BROADWAY
Topline Results

December 10, 2024

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BROADWAY

Pursuing a New Treatment Paradigm for Cardiometabolic Disease

- In the three trials completed to date, we have successfully achieved each primary endpoint ($p<0.0001$) of LS mean difference with imputation at day 84 versus placebo.
- LDL-C reductions across our phase 3 studies:

	BROADWAY	BROOKLYN	TANDEM
Day 84 – from placebo	Obicetrapib 10mg	Obicetrapib 10mg	Obicetrapib 10mg + ezetimibe 10mg
Mean	-33%	-36%	-52%
Median	-36%	-39%	-54%
LS mean (with imputation)	**-33%**	**-36%**	**-49%**

- Promising trends observed across a variety of cardiometabolic markers, including a 21% reduction from placebo in first 4-point MACE observed at a one-year endpoint
- Obicetrapib was observed to be well-tolerated with safety results comparable to placebo

Note: MACE was evaluated in BROADWAY as an exploratory endpoint

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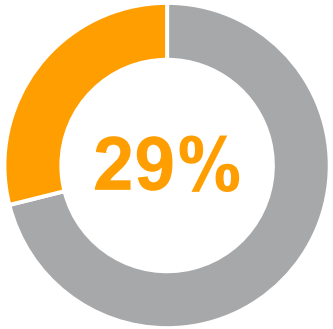
Majority of ASCVD/HeFH patients do not achieve LDL-C Targets

Primary prevention HeFH patients with an LDL-C target <100 mg/dL (2011-2017)[1]

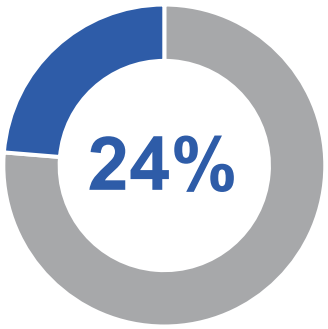
Target: LDL-C < 100 mg/dL



<1/3 achieved LDL-C <100 mg/dL

ASCVD patients with an LDL-C target of LDL<70 or <55 mg/dL (2017-2018)[2]

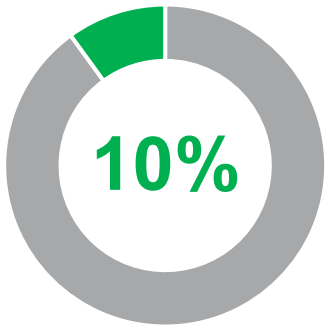
Target: LDL-C < 70 mg/dL



<1/4 achieved LDL-C <70 mg/dL

Very high risk ASCVD patients with an LDL-C target <55 mg/dL (2020-2021)[3]

Target: LDL-C < 55 mg/dL



10% achieved LDL-C <55 mg/dL

ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein-cholesterol.

1. Schreuder MM, et al. LDL cholesterol targets rarely achieved in familial hypercholesterolemia patients: A sex and gender-specific analysis. Atherosclerosis. 2023 2. Gao Y, Shah LM, Ding J, Martin SS. US trends in cholesterol screening, lipid levels, and lipid-lowering medication use in US adults, 1999 to 2018. J Am Heart Assoc. 2023;12(3):e028205; 3. Katzmann JL, et al. Simulation study on LDL cholesterol target attainment, treatment costs, and ASCVD events with bempedoic acid in patients at high and very-high cardiovascular risk. PLoS One. 2022;17(10):e0276898

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Trial Design and Baseline Characteristics

Obicetrapib on Top of Maximum Tolerated Lipid-Modifying Therapies: A Placebo-Controlled, Double-Blind, Randomized Phase 3 Study to Evaluate the Effect of 10 mg Obicetrapib in Participants with Underlying HeFH and/or Atherosclerotic Cardiovascular Disease (ASCVD) who are Not Adequately Controlled by Their Lipid-Modifying Therapies

Trial Design

Key Inclusion Criteria

- ASCVD or HeFH
- LDL-C ≥55 mg/dL w/risk factors, or
- LDL-C≥ 100 mg/dL
- Maximally tolerated lipid lowering therapy

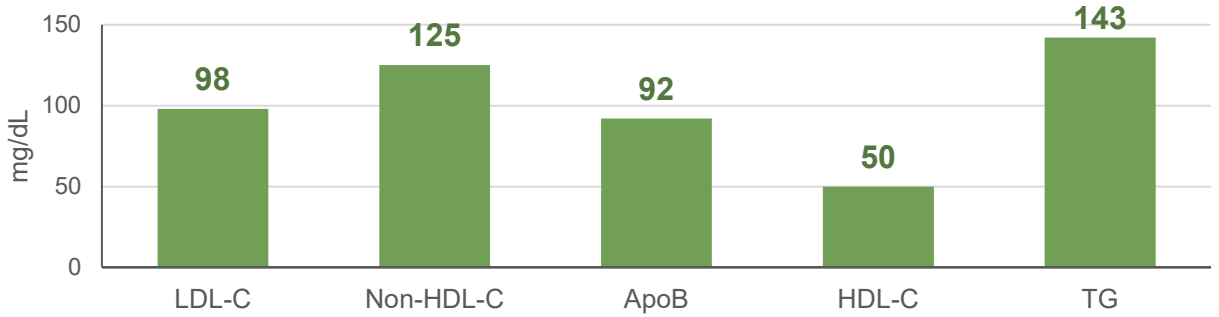
Key Exclusion Criteria

- HoFH
- Uncontrolled hypertension

Endpoints

- Primary: LDL-C at 12-weeks
- Secondary: ApoB, Lp(a), non-HDL-C
- MACE = additional, exploratory endpoint
- Safety: AE's and ABPM

Baseline Lipids (total population mean)



Demographics

- 34% Female
- 65 years of age
- BMI: 30 kg/m^2

Baseline Lipid Modifying Therapy

- Any statin 91%
- High intensity statin: 65%
- Ezetimibe: 27%
- PCSK9i 4%
- Other 11%

Regions

- N. America
- Europe
- Asia/Australia

Medical History

- ASCVD 76%
- HeFH 17%
- Diabetes 38%

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Disposition of All Randomized Participants

	Placebo	Obicetrapib 10 mg
Randomized	844	1686
Completed treatment	739 (87.6)	1499 (88.9)
Discontinued treatment	105 (12.4)	187 (11.1)
Discontinued due to AE's	43 (5.1)	68 (4.0)
Subject decision	33 (3.9)	57 (3.4)
Lost to follow-up	12 (1.4)	30 (1.8)
Withdraw of consent	6 (0.7)	7 (0.4)
Death	6 (0.7)	8 (0.5)
Other	5 (0.6)	17 (1.0)
Completed the trial	795 (94.2)	1600 (94.9)
Discontinued trial early	49 (5.8)	86 (5.1)
Vital status known at trial completion	844 (100.0)	1686 (100.0)

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Demographics

	Placebo N=844	Obicetrapib 10 mg N=1686
Mean Age (years)	65.3	65.4
<65 years	360 (42.7)	706 (41.9)
65 to 74 years	352 (41.7)	683 (40.5)
75+ years	132 (15.6)	297 (17.6)
Sex (F) n (%)	280 (33.2)	573 (34.0)
Region n (%)		
North America	313 (37.1)	591 (35.1)
Eastern Europe	282 (33.4)	580 (34.4)
Western Europe	104 (12.3)	213 (12.6)
Asia	145 (17.2)	302 (17.9)
Race n (%)		
White	647 (76.7)	1241 (73.6)
Asian	150 (17.8)	312 (18.5)
African American	39 (4.6)	112 (6.6)
Other	8 (1.0)	21 (1.3)

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Demographics

	Placebo N=884	Obicetrapib 10 mg N=1686
Height (cm)	170.1	169.9
Weight (kg)	86.3	85.2
BMI (mean)	29.7	29.4
< 25 kg/m²	162 (19.2)	352 (20.9)
25 - 30 kg/m²	334 (39.6)	657 (39.0)
> 30 kg/m²	346 (41.0)	676 (40.1)
Diabetes n (%)	336 (39.8)	624 (37.0)
HeFH	143 (16.9)	284 (16.8)
Statin n (%)	782 (93.0)	1533 (91.0)
High Intensity	581 (68.8)	1152 (68.3)
Low or Moderate Intensity	201 (23.8)	381 (22.6)
None	62 (7.3)	153 (9.1)
Ezetimibe n (%)	220 (26.1)	453 (26.9)
PCSK9i n (%)	33 (3.9)	62 (3.7)
GLP1 n (%)	48 (5.7)	111 (6.6)
SGLT2 n (%)	92 (10.9)	188 (11.2)

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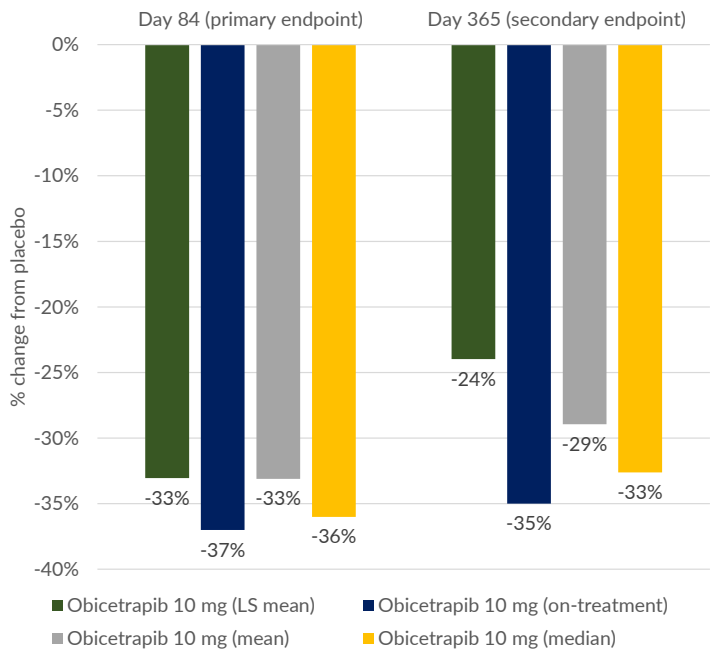
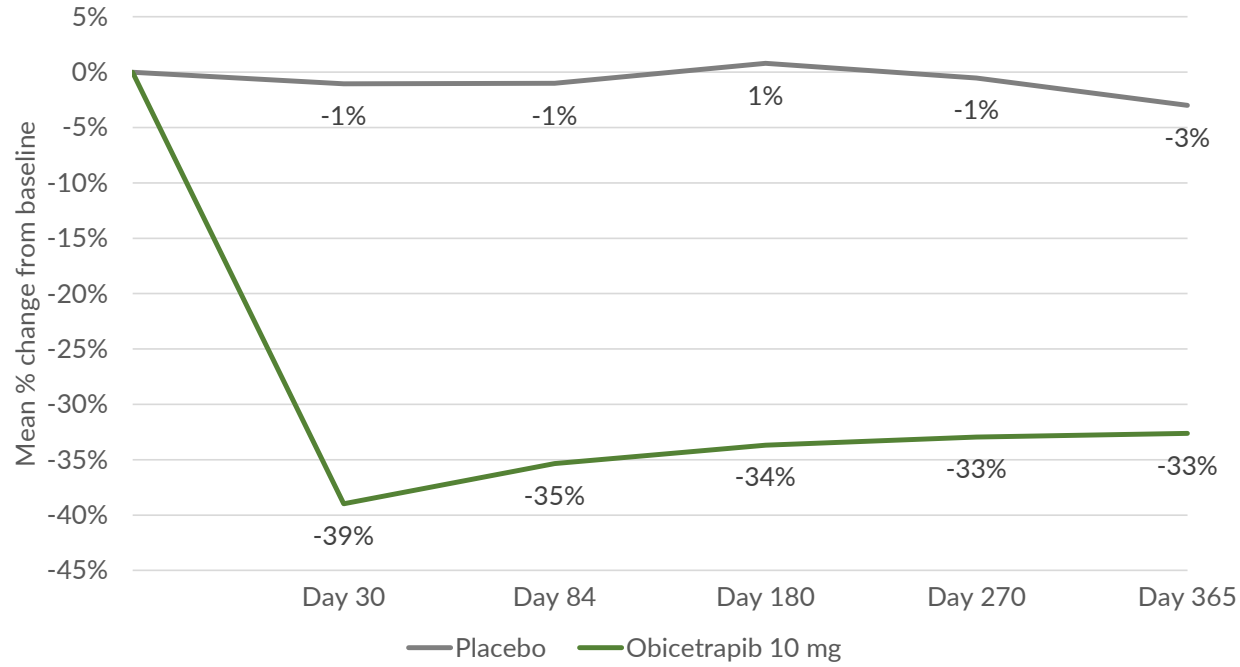
Consistent LDL-C reduction observed over one year trial duration

LDL-C at day 84 and 365



Mean LDL-C reduction over time



Note: LDL-C at day 84 and 365 chart via PUC. Mean reduction over time chart via Martin/Hopkins.

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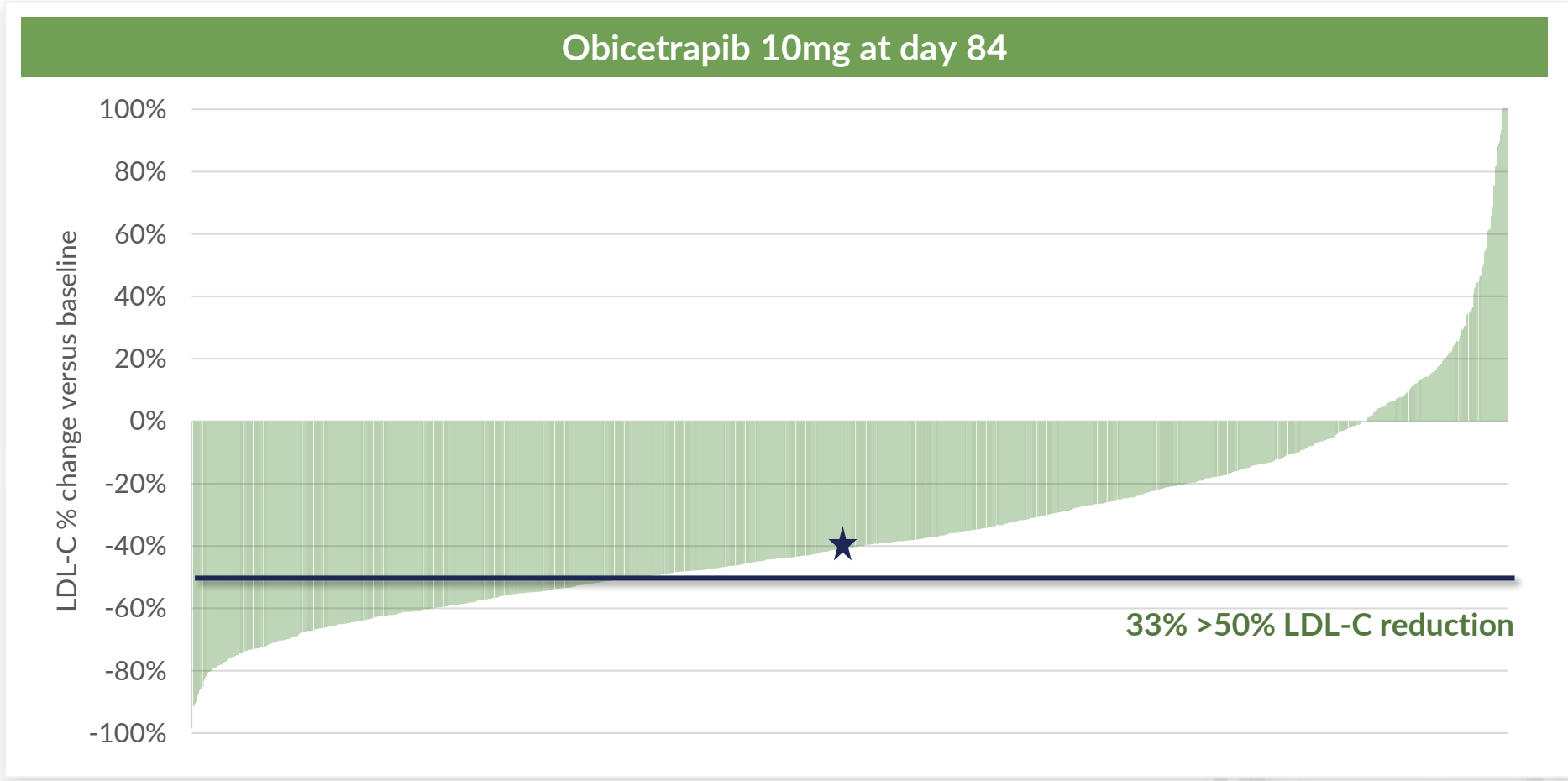
Median change from baseline of 40%



Note: each line represents a single patient in the obicetrapib 10 mg arm, five patients increase more than 100%

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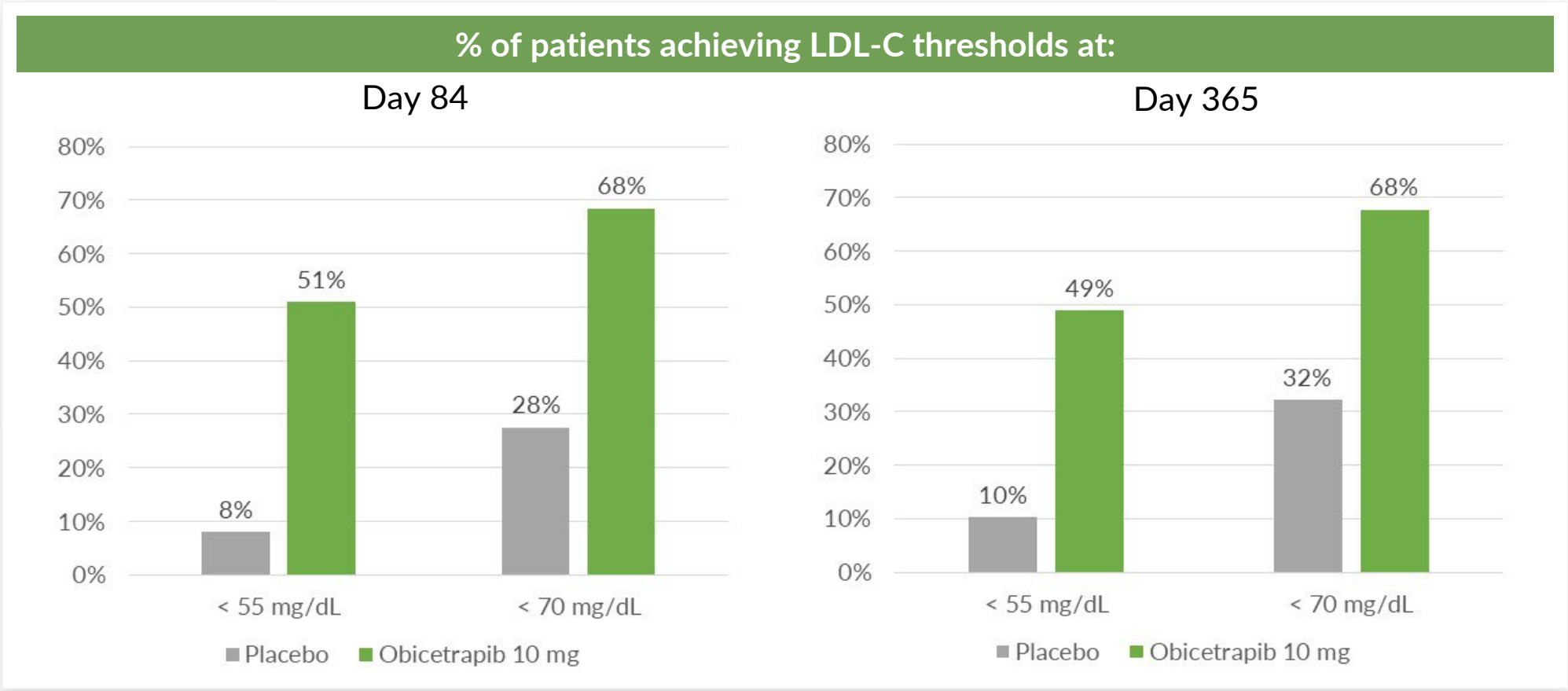
Half of the patients on obicetrapib 10 mg achieved less than <55 mg/dL



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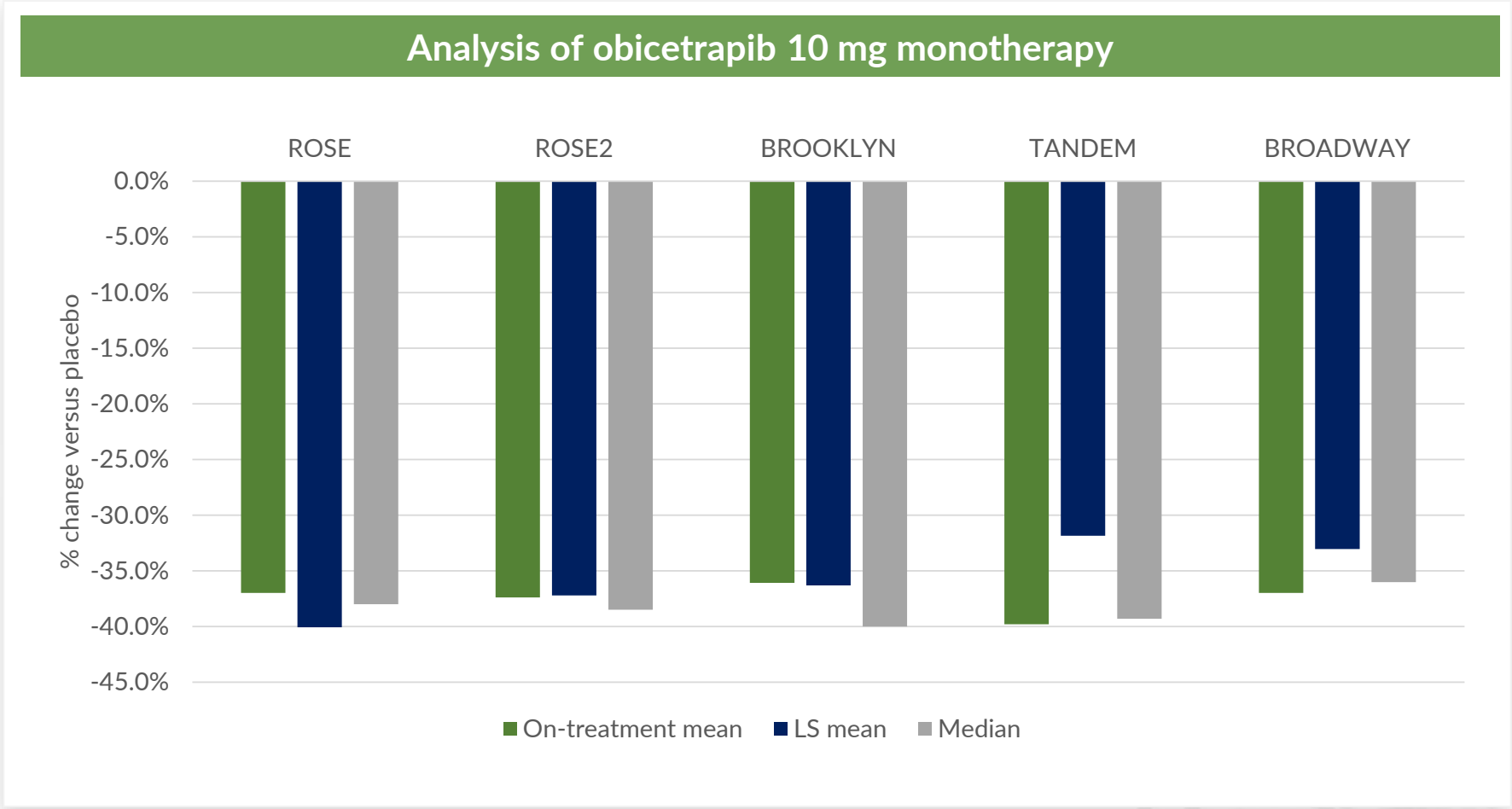
Consistent observed LDL-C reduction for obicetrapib across our Phase 2 and Phase 3 trials



Note: ROSE at week 8, ROSE2, BROOKLYN, BROADWAY, and TANDEM as of week 12.

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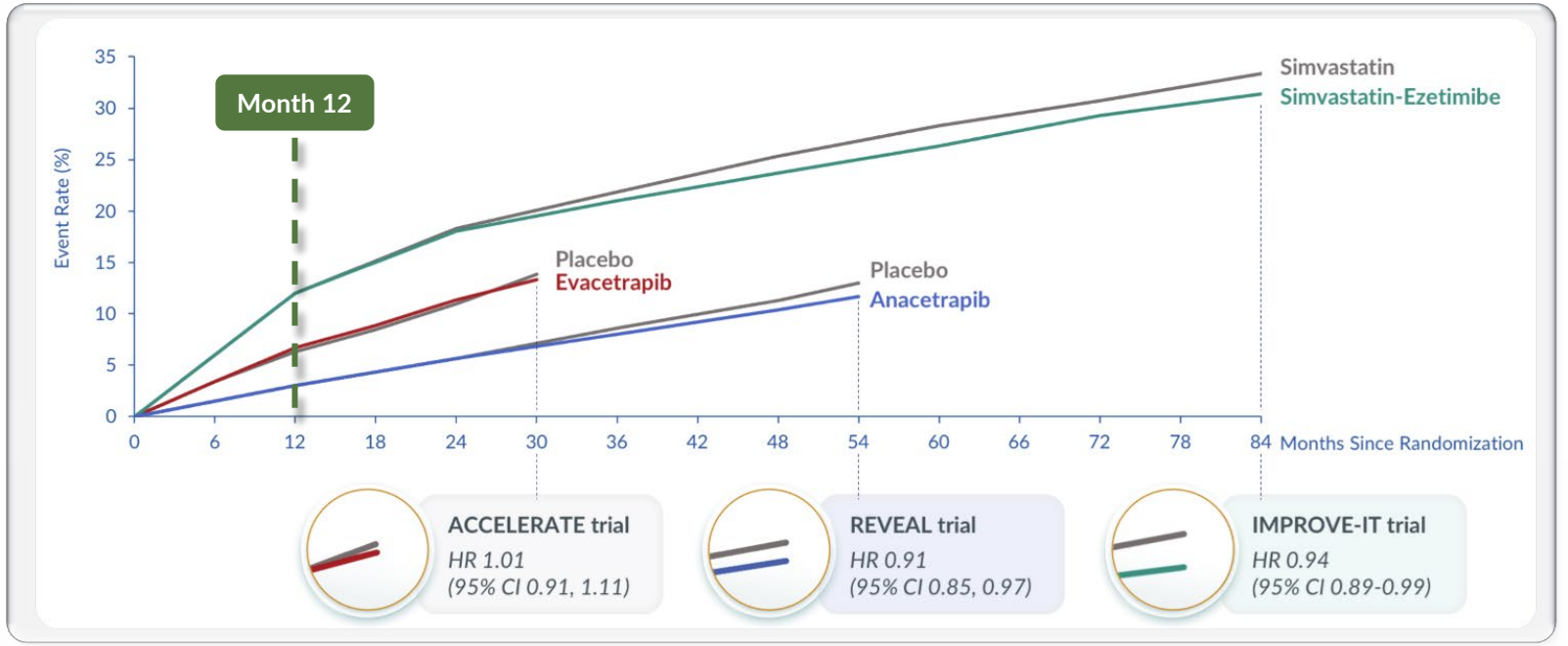
Expectation heading into BROADWAY was no difference in MACE (HR=1.0)

Separation of curves after one year not seen in prior CETP CVOT trials



Curves are for the primary efficacy endpoint, which in IMPROVE-IT was defined as the composite of death from cardiovascular disease, a major coronary event (nonfatal myocardial infarction, documented unstable angina requiring hospital admission, or coronary revascularization occurring at least 30 days after randomization), or nonfatal stroke, in ACCELERATE as the composite of death from cardiovascular causes, myocardial infarction, stroke, coronary revascularization, or hospitalization for unstable angina, and in REVEAL as the composite of coronary death, myocardial infarction, or coronary revascularization.

Cannon CP, et al. N Engl J Med 2015;372:2387-2397. Lincoff AM, et al. N Engl J Med 2017;376:1933-1942. Bowman L, et al. N Engl J Med 2017;377:1217-1227.

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Exploratory endpoint: Major adverse cardiovascular events (MACE)

BROADWAY MACE Data[1]

	Placebo N = 844	Obicetrapib N= 1686	Hazard Ratio	95% CI
All-cause mortality – no. (%)	12 (1.4)	19 (1.1)	0.83	(0.40-1.71)
Coronary heart death – no. (%)	5 (0.6)	8 (0.5)	0.80	(0.26-2.44)
First 4-point MACE – no. (%)	44 (5.2)	70 (4.2)	0.79	(0.54-1.15)

BROADWAY + BROOKLYN Pooled MACE Data [1]

	Placebo N = 962	Obicetrapib N= 1920	Hazard Ratio	95% CI
All-cause mortality – no. (%)	14 (1.5)	20 (1.0)	0.78	(0.39-1.58)
Coronary heart death – no. (%)	7 (0.7)	9 (0.5)	0.63	(0.24-1.70)
First 4-point MACE – no. (%)	49 (5.1)	75 (3.9)	0.75	(0.53-1.08)

4-point MACE: CHD death, Non-fatal myocardial infarction, non-fatal stroke, coronary revascularization

1. MACE was evaluated in BROADWAY as an exploratory endpoint. There may be limitations on the interpretation of MACE data derived from both BROOKLYN and BROADWAY studies given they were not designed to assess MACE as the primary and secondary endpoints.

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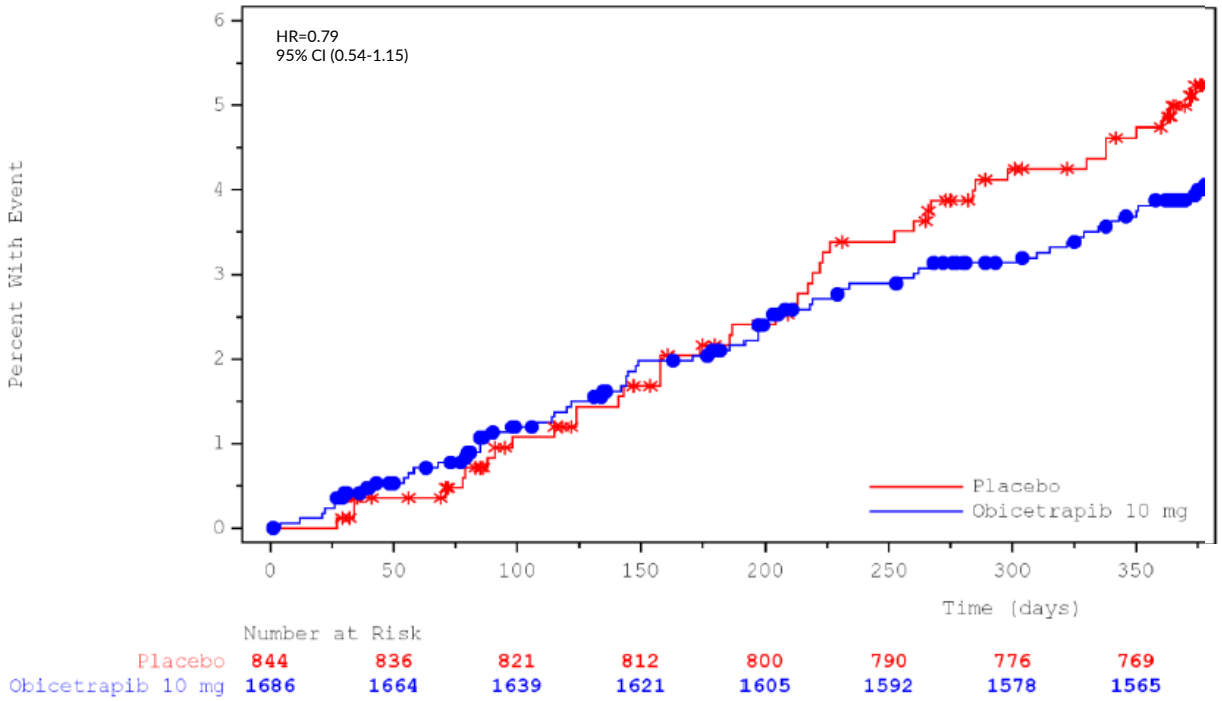
Kaplan-Meier curve separates at day 200



4-point MACE: CHD death, Non-fatal myocardial infarction, non-fatal stroke, coronary revascularization
Note: While not powered to detect a MACE benefit, we observed positive MACE data as part of our review of the exploratory endpoint. BROADWAY was not powered to measure MACE benefit and the MACE data presented below may not be predictive of the MACE data we observe in PREVAIL, which has been designed to measure MACE benefit.

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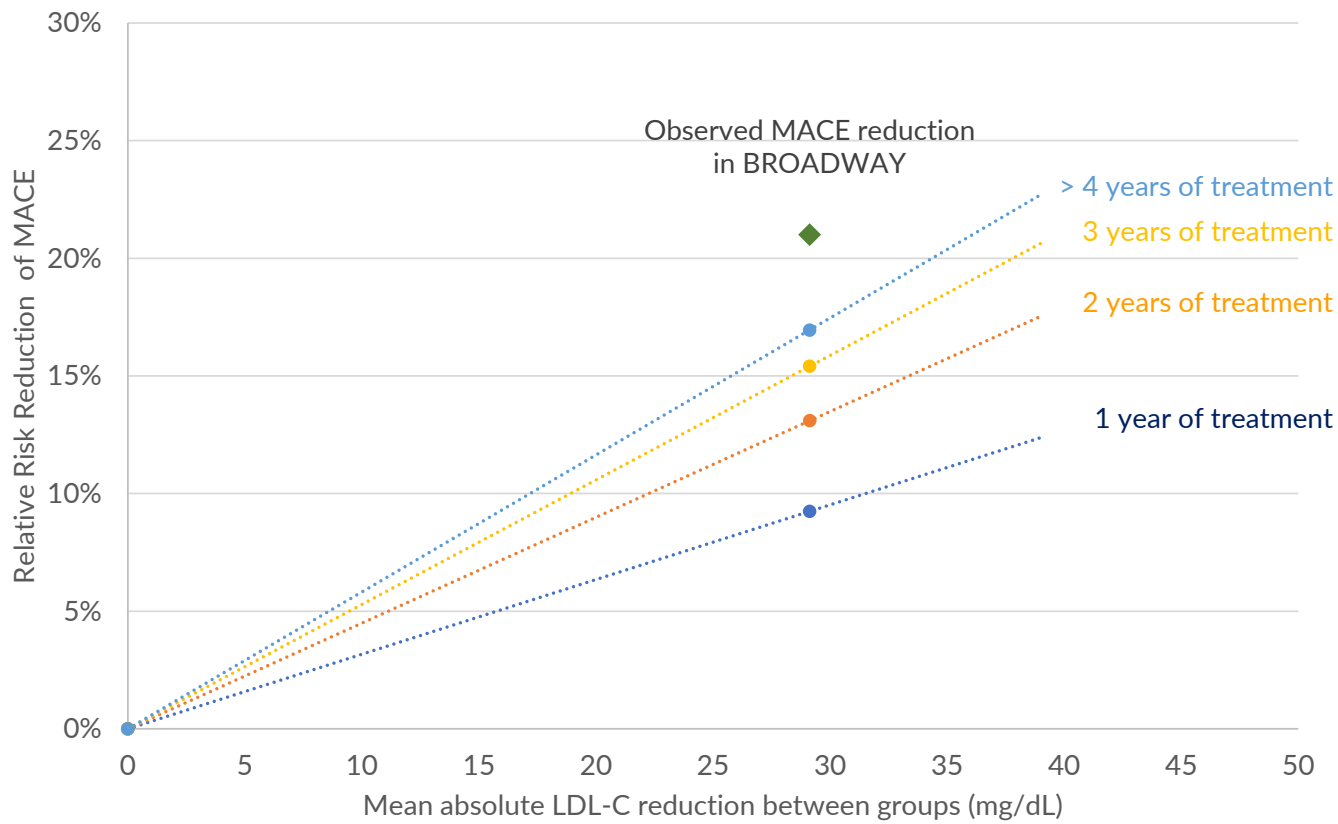
Observed MACE reduction in BROADWAY suggests potential benefit beyond LDL-C



CTT regression Line

- The CTT regression line (dotted lines) represents the expected relationship between a mean absolute reduction in LDL-C versus placebo and the predicted MACE benefit at different time points based on historical trials
- In BROADWAY, we observed a 21% difference in MACE from placebo, after one year of treatment

Note: The 1-4 treatment lines in the chart above reflects the meta-analysis of 26 statin clinical trials conducted by the CTT collaboration which showed that there is a consistent, linear decrease in MACE for every absolute unit of non-HDL (which is primarily composed of LDL-C) cholesterol reduction. Actual results may differ materially as MACE was evaluated in BROADWAY as an exploratory endpoint. This is not a head-to-head analysis

Source: 1. JAMA. 2016;316(12):1289-1297 2. European Heart Journal (2018)39,2540–2545

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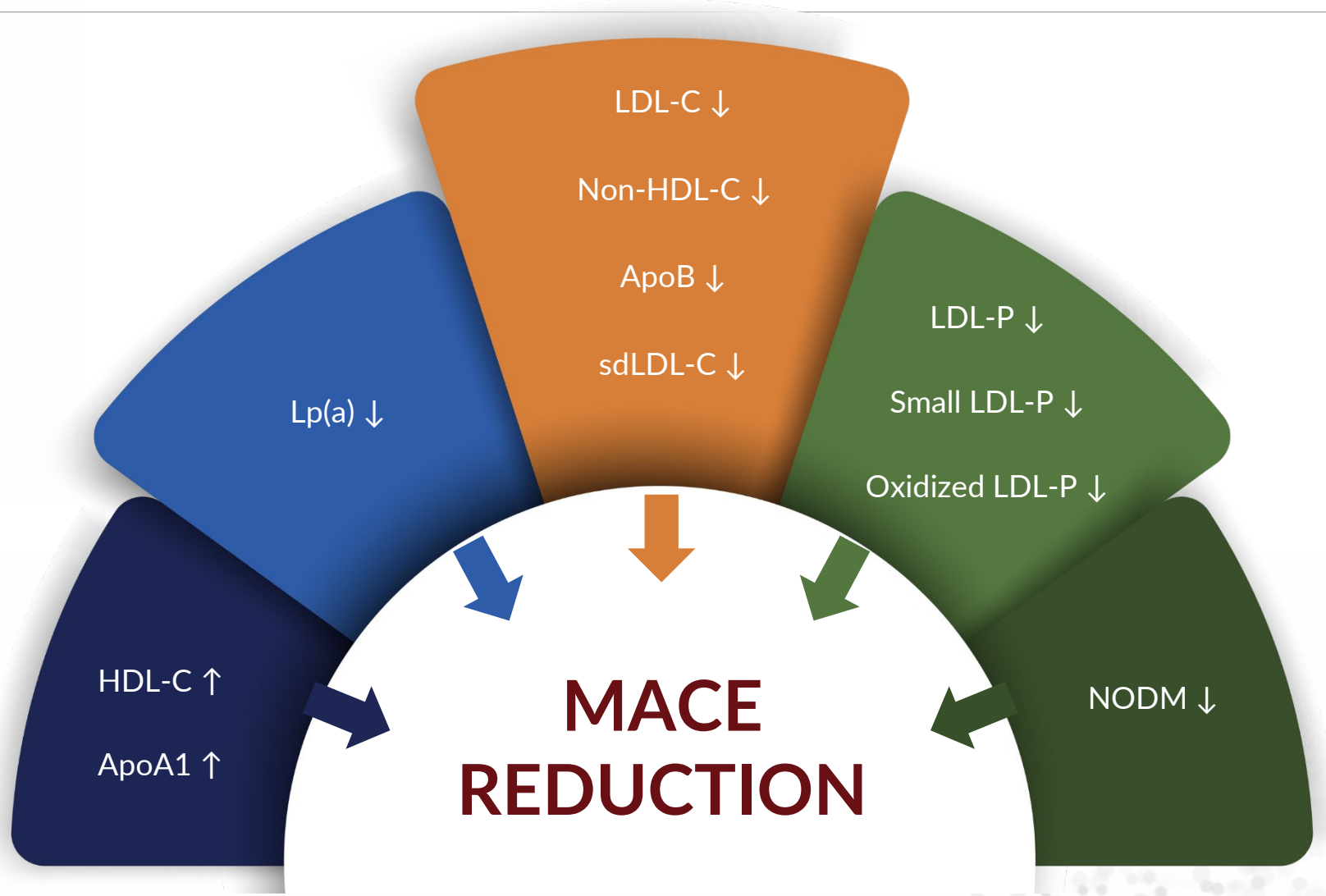
Obicetrapib observed to impact multiple factors believed to be associated with MACE



Note: NODM = New onset diabetes mellitus

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Safety population: Adverse event comparable to placebo

	Placebo N= 843 n (%)	Obicetrapib 10 mg N= 1685 n (%)
Any treatment-emergent AEs (TEAEs)	513 (60.9)	1007 (59.8)
Any TEAEs by maximum severity		
Mild	228 (27.0)	481 (28.5)
Moderate	217 (25.7)	408 (24.2)
Severe	68 (8.1)	118 (7.0)
Any trial drug related TEAEs	39 (4.6)	76 (4.5)
Any trial drug-related TEAEs by maximum severity		
Mild	25 (3.0)	51 (3.0)
Moderate	14 (1.7)	23 (1.4)
Severe	0 (0.0)	2 (0.1)
Any TEAEs leading to discontinuation of trial drug	43 (5.1)	68 (4.0)
Any treatment-emergent serious AEs (TESAEs)	117 (13.9)	211 (12.5)
Any treatment-emergent non-serious Aes	495 (58.7)	959 (56.9)
Any trial drug-related TESAEs	0 (0.0)	1 (0.1)
Any TEAEs leading to death	12 (1.4)	19 (1.1)

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Overview of Events of Special Interest

	Placebo N= 843 n (%)	Obicetrapib N= 1685 n (%)
AST or ALT > 3 x ULN	8 (0.9)	10 (0.6)
Bilirubin > 2 x ULN	4 (0.5)	2 (0.1)
CK > 5 x ULN	3 (0.4)	5 (0.3)
NODM or worsening of glycemic control	338 (40.1)	592 (35.1) (p = 0.015)
- AE indicating new/worse type 1 or 2 diabetes	30 (3.6)	58 (3.4)
- Initiation of diabetes medication	104 (12.3)	186 (11.0)
- HbA1c ≥ 6.5% (where baseline HbA1c < 6.5%)	55 (6.5)	84 (5.0)
- Two consecutive glucose values > 126 mg/dL	248 (29.4)	459 (27.2)
- HbA1c increase from baseline >0.5%	133 (15.8)	234 (13.9)
- Worsening glycemic control	199 (23.6)	350 (20.8)
Renal function worsening	77 (9.1)	127 (7.5)
- eGFR < 30 mL/min/1.73m2	13 (1.5)	13 (0.8)
- 25% decrease in eGFR from baseline:	70 (8.3)	115 (6.8)
- Increase of Serum Creatinine ≥ 0.3 mg/dL from baseline	61 (7.2)	91 (5.4)
Macular degeneration	0 (0.0)	1 (0.1)

Key observations from overall phase 3 program

Efficacy

- Obicetrapib monotherapy: 33-36% based on BROOKLYN and BROADWAY data
- Obicetrapib + ezetimibe FDC: 49% based on TANDEM data
- Obicetrapib or obicetrapib+ezetimibe gets vast majority of patients to LDL-C goal

Tolerability

- Adverse events, vital signs and laboratory parameters comparable to placebo
- No observed increase in blood pressure, hs-CRP, liver or muscle enzymes
- Fewer glycemic and renal adverse events were noted in the obicetrapib arm compared to placebo in BROADWAY

Outcomes

- Encouraging MACE findings – 21% reduction in BROADWAY - provide optimism for CV outcomes being studied in PREVAIL of >20%

Note: MACE was evaluated in BROADWAY as an exploratory endpoint. There may be limitations on the interpretation of MACE data derived from the BROADWAY trial given it was not designed to assess MACE as a primary or secondary endpoint.