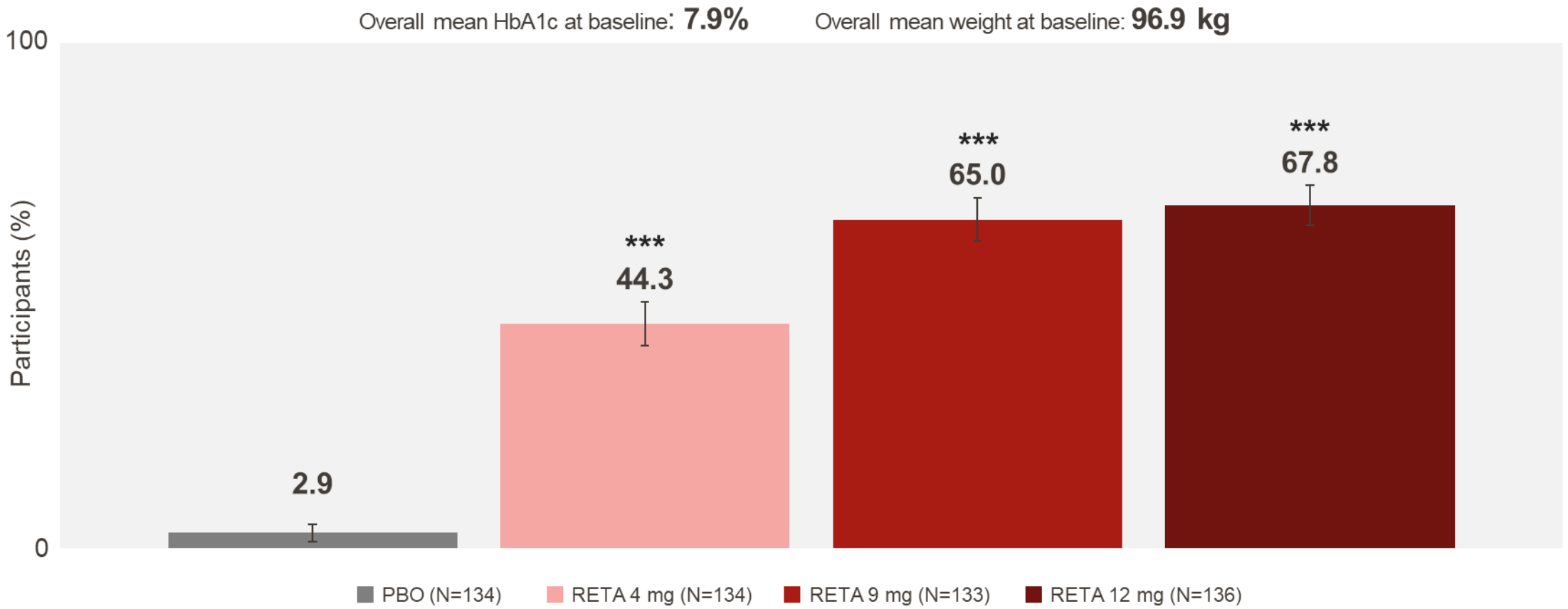


Clinically meaningful weight reduction (≥5%) was observed in >82% of participants treated with RETA, with up to 75% and 55% reaching the weight reduction thresholds of ≥10% and ≥15%, respectively

**p<0.01, ***p<0.001 vs. PBO.
Notes: Data presented are MBE ± SE. EE analysis from logistic regression model. The weight reduction thresholds of ≥20% and ≥25% were not controlled for type I error for any RETA dose and the threshold of ≥15% was also not controlled for type I error in the RETA 4 mg arm.
EE=efficacy estimand; MBE=model-based estimate; N=number of participants; PBO=placebo; RETA=retatrutide; SE=standard error.

Proportion of Participants Reaching HbA1c ≤6.5% AND ≥10.0% Weight Reduction at Week 40 With Retatrutide

Efficacy Estimand



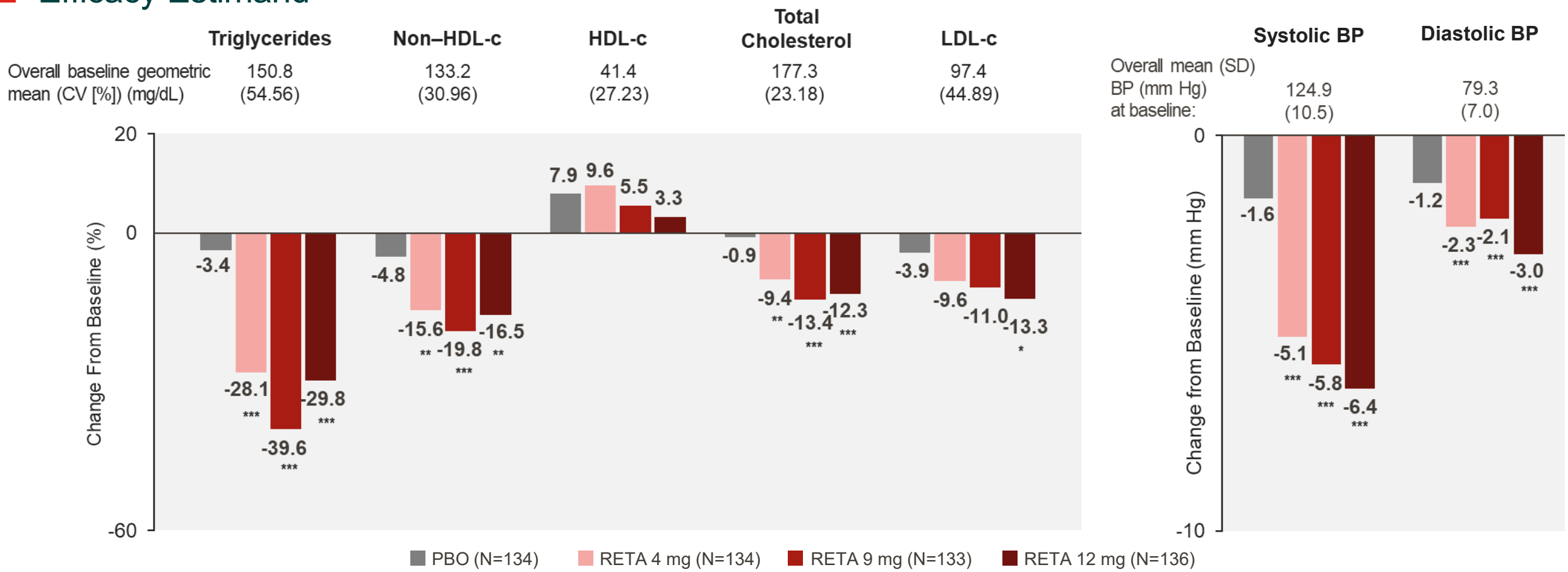
Up to ~68% of participants reached HbA1c ≤6.5% and ≥10.0% weight reduction at Week 40 with RETA 12 mg

***p<0.001 vs. PBO.
Notes: Data presented are MBE ± SE. EE analysis from logistic regression model.
EE=efficacy estimand; HbA1c=glycated hemoglobin; MBE=model-based estimate; N=number of participants; PBO=placebo; RETA=retatrutide; SE=standard error.

Percentage Change in Lipid and Blood Pressure Parameters From Baseline to Week 40 With Retatrutide

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Efficacy Estimand



Improvements in triglycerides, non–HDL-c, and systolic BP were observed in all RETA arms

RETA vs. PBO: *p<0.05, **p<0.01, ***p<0.001. p-values are for MBE percent change difference.

Notes: Data presented are MBE. EE analysis was conducted using MMRM. The comparisons of RETA 9 mg and 12 mg vs. PBO for triglycerides and non–HDL-c were controlled for type I error. No other endpoints or dose comparisons were included in the multiplicity adjustment procedure. For systolic BP, RETA 9 mg and 12 mg adjusted for multiplicity. All other doses across systolic and diastolic BP not adjusted for multiplicity.

BP=blood pressure; CV=coefficient of variation; EE=efficacy estimand; HDL-c=high-density lipoprotein calculated; LDL-c=low-density lipoprotein calculated; MBE=model-based estimate; MMRM=mixed model for repeated measures; N=number of participants; PBO=placebo; RETA=retatrutide.

Overview of Adverse Events

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Adverse Events, n (%)	PBO (N=134)	RETA 4 mg (N=134)	RETA 9 mg (N=133)	RETA 12 mg (N=136)
Participants with ≥1 TEAE	77 (57.5)	84 (62.7)	85 (63.9)	85 (62.5)
Participants with ≥1 serious AE	2 (1.5)	6 (4.5)	1 (0.8)	5 (3.7)
Death[a]	0	2 (1.5)	0	0
Selected AEs of Special Interest				
Hypotension	0	0	2 (1.5)	2 (1.5)
Dysesthesia	0	6 (4.5)	3 (2.3)	6 (4.4)
Diabetic retinopathy complications	1 (0.7)	2 (1.5)	3 (2.3)	3 (2.2)
Injection site reactions	1 (0.7)	2 (1.5)	2 (1.5)	2 (1.5)
Hypoglycemia (Level 2)	0	0	2 (1.5)	1 (0.7)
Adjudicated MACE[b]	0	3 (2.2)	0	0
Arrhythmias and cardiac conduction disorders	0	4 (3.0)	2 (1.5)	1 (0.7)

Treatment-emergent AEs were reported in ~57% of PBO recipients and ~63%-64% of participants receiving RETA
Serious AEs were reported in 1.5% of PBO recipients and ~<1%-4% of participants receiving RETA
No severe hypoglycemia reported

[a]Deaths are also included as serious AEs and discontinuation due to AEs. [b]MACE (confirmed by Clinical Endpoint Committee) includes: deaths due to cardiovascular cause, myocardial infarction, hospitalization for unstable angina, hospitalization/urgent visit for heart failure, coronary interventions (such as CABG or PCI), and cerebrovascular events, including cerebrovascular accident (stroke) and TIA.
Notes: Data are reported for the safety data points set. Safety population defined as all participants who were randomly assigned a study intervention and who received ≥1 dose of double-blind study intervention.
MedDRA Version 28.1 (September 2025).
AE=adverse event; CABG=coronary artery bypass graft; MACE=major adverse cardiovascular event; MedDRA=Medical Dictionary for Regulatory Activities; n=number of participants in the specified category; N=all randomly assigned participants who took ≥1 dose of study intervention; PBO=placebo; PCI=percutaneous coronary intervention; RETA=retatrutide; TEAE=treatment-emergent AE; TIA=transient ischemic attack.

Adverse Events Occurring in ≥5% of Participants in Any Group

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Participants With AEs, n (%)	PBO (N=134)	RETA 4 mg (N=134)	RETA 9 mg (N=133)	RETA 12 mg (N=136)
Nausea	5 (3.7)	22 (16.4)	26 (19.5)	36 (26.5)
Diarrhea	6 (4.5)	25 (18.7)	35 (26.3)	31 (22.8)
Vomiting	3 (2.2)	21 (15.7)	20 (15.0)	24 (17.6)
Abdominal distension	3 (2.2)	7 (5.2)	8 (6.0)	13 (9.6)
Decreased appetite	2 (1.5)	10 (7.5)	15 (11.3)	11 (8.1)
Constipation	1 (0.7)	6 (4.5)	11 (8.3)	10 (7.4)
Fatigue	4 (3.0)	1 (0.7)	8 (6.0)	10 (7.4)
Headache	13 (9.7)	5 (3.7)	8 (6.0)	7 (5.1)
Eructation	0	1 (0.7)	2 (1.5)	7 (5.1)
Hyperglycemia	35 (26.1)	5 (3.7)	10 (7.5)	5 (3.7)
Asthenia	9 (6.7)	5 (3.7)	5 (3.8)	5 (3.7)
Upper abdominal pain	7 (5.2)	7 (5.2)	1 (0.8)	5 (3.7)
Abdominal discomfort	1 (0.7)	6 (4.5)	10 (7.5)	4 (2.9)
Nasopharyngitis	9 (6.7)	6 (4.5)	2 (1.5)	4 (2.9)
Pain	11 (8.2)	3 (2.2)	5 (3.8)	4 (2.9)
Back pain	10 (7.5)	4 (3.0)	3 (2.3)	2 (1.5)

Generally transient, mostly mild or moderate gastrointestinal AEs (nausea, vomiting, and diarrhea) were the most commonly reported AEs in participants treated with RETA

Notes: Data are reported for the safety data points set. Safety population defined as all participants who were randomly assigned a study intervention and who received ≥1 dose of double-blind study intervention.
MedDRA Version 28.1 (September 2025).
AE=adverse event; MedDRA=Medical Dictionary for Regulatory Activities; n=number of participants in the specified category; N=all randomly assigned participants who took ≥1 dose of study intervention; PBO=placebo; RETA=retatrutide.

Adverse Events Leading to Treatment Discontinuation Reported by Preferred Term

RETATRUTIDE
T2D
TRANSCEND-T2D-1

Safety Event, n (%)	PBO (N=134)	RETA 4 mg (N=134)	RETA 9 mg (N=133)	RETA 12 mg (N=136)
Discontinuation from treatment due to GI AEs	0	0	1 (0.8)	4 (2.9)
Discontinuation from treatment due to AEs	0	3 (2.2)	6 (4.5)	7 (5.1)
Nausea	0	0	1 (0.8)	1 (0.7)
Sensitive skin	0	0	1 (0.8)	1 (0.7)
Abdominal pain upper	0	0	0	1 (0.7)
Cholelithiasis	0	0	0	1 (0.7)
Constipation	0	0	0	1 (0.7)
Dyspepsia	0	0	0	1 (0.7)
Fatigue	0	0	0	1 (0.7)
Psychotic disorder	0	0	0	1 (0.7)
Dehydration	0	0	1 (0.8)	0
Muscle spasms	0	0	1 (0.8)	0
Nephrolithiasis	0	0	1 (0.8)	0
Pruritus	0	0	1 (0.8)	0
Cardiac arrest	0	1 (0.7)	0	0
Death	0	1 (0.7)	0	0
Small cell lung cancer	0	1 (0.7)	0	0

Treatment discontinuation due to gastrointestinal AEs occurred only in the 9 mg (1) and 12 mg (4) RETA groups

Notes: Data are reported for the safety data points set. Safety population defined as all participants who were randomly assigned a study intervention and who received ≥1 dose of double-blind study intervention.
MedDRA Version 28.1 (September 2025).
AE=adverse event; GI=gastrointestinal; MedDRA=Medical Dictionary for Regulatory Activities; n=number of participants in the specified category; N=all randomly assigned participants who took ≥1 dose of study intervention; PBO=placebo; RETA=retatrutide.

TRANSCEND-T2D-1: Retatrutide Efficacy Summary

Retatrutide **met the primary and all key secondary endpoints** for both estimands

Superior glycemic control vs. placebo
- **HbA1c improvement up to -1.9%**
- **Up to 85% reaching HbA1c ≤6.5%, and up to 46% near-normoglycemia (<5.7%)**

Superior weight reduction vs. placebo with **up to -16.8% weight reduction** (-17 kg/-37 lb)

Up to 68% of retatrutide-treated participants **reached HbA1c of ≤6.5%** and **≥10% weight reduction**

Clinically meaningful improvements in cardiometabolic markers: **Systolic blood pressure**, **non–HDL-C**, and **triglycerides**

HbA1c=glycated hemoglobin; HDL-C=high-density lipoprotein cholesterol.

TRANSCEND-T2D-1: Retatrutide Safety Summary

Overall safety profile generally consistent with GLP-1 RA–based therapy

- The most common AEs with retatrutide were **gastrointestinal, mostly mild to moderate, and occurred primarily during dose escalation**
- **Treatment discontinuation due to an AE** was **2-5%**
- **Treatment discontinuation due to a GI AE** was **0-3%**
- **No new safety signals** were observed
  No severe hypoglycemia was reported

AE=adverse event; GI=gastrointestinal; GLP-1=glucagon-like peptide-1; RA=receptor agonist.

Thank You

We would like to thank the trial participants and site staff

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THE LANCET

Efficacy and safety of retatrutide, a GIP, GLP-1, and glucagon receptor agonist, in people with type 2 diabetes and inadequate glycaemic control with diet and exercise (TRANSCEND-T2D-1): a double-blind, randomised, phase 3 trial

Harpreet S Bajaj, Michelle Welch, Parag Shah, Eduardo Luna, Fatima-Zahra Jaouimaa, Bing Liu, Rong Liu, Yanyun Chen, Hiren Patel, Amy Bartee

MANUSCRIPT

Multireceptor modulation in metabolic disease: are more targets better?

COMMENTARY