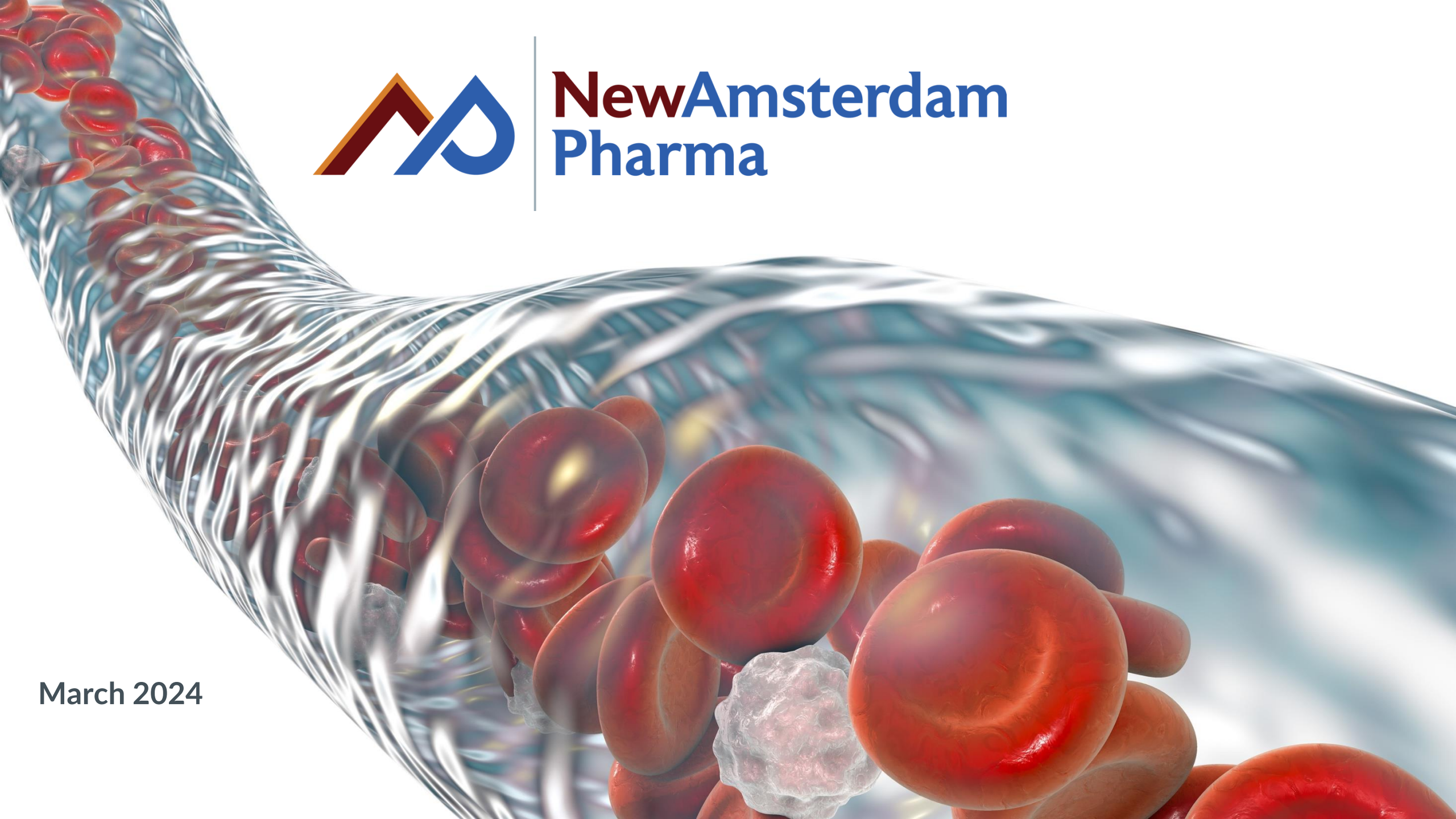

NewAmsterdam Pharma

March 2024

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Obicetrapib in multiple Phase 3 trials for hypercholesterolemia – Key value-driving data expected in 2024

Significant unmet need for oral LDL-lowering therapy as adjunct to statins:

- **35mm+** patients in US/EU5 are not achieving LDL-lowering goals despite standard-of-care
- **$3-4B+** global market opportunity

Simple, oral, once-daily, low dose CETP inhibitor with strong LDL-lowering observed through five Phase 2 trials:

- **43%** mean LDL-lowering as monotherapy, **59%** mean in combination with ezetimibe, observed on top of high-intensity statins
- Tolerability data in **>800 pts,** with blinded data in **>10,000 pts**
- Robust effects on **ApoB, non-HDL-C, HDL-C and Lp(a)**

Convenient oral format potentially enables broad market access to address unmet need

Cash post February financing: ~$500 million[1]

Multiple pivotal data readouts
expected from 2024-2026

- **1Q 2024:** Complete Phase 3 enrollment for PREVAIL
- **1Q 2024:** Initiate Phase 3 fixed-dose combination ("FDC") trial

Anticipated Phase 3 data readouts:

- **3Q 2024:** BROOKLYN
- **4Q 2024:** BROADWAY
- **1Q 2025:** TANDEM Fixed-Dose Combination
- **2026:** PREVAIL CVOT

Additional pipeline expansion potential in Alzheimer's disease and diabetes

Upcoming catalysts build on 2023 progress:

- Enrollment complete in BROOKLYN & BROADWAY
- Positive data in ROSE2, Phase 2b Trial in Japanese Patients
- Initial data from Phase 2a Trial in Early Alzheimer's

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Source: Company data for obicetrapib 10mg monotherapy, Pooled data includes TULIP, ROSE, ROSE2, and Japan Phase 2 data sets
1. $340 million cash balance at year end 2023 plus $190 million net proceeds from secondary

Obicetrapib designed to address the ~30M patients in US on drug but not at goal

~72 million
Adults in US diagnosed with hypercholesterolemia

~43 million
Treated primary prevention patients

~19 million
Treated secondary prevention patients

~10 million
Diagnoses patients not treated with statin or LLT

~18 million
Not at goal of LDL-C <100mg/dl

~8 million
High Risk ASCVD not at goal of LDL-C <55 mg/dl

~5 million
ASCVD not at goal of LDL-C <70 mg/dl

Of the ~30M treated patients not at goal, **~18M** were **"far from goal" (greater than 20%)** and 6M were not taking statins

US Branded Lipid Lowering Market

Potential key factors limiting penetration include **product limitations** and **market access** hurdles:
Low prescriber enthusiasm for existing TPPs
Payors restrict access

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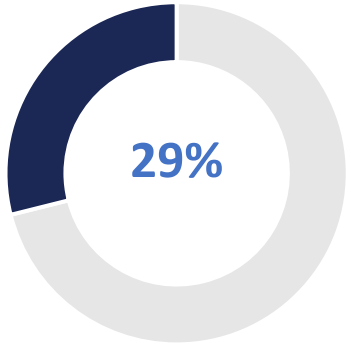
ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein-cholesterol; LLT=lipid lowering treatment.
Source: Merative Marketscan Claims Linked with Lab Data, 2019 - 2022, 12 months continuous data for each patient (6 months LB and 6 months LF from 1st observed statin treatment

Majority of ASCVD/HeFH patients are not achieving LDL-C targets

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

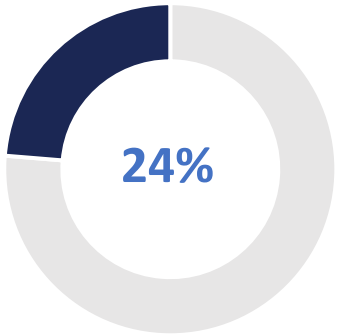
LDL-C < 100 mg/dL



<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]

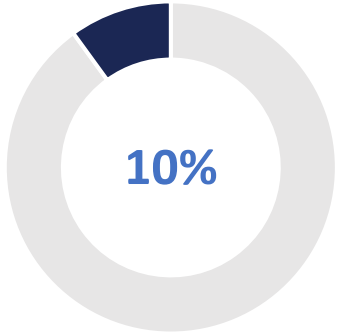
LDL-C < 70 mg/dL



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

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

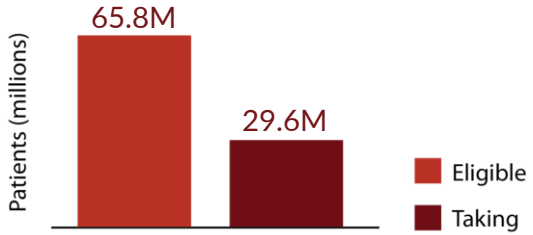
LDL-C < 55 mg/dL



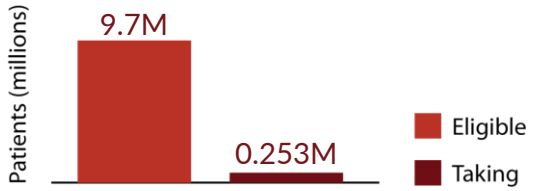
10% achieved LDL-C <55 mg/dL

Despite availability of treatments continue to see minimal uptake, especially adjunct to statins[4]

Statin utilization



PCSK9i utilization



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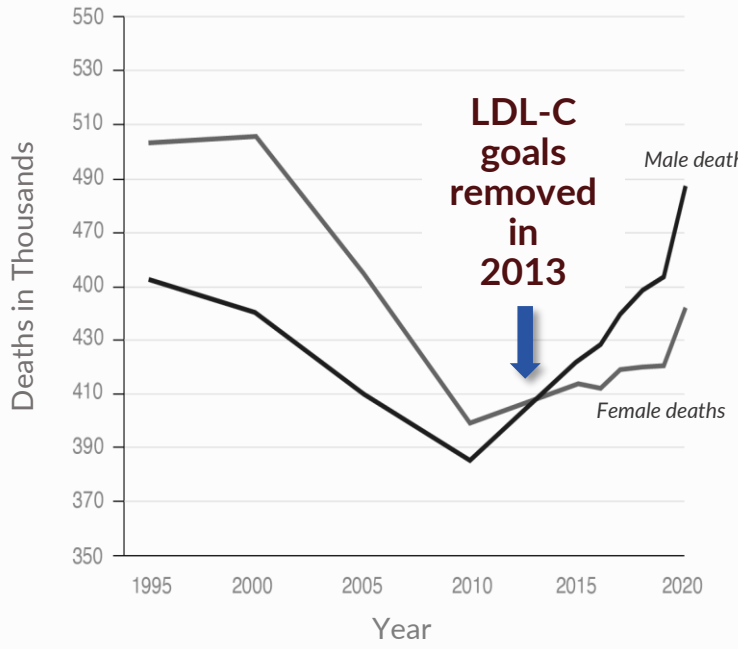
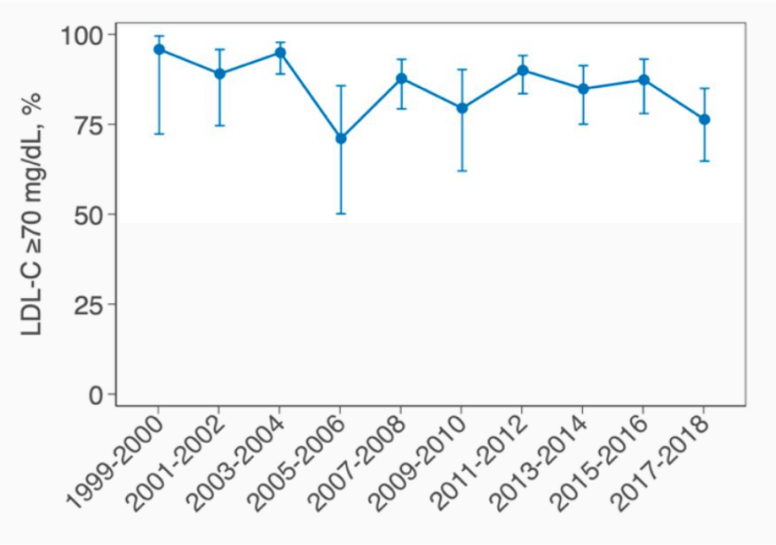
ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein-cholesterol.

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; 4. J Am Heart Assoc 2022;11:3026075; doi: 10.1161/JAHA.122.026075

Increased CV events following removal of LDL-C guidelines in 2013

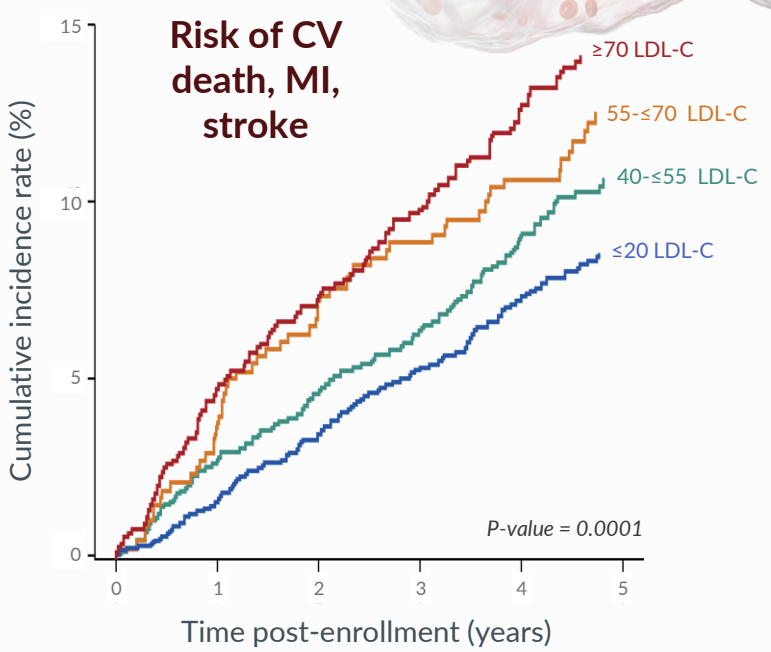


Despite statins, **CVD deaths are on the rise**



Trends in prevalence of high LDL-C in US adults, NHANES 1999-2018 with history of ASCVD[2]

~75% of ASCVD patients are NOT at their **risk-based LDL-C goal**



Numerous studies demonstrate resurgence of paradigm **"lower is better"**

Sources: Trinity NewAmsterdam Market Research Summary; Trinity quantitative market research with N = 100 PCPs and Cardiologists; Bloomberg Prescription Data; IQVIA Rx Tracker. (1) Literature review suggesting hypercholesterolemia prevalence of ~94mm in the US (average of He et al. 2020, Mercado et al. 2015, Muntner et al. 2013) and ~137mm in EU5 (average of Gomez-Huelgas et al. 2010, Guallar-Castillon et al. 2012, Tragni et al. 2012, Grau et al. 2011 (3) 8mm statin-intolerant & 22mm above LDL-C target: Percentage of patients in each category estimated from Trinity quantitative market research and the – percentages were then applied to the estimated 84mm treated number above. (4) <1mm branded patients: 2020 US prescription data for Repatha, Praluent, and Nexletol/Nexlizet were pulled from the Bloomberg Prescription Data Portal that Trinity subscribes to; assuming 12 scripts/year and 70% compliance for PCSK9s (based on PCSK9 literature) and 59% compliance for Nex/Nex (based on statin literature) patient volume estimates were derived from the prescription data and extrapolated to the EU5. (5) Gaba P, et. al., Association Between Achieved Low-Density Lipoprotein Cholesterol Levels and Long-Term Cardiovascular and Safety Outcomes: An Analysis of FOURIER-OLE. Circulation. 2023 Feb 13. doi: 10.1161/CIRCULATIONAHA.122.063399.

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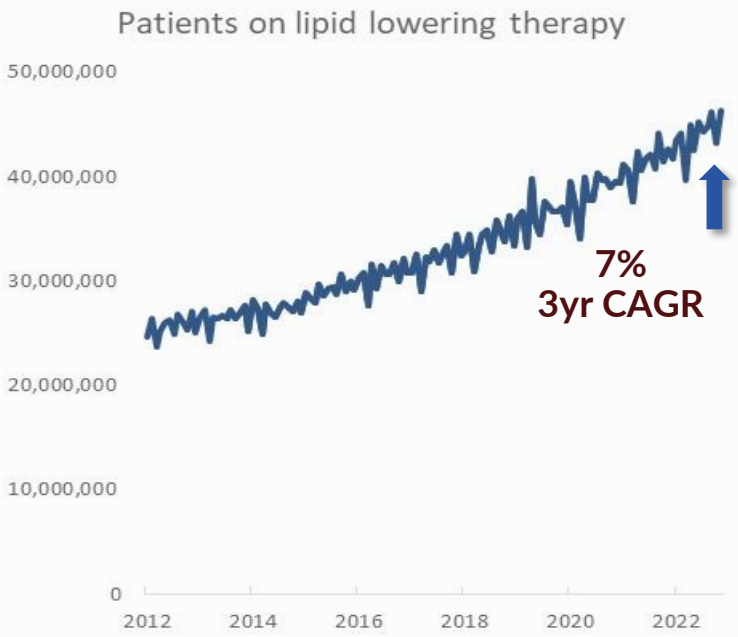
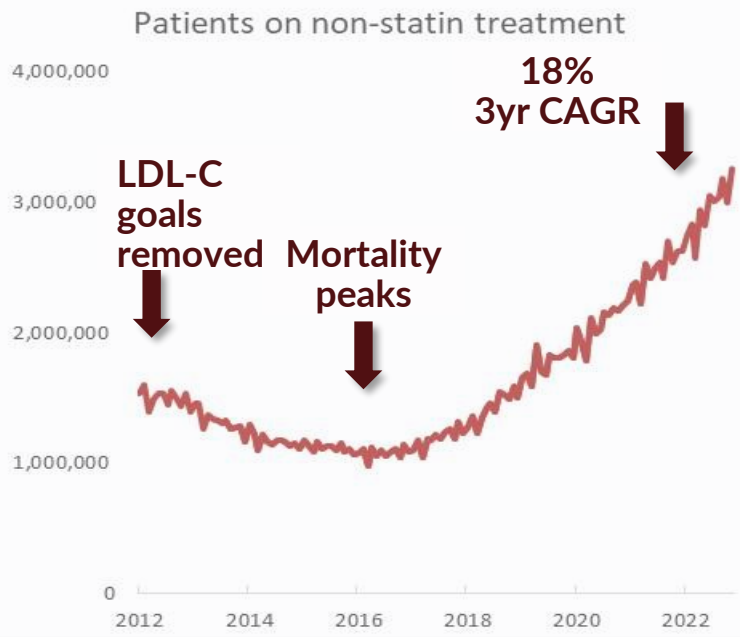
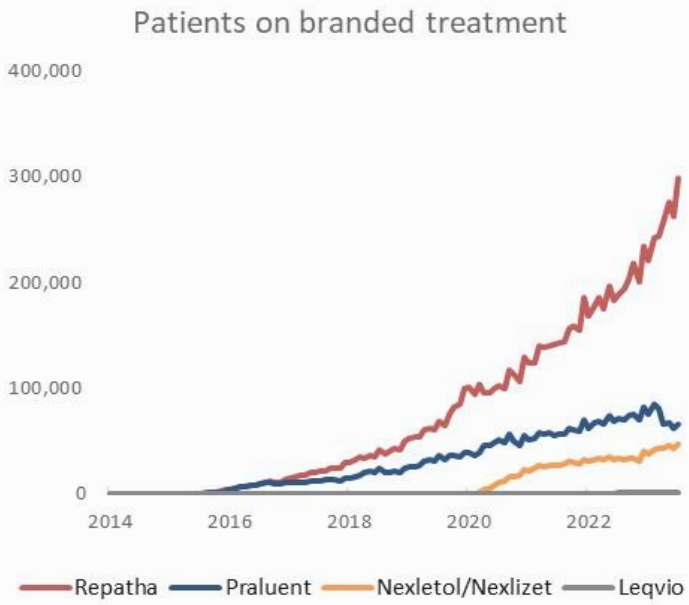
Resurgence of the "lower is better" paradigm leading to significant US market growth



7% total market growth in the US



18% non-statin patient growth



Driven by generic ezetimibe, given **lack of convenient and efficacious alternatives**

Recent guideline and label changes driving renewed acceleration

June 2023: ACC **updated guidelines** to target LDL-C <55 mg/dl in high risk patients in line with ESC/EAS
November 2023: FDA highlights need to **reduce access restrictions** for LLTs. Labels updated from "on top of maximally tolerated statins" to "treatment of primary hyperlipidemia" for some LLTs

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Source: Symphony Health data through October 2023
Note: LLT=lipid lowering treatment.

Few approved post-statin LDL lowering products, which are limited by efficacy, convenience and/or payor access

	Ezetimibe[1]	Nexletol[2]	PCSK9i[3]	Oral PCSK9[4]	Obicetrapib[5]	Obi + Eze[5]
Approval	Approved	Approved	Approved	LDL data 2026E (CVOT data 2029E)	LDL data 2024E (CVOT data 2026E)	LDL data 2025E
MACE Benefit	7%	13%	15%	TBD	TBD	TBD
Observed LDL-C Reduction	25%	15%	45-50%	50-59%	43-51%	63%
Administration	Oral (small molecule)	Oral (small molecule)	Injectable (mAb)	Oral (peptide)	Oral (small molecule)	Oral (small molecule)
Dosing	10mg	180mg	140-150mg	380mg (20mg API + 360mg SNAC)	10mg	20mg (10mg Obi + 10mg Eze)
Food Effect	No	No	No	Yes (8hr fast & 30min wait)	No	No
Safety & Tolerability	Safe, Well-Tolerated	Tendon rupture & gout warning on label	Safe, injection site reactions	SNAC technology has previously been observed to have tolerability concerns[6]	Well-Tolerated compared to placebo	Well-Tolerated compared to placebo
Lp(a) lowering	Raises	None	15-30%	20-25%	47-57%	40%
						

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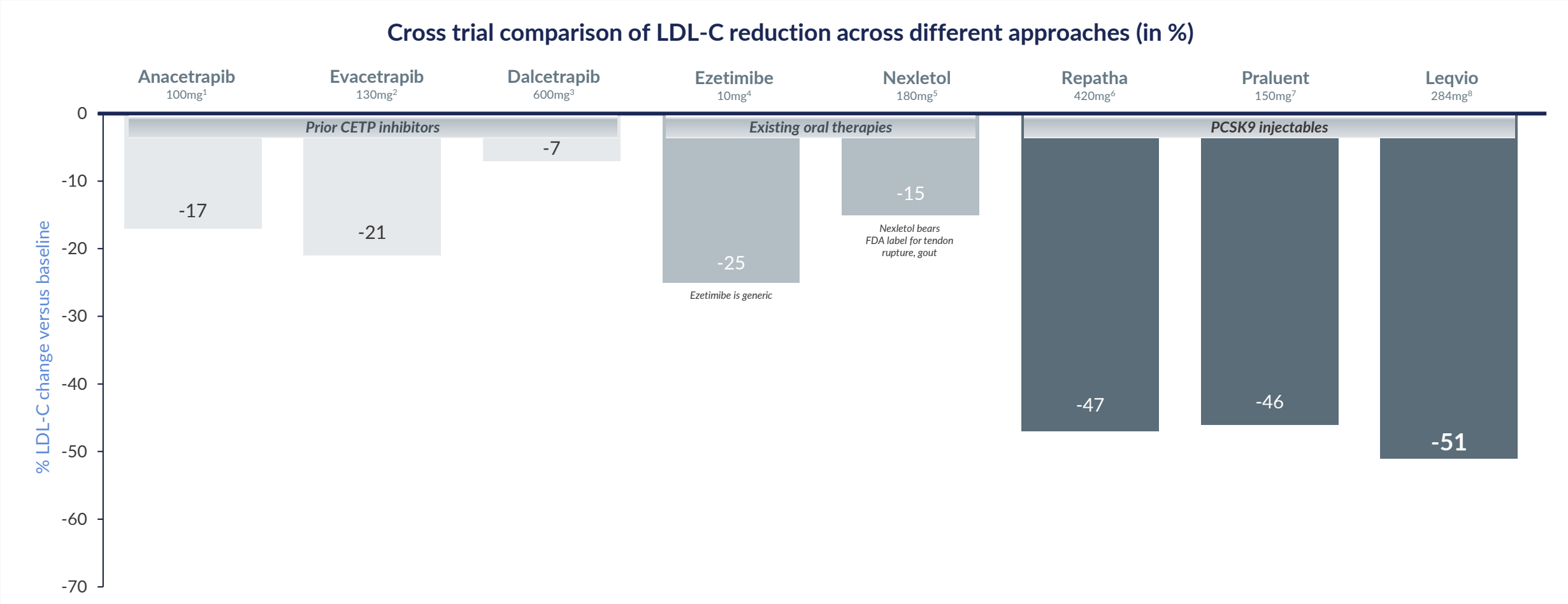
Note: The above data do not represent head-to-head comparisons. Actual results may differ from expectations. Obicetrapib mono and Ezetimibe combo, along with the Oral PCSK9 have not been approved by any regulatory authority. E= estimated dates.
Sources: **1.** PI Zetia table 7. refers to; Gagne, C et al. Am J Cardiol 2002. LDL-C measured only using Friedewald **2.** PI Nexletol; study 2. refers to; Goldberg, A et al. JAMA 2019;322(18):1780-1788. LDL-C measured using Friedewald and direct assay for LDL-C <50 mg/dL. **3.** multiple studies: Blom, D et al. N Engl J Med 2014; Kereiakes, D et al. Am Heart J 2015.; Ray, K. N Engl J Med 2020. **4.** Ballantyne, C et al. JACC 2023;81(16) **5.** See slide 12 and 20 **6.** MK0616 was observed to have adverse events comparable to pbo in Phase 2b trials

40-50% LDL-C reduction comparable to high efficacy PCSK9 injectables



The trials represented were selected due to their shared features that reflect the Phase 3 obicetrapib studies. Selecting trials with shared features allows for a potentially more accurate comparison of the LDL-C lowering results, with factors being considered such as: **a)** presence of intensive LDL-lowering therapy including (high intensity) statins and PCSK9 inhibitors, **b)** patient population – ASCVD or ASCVD risk equivalent patients (including primary hypercholesterolemia and HefH) and **c)** where possible, selected studies where LDL-C measured by preparative ultracentrifugation (PUC) as opposed to Friedewald; noted below are those instances where PUC was not used – this is important because at low LDL-C levels (< 50 mg/dL), calculated LDL-C by Friedewald is overestimated; certain significant deviations from these parameters are provided in the footnotes.

Note: The above trials and data do not represent head-to-head comparisons. Actual results may differ from expectations.

Sources: * Circulation. 2021;144:e564–e593 17065. **1.** Bowman, L et al. N Engl J Med 2017. **2.** Amirhossein, S et al. Curr Pharmaceutical Design 2016. Meta-analysis - Also included hyperlipidaemia patients. LDL-C measured using direct assays and Friedewald. **3.** de Grooth et al. Circulation 2002. LDL-C measured only using Friedewald and did not require subjects to be on prior statin therapy or present with ASCVD. **4.** PI Zetia table 7. refers to; Gagne, C et al. Am J Cardiol 2002. LDL-C measured only using Friedewald. **5.** PI Nexletol; study 2. refers to; Goldberg, A et al. JAMA 2019;322(18):1780-1788. LDL-C measured using Friedewald and direct assay for LDL-C <50 mg/dL. **6.** DESCARTES study. refers to; Blom, D et al. N Engl J Med 2014. Also included hyperlipidaemia patients. **7.** PI Praluent; study 3. refers to; Kereiakes, D et al. Am Heart J 2015. **8.** PI Leqvio; study 1. Refers to; Ray, K. N Engl J Med 2020.

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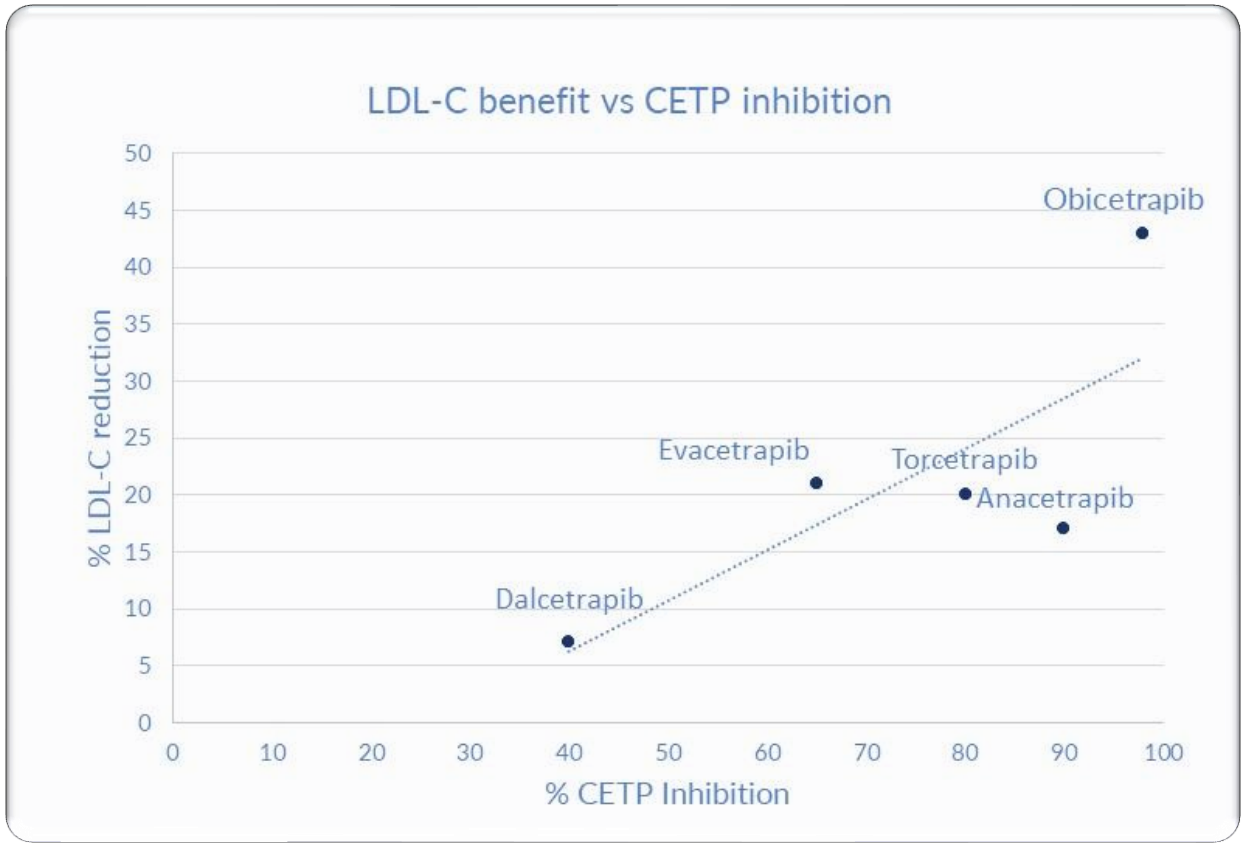
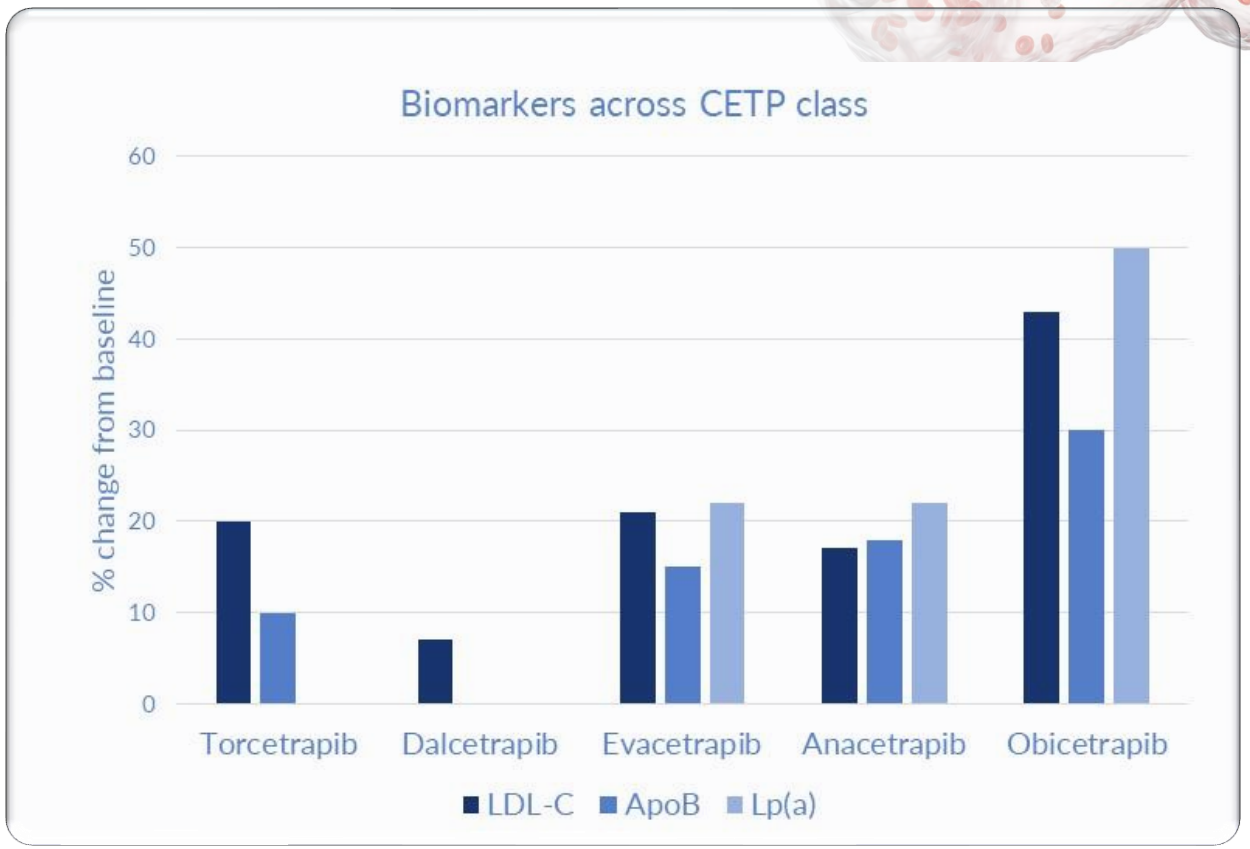
Enhanced LDL-C reduction with Obicetrapib's greater potency





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Note: The above trials and data do not represent head-to-head comparisons. Actual results may differ from expectations.
Sources: **1.** Barter et al. NEJM.2007; **2.** Schwartz et al. NEJM.2012; **3.** Lincoff et al. NEJM.2017 **4.** Bowman et al. NEJM.2017 **5.** Company Data

Obicetrapib program designed to overcome limitations of prior CETP inhibitors

	Torcetrapib[1]	Dalcetrapib[2]	Evacetrapib[3]	Anacetrapib[4]	Obicetrapib[5]
Observed LDL-C reduction	20%	7%	11-21%	17%	43%
CETP inhibition	35%	30%	65%	80%	97%
Dosing	60mg	600mg	100mg	100mg	10mg
Blood pressure increase	Yes	No	No	No	No
Aldosterone increase	Yes	No	No	No	No
Lp(a) lowering	unknown	unknown	20-25%	20-25%	47-57%
ApoB lowering	10%	None	15%	18%	25%-35%
OUTCOMES STUDIES					
Name	ILLUMINATE	Dal-OUTCOMES	ACCELERATE	REVEAL	PREVAIL
Patients	15,067	15,871	12,092	30,449	>9,000 (expected)
Baseline LDL-C (mg/dl)	79.7	76.4	81.1	61	~105 (expected)
LDL-C reduction (mg/dl)	20	NS	25	11	TBD
Median follow-up	18 mo	31 mo	26 mo	49 mo	42 mo (expected)
Result (HR)	1.25	1.04	1.01	0.91	TBD
Explanation	Off target tox	No LDL-C benefit	Short follow-up but mortality benefit (HR 0.84)	As expected, low baseline and LDL reduction	TBD

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Note: The above trials and data do not represent head-to-head comparisons. Actual results may differ from expectations.
Sources: **1.** Barter et al. NEJM.2007; **2.** Schwartz et al. NEJM.2012; **3.** Lincoff et al. NEJM.2017 **4.** Bowman et al. NEJM.2017 **5.** Company Data

REVEAL data in high tercile in non-HDL-C supports larger MACE benefit

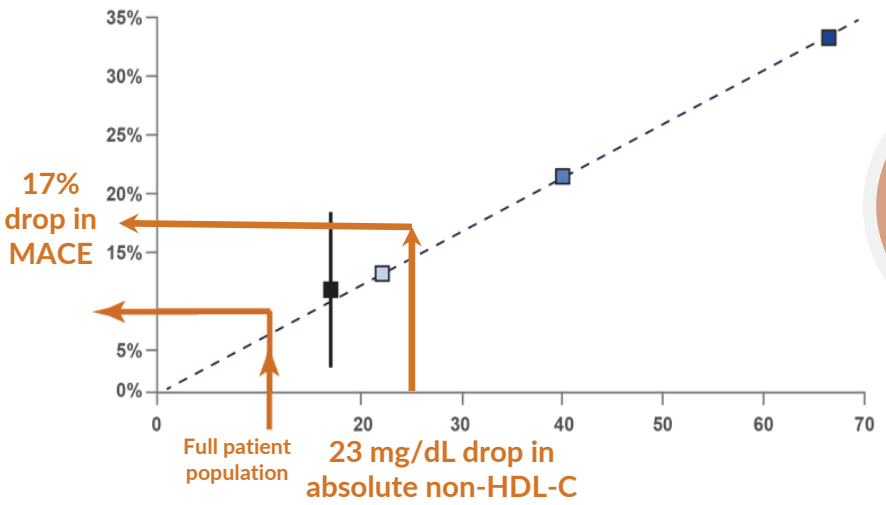
EXPERIENCE: *REVEAL (anacetrapib)*

~110 mg/dL × 21% = 23 mg/dL

non-HDL-C high tercile baseline

Drug showed modest Non-HDL-C lowering %

Results in SMALL absolute non-HDL-C reduction



17% *drop*

Smaller MACE* benefit

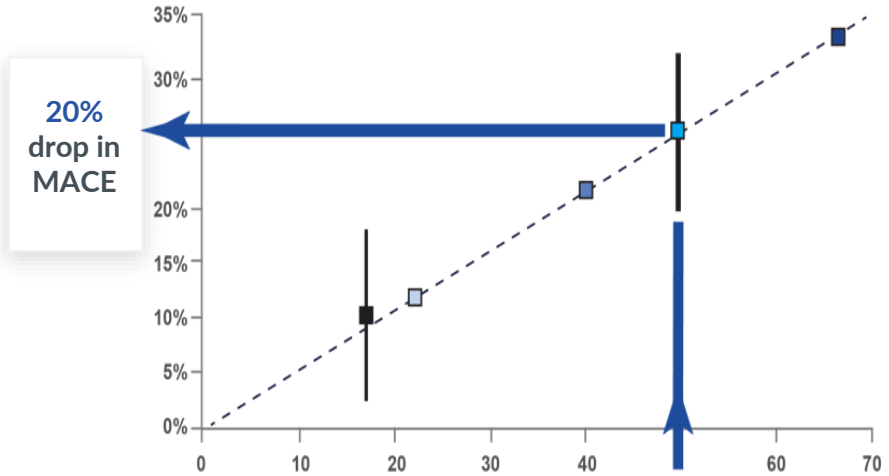
Hypothetical: Obicetrapib *(Phase 2 Studies)*

~140 mg/dL × 40% = ~56 mg/dL

Non-HDL-C PREVAIL baseline

Non-HDL-C lowering in Obi P2s

absolute non-HDL-C reduction



20% *drop*

Bigger expected MACE** benefit

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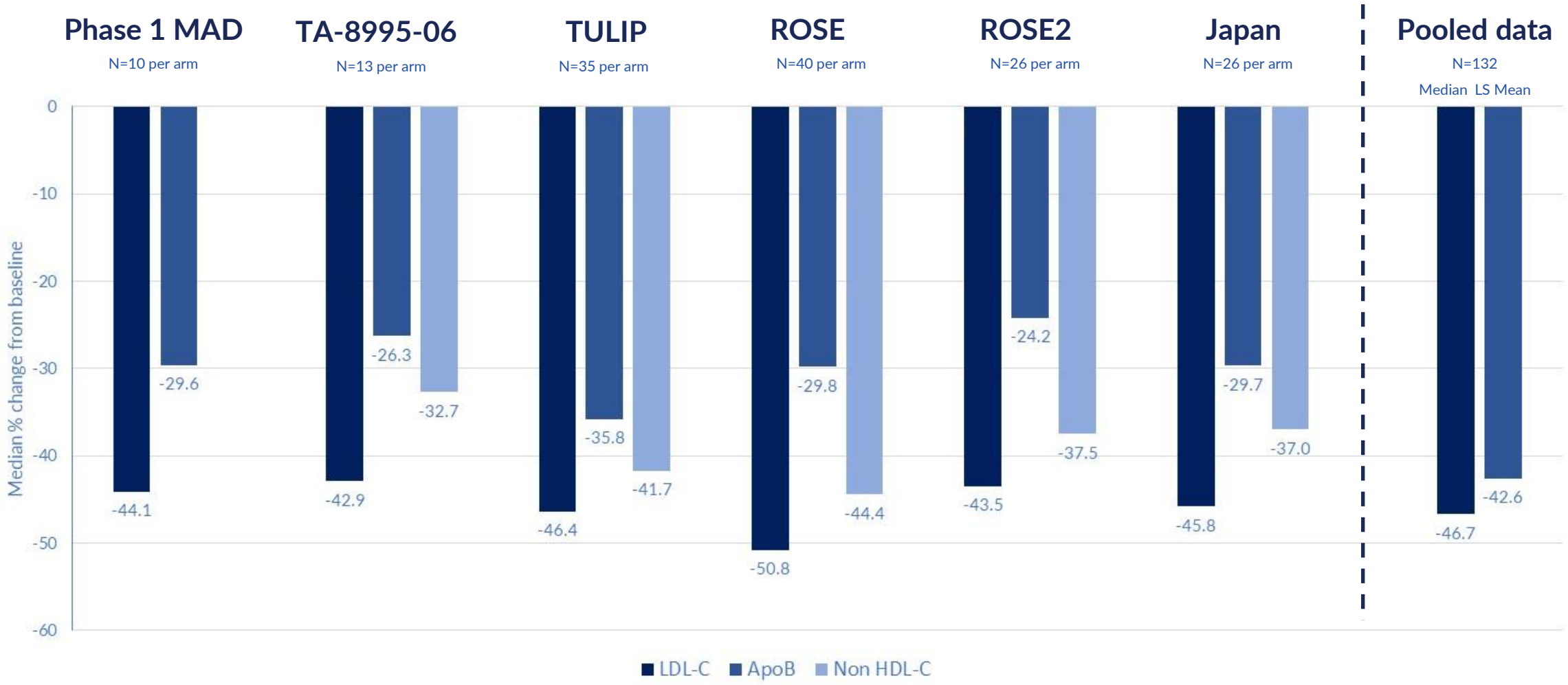
Source: The HPS3/TIMI55–REVEAL Collaborative Group. N Engl J Med 2017; 377:1217-1227
Cholesterol Treatment Trialists Collaboration. Lancet. 2010 376:1670-81.
*Composites of MACE included in this analysis were coronary death, myocardial infarction or coronary revascularization.

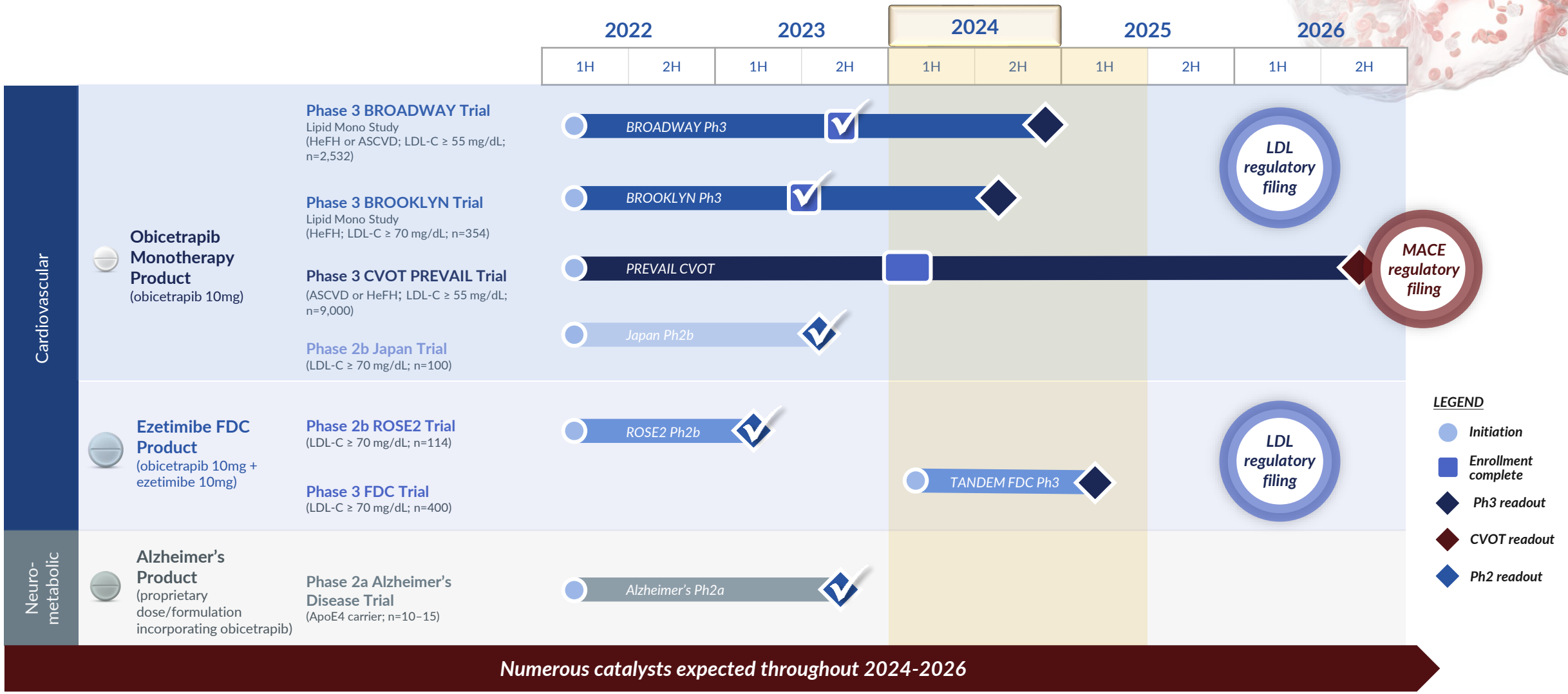
Note: Actual results may differ from hypothetical calculation.
Source: Nicholls SJ, Ditmarsch M, Kastelein JJ, et al. Nat Med 2022;28:1627-1678.
** MACE includes cardiovascular death, myocardial infarction, stroke and non-elective coronary revascularization in adults

Obicetrapib Phase 1/2 studies: Consistent benefits observed in lipid biomarkers



Source: Company data for obicetrapib 10mg monotherapy, Pooled data includes TULIP, ROSE, ROSE2, and Japan Phase 2 data sets

Multiple potential pivotal data readouts in next 12 months



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Note: Other than as noted, the pipeline represents trials that are currently ongoing. Projections are subject to inherent limitations. Actual results may differ from expectations. The timing of regulatory submissions is subject to additional discussions with regulators.

BROOKLYN study design

Objective: **To evaluate the effects of obicetrapib in patients with heterozygous familial hypercholesterolemia (HeFH)**

Inclusion criteria

- HeFH by genetic confirmation, and/or WHO Criteria/Dutch Clinical Network, and/or Simon Broome criteria
- 70% of patients on HS
- 10% Statin Intolerant
- Stable lipid lowering therapies with an LDL ≥ 70 mg/dL and TG ≤ 400 mg/dL

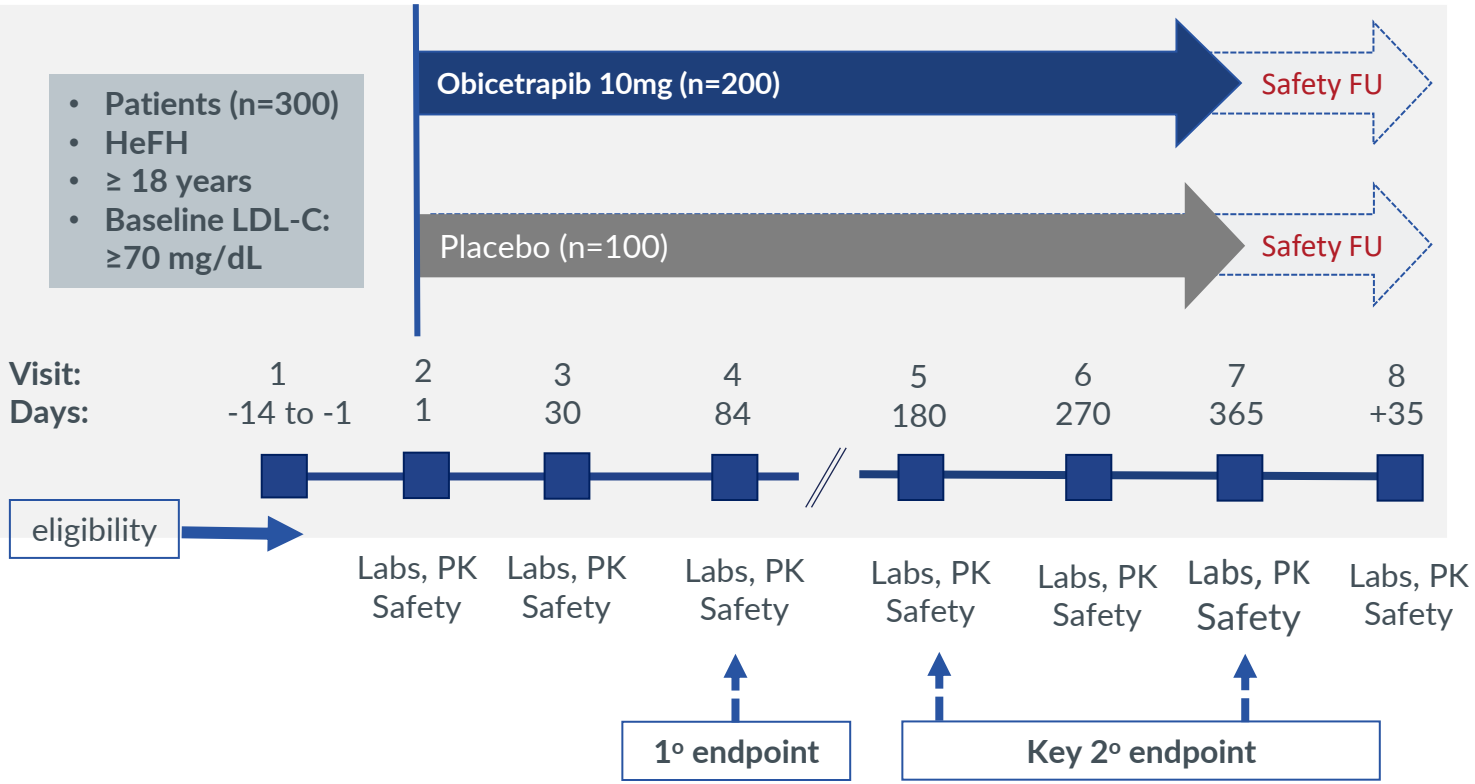
Exclusion criteria

- CV disease < 3 months
- HoFH
- Uncontrolled hypertension

Primary efficacy endpoint

- Percent change from baseline in LDL-C compared to the placebo group

Study design: Randomized, double-blind, placebo-controlled



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BROADWAY study design

Objective: To evaluate the effect of obicetrapib on top of max tolerated lipid-modifying therapy in patients with HeFH and or ASCVD

Inclusion criteria

Have a fasting serum LDL-C at Screening (Visit 1) as follows:

- Have a fasting serum LDL-C ≥ 55 mg/dL (≥ 1.4 mmol/L) to <100 mg/dL (<1.8 mmol/L) OR non-HDL-C ≥ 85 mg/dL (≥ 2.2 mmol/L) to <130 mg/dL (<2.6 mmol/L) with at least 2 risk enhancers

OR

- Have a fasting serum LDL-C ≥ 100 mg/dL (≥ 2.6 mmol/L) OR non-HDL-C ≥ 130 mg/dL (≥ 3.4 mmol/L).

Risk enhancers:

- Age of >60 years;
- Recent MI (>3 and <24m prior to Randomization);
- Type 2 diabetes mellitus;
- Current cigarette smoking;
- hsCRP ≥ 2.0 mg/L;
- TG >150 mg/dL (>1.7 mmol/L);
- Lp(a) >30 mg/dL (>70 nmol/L);
- HDL-C <40 mg/dL (<1.0 mmol/L);

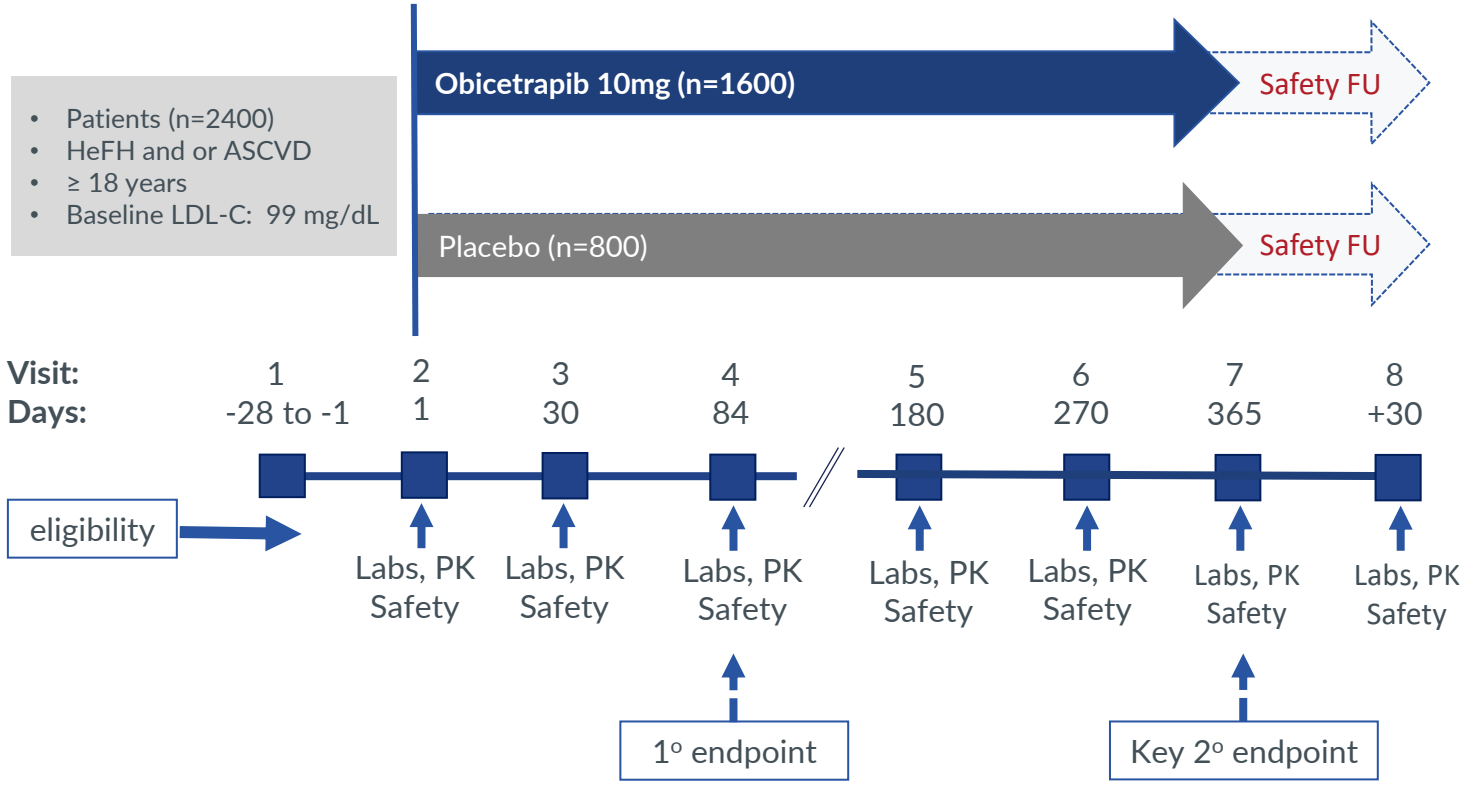
Exclusion criteria

- CV disease < 3 months
- HoFH
- Uncontrolled hypertension

Primary efficacy endpoint

- % change from BL to Day 84 in LDL-C for obicetrapib vs placebo

Study design: Randomized, double-blind, placebo-controlled



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PREVAIL trial design leverages lessons learned

- **Study design:**
  - n = 9000
  - Inclusion: ASCVD patients on maximally tolerated statins with risk enhancers and LDL-C > 55mg/dl
  - Minimum follow up 2.5 years
- **Primary endpoint:** 4-point MACE
- **First secondary:** 3-point MACE
- **Prespecified endpoints:**
  - Conversion of pre-diabetes to diabetes
  - A1c levels in diabetes patients
- **Patient populations of interest**
  - Patients on PCSK9
  - Patients on GLP-1
  - Patients on SGLT-2

Applying lessons from prior CVOTs

Greater LDL-lowering activity anticipated
42.6% observed in Phase 2
plus
Targeting higher baseline LDL patients
~100mg/dl anticipated

→ **Higher *absolute* LDL-C reduction expected to lead to greater MACE benefit**

Longer duration of follow up
Median of 42 months vs. only 2.1 years in ACCELERATE
plus
Targeting higher-risk patient population
ASCVD patients further enriched with with risk enhancers shown in REVEAL long-term follow up to have stronger relative risk reduction ***(high LDL/ApoB, diabetes, high triglycerides, recent MI)***

→ **More time + higher patient risk potentially maximizes opportunity for MACE reduction**

Differentiated secondary endpoints
Lp(a)-lowering, HDL-raising, diabetes, and Alzheimer's benefits

→ **Potentially enhanced commercial profile vs. other LDL-lowering agents + potential therapeutic area expansion**

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Note: Actual results may differ from expectations.

2023 achievements pave the way for potential 2024 value inflection milestones

2023

2Q 2023
- Complete enrollment for BROOKLYN Phase 3 ✓
- Present ROSE2 full data at NLA ✓

3Q 2023
- Complete enrollment for BROADWAY Phase 3 ✓

2H 2023
- Topline Japan Phase 2b results ✓
- Initial Alzheimer's Phase 2a data ✓
- Select formulation for FDC Phase 3 trial ✓

2024

1Q 2024
- Complete enrollment for PREVAIL CVOT
- Initiate FDC Phase 3 trial

3Q 2024
- BROOKLYN Phase 3 topline

4Q 2024
- BROADWAY Phase 3 topline

2025

1Q 2025
- TANDEM FDC Phase 3 topline

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Note: Projections are subject to inherent limitations. Actual results may differ from expectations. The timing of regulatory submissions is subject to additional discussions with regulators.

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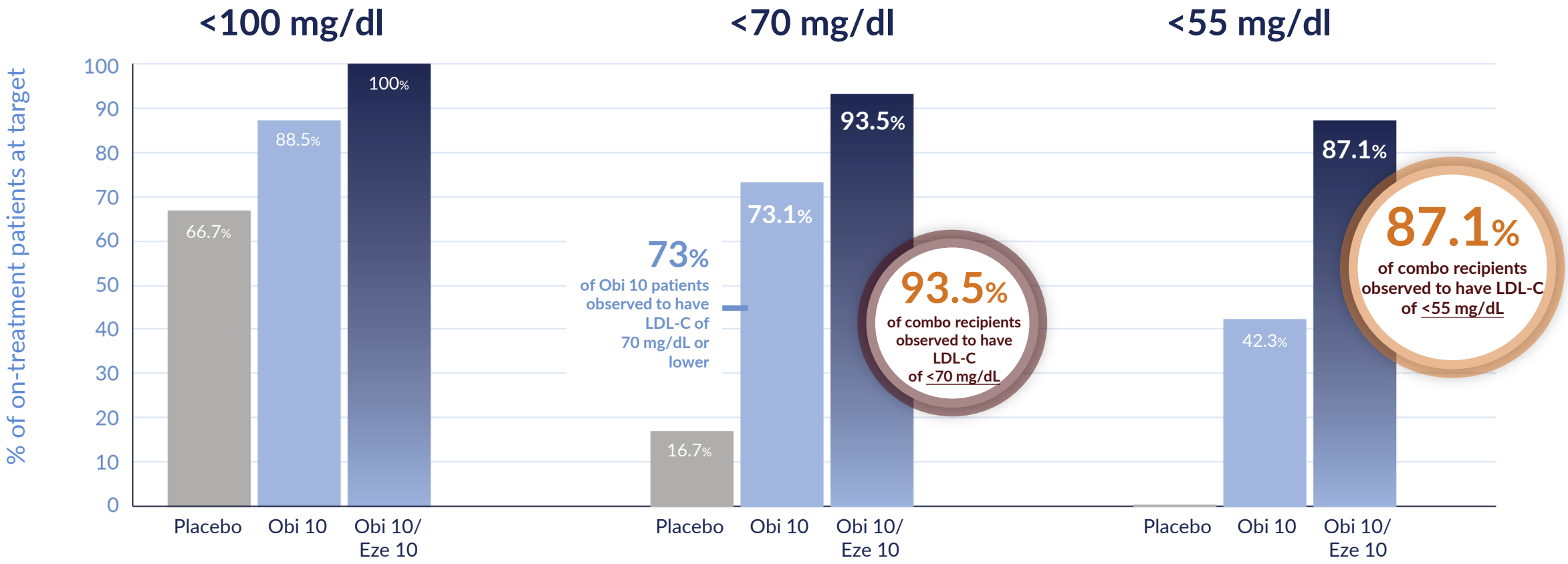
Obicetrapib for Cardiovascular Disease

Exceptional LDL goal attainment observed with ezetimibe + obicetrapib combination, including >87% of patients observed to attain <55 mg/dl LDL-C levels

% of patients observed with the following LDL-C levels:



Source: Ballantyne CM, et al. J. of Clinical Lipidology 2023

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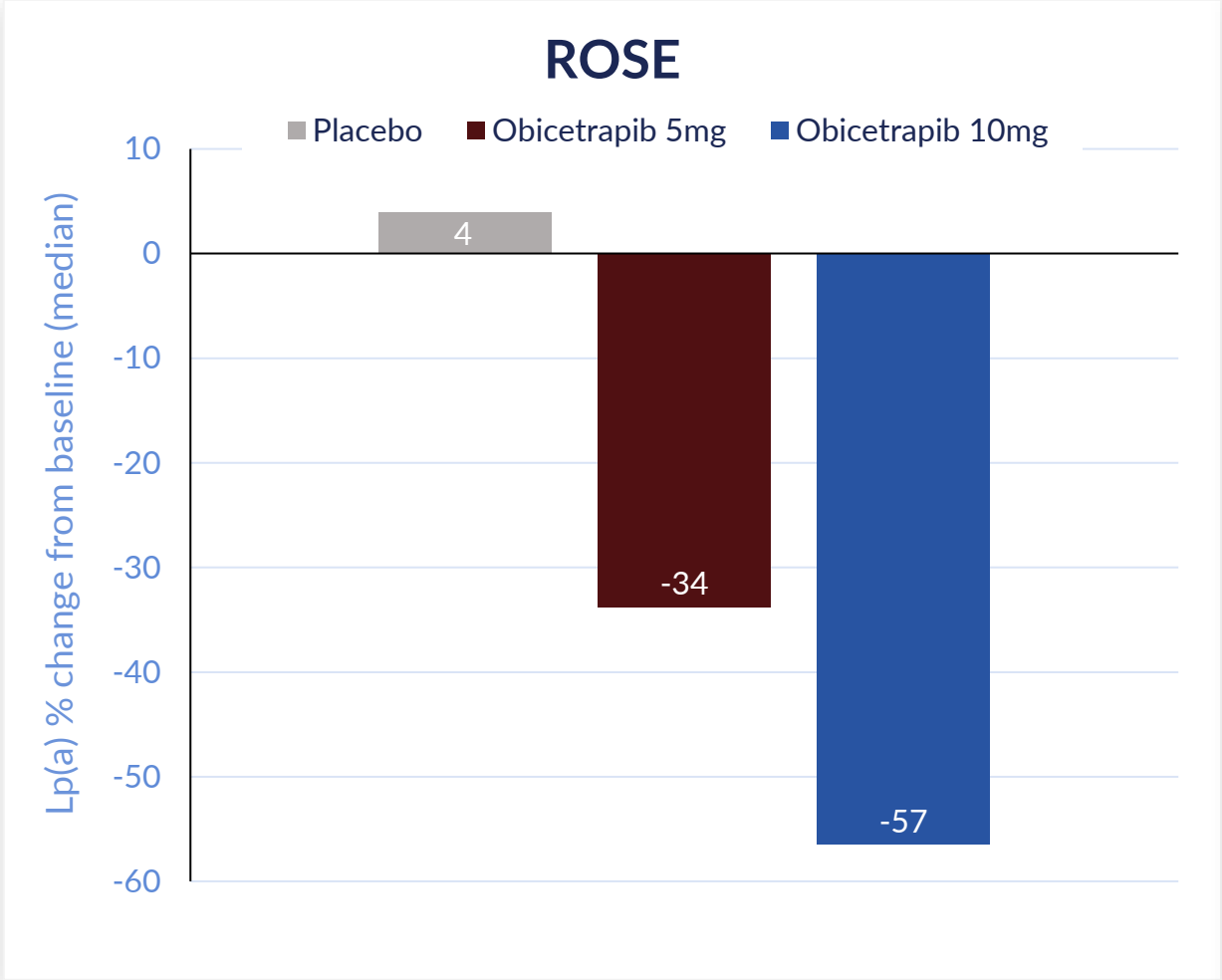
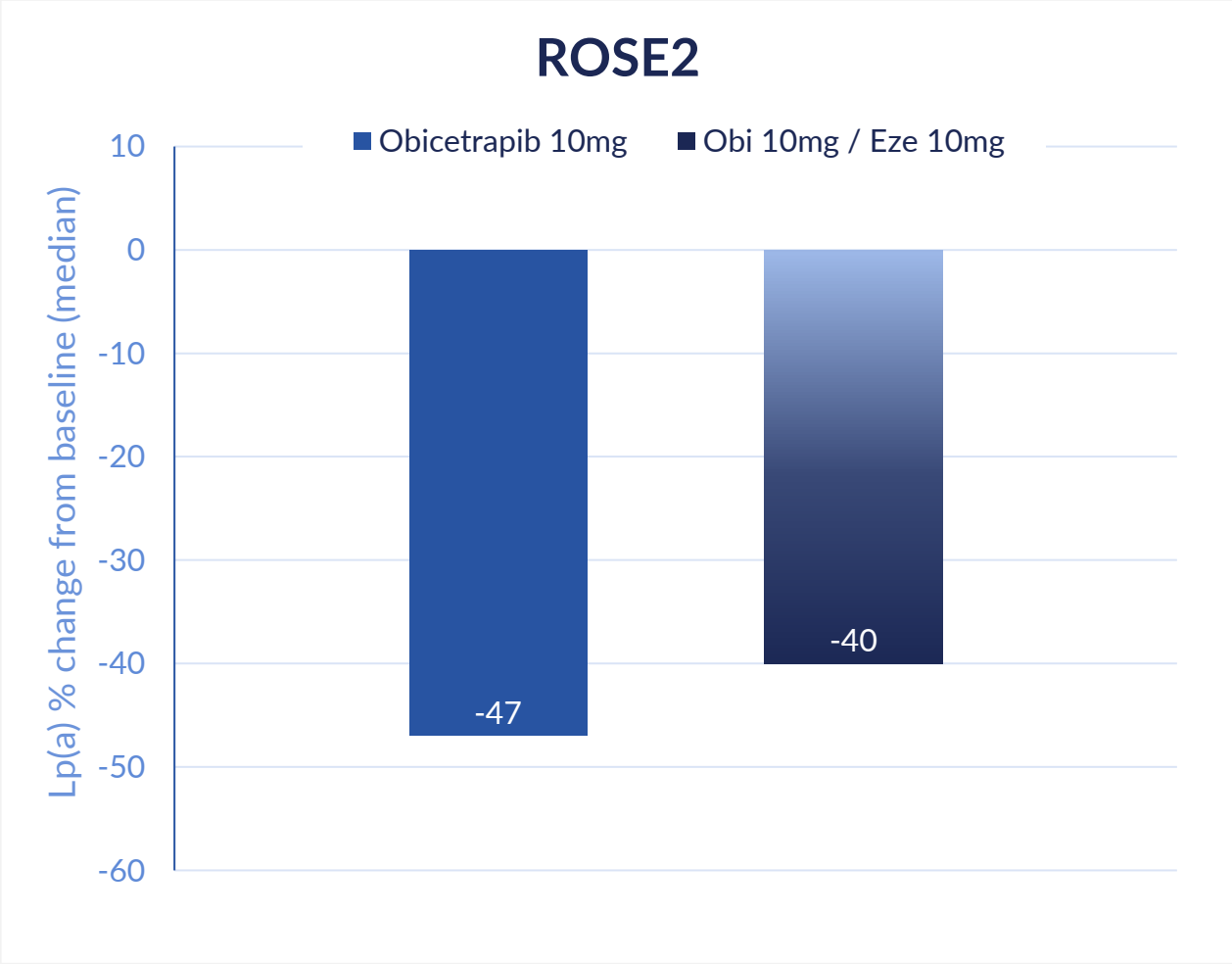
Lp(a) percent reduction from baseline in ROSE[1] and ROSE2[2]

- *Lp(a) is emerging as a strong and independent marker of CVD risk and an exciting new CVD drug target*





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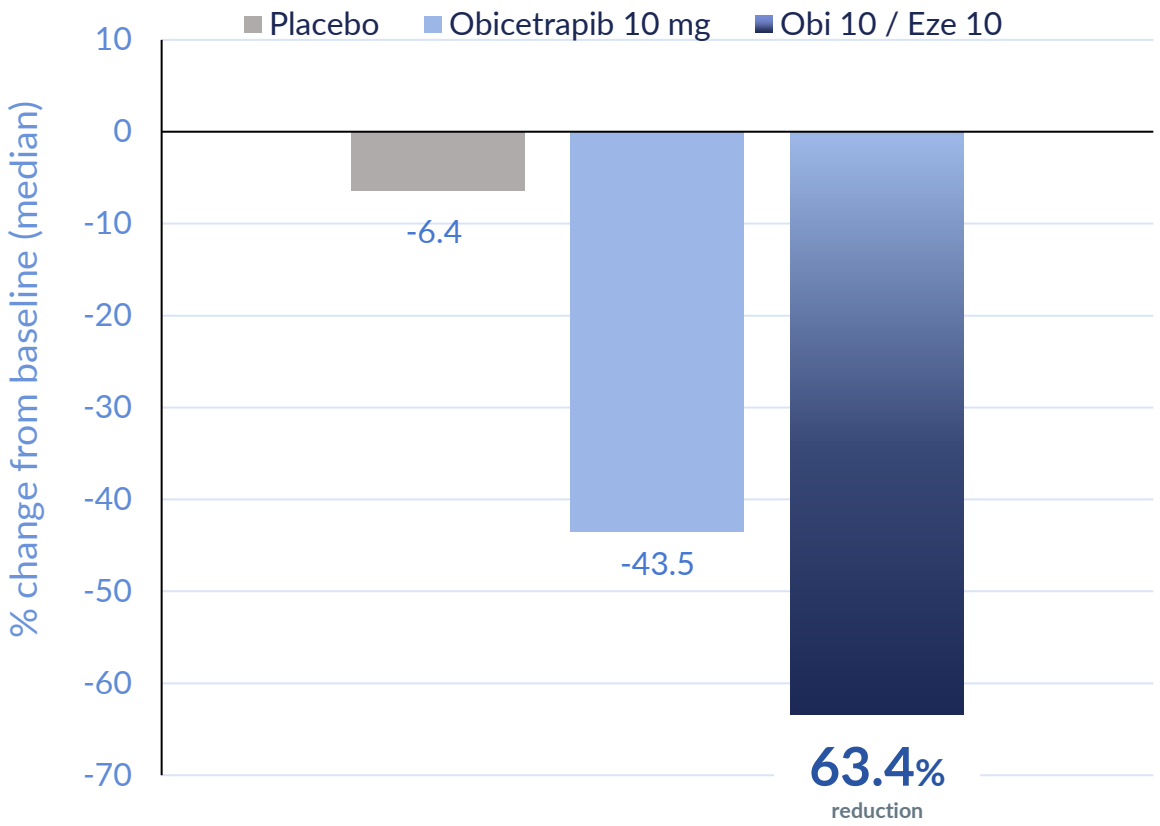
Source: 1. Nicholls SJ, et al. Nat Med 2022;28:1672-1678. 2. Ballantyne CM, et al. J. of Clinical Lipidology 2023

Obicetrapib/ezetimibe observed to lower LDL-C by 63.4% on top of HIS in ROSE2

LDL-C (mg/dL), on-treatment population



Median (min, max) LDL-C levels (mg/dL) at baseline & EoT

Time	Placebo	Obi 10 mg	Obi 10 / Eze 10
Baseline Median	95.5 (60, 211) (N=40)	100.0 (35, 189) (N=26)	87.0 (62, 152) (N=31)
EoT Median	88.0 (55, 188) (N=36)	55.5 (21, 148) (N=26)	39.0 (15, 96) (N=31)
% Change from Baseline (Median)	-6.4 (-36.4, 96.7) (N=36)	-43.5 (-78.4, 22.6) (N=26)	-63.4 (-83.7, -29.7) (N=31)
% Change from Baseline LS mean (95% CI)	-0.85 (-7.75, 6.05)	-39.20 (-47.41, -30.99)	-59.23 (-66.75, -51.71)
P-value	-	**<0.0001**	**<0.0001**

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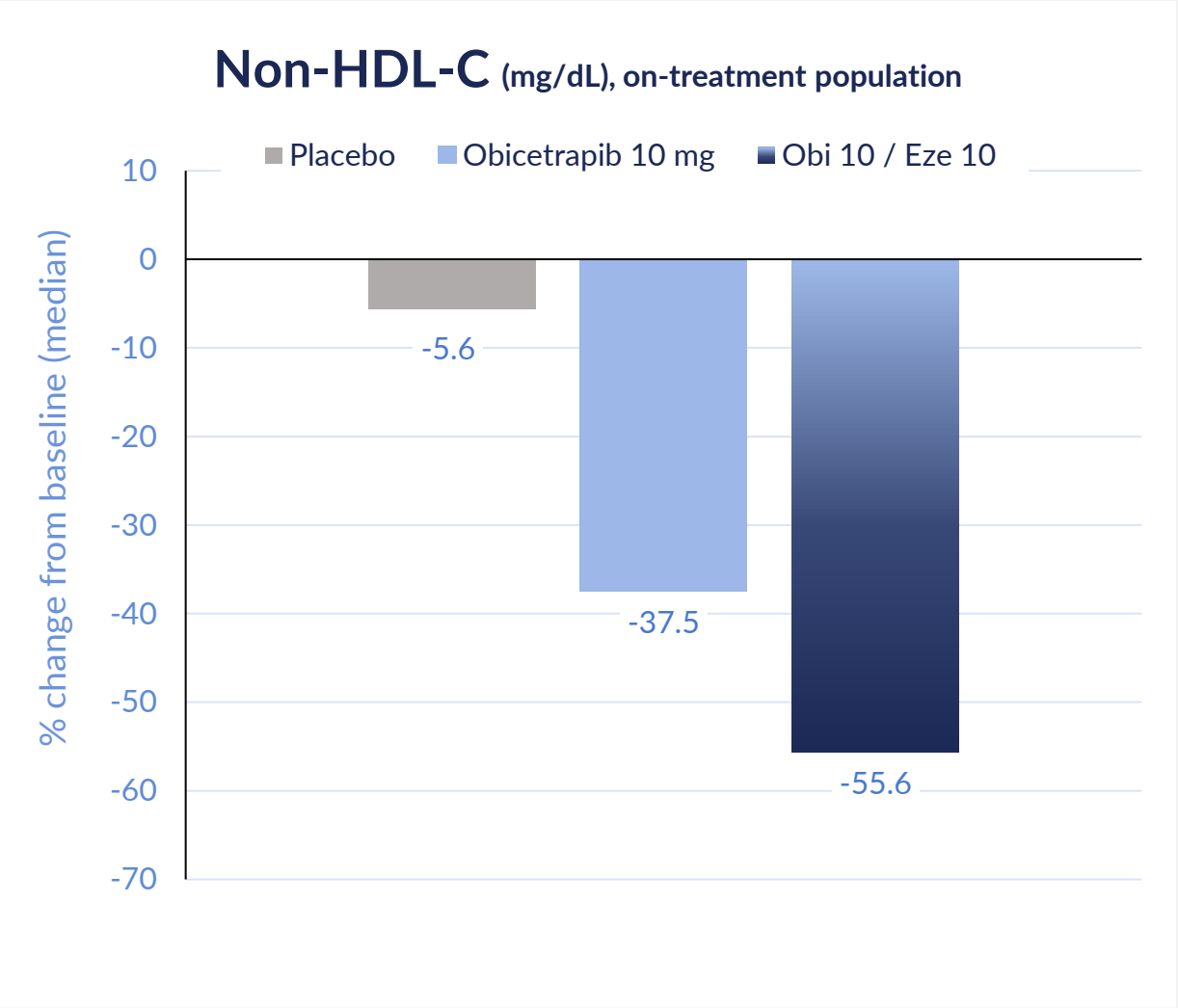
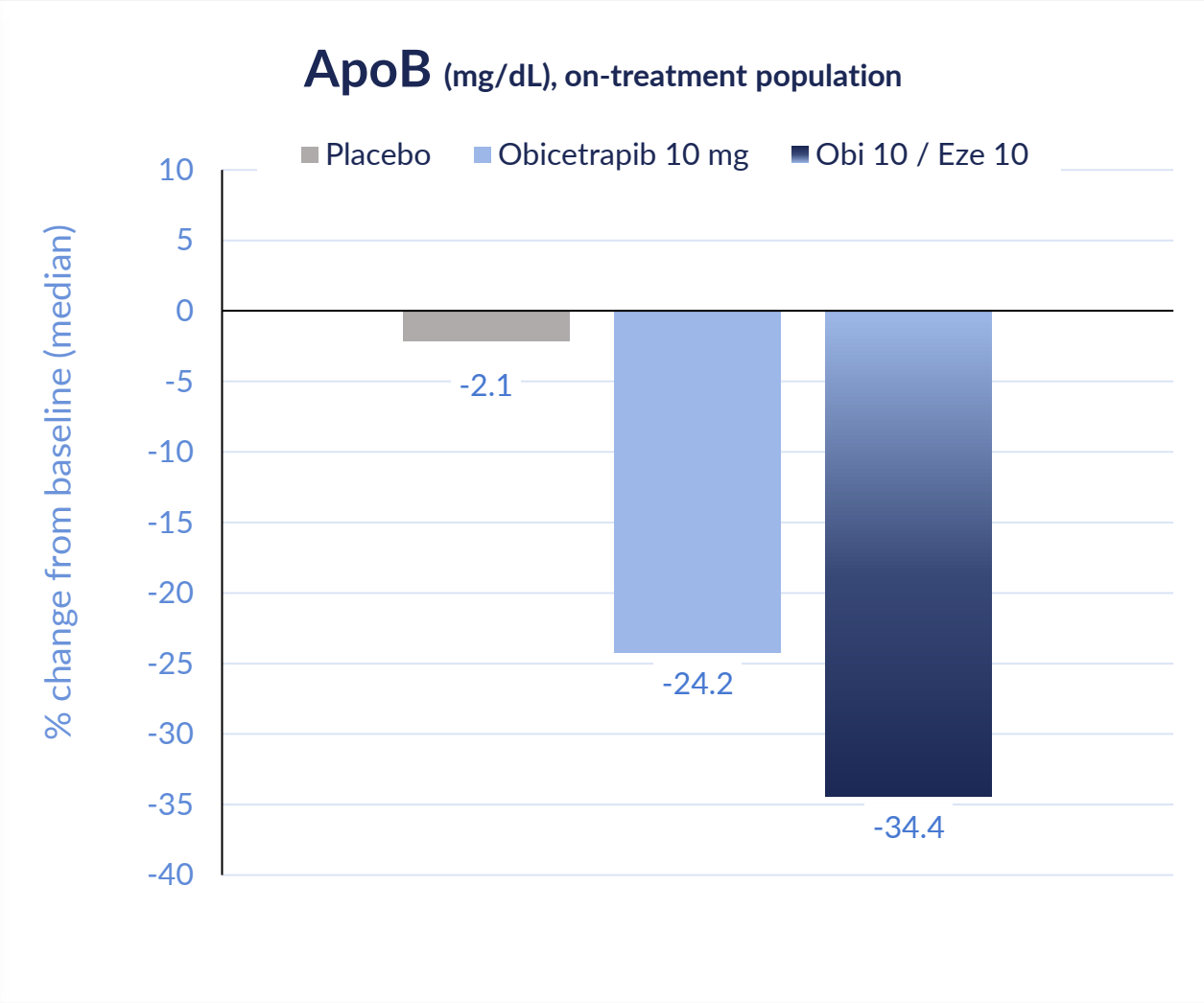
Source: Ballantyne CM, et al. J. of Clinical Lipidology 2023

ROSE2: Non-HDL-C and ApoB percent change from baseline (Day 84)





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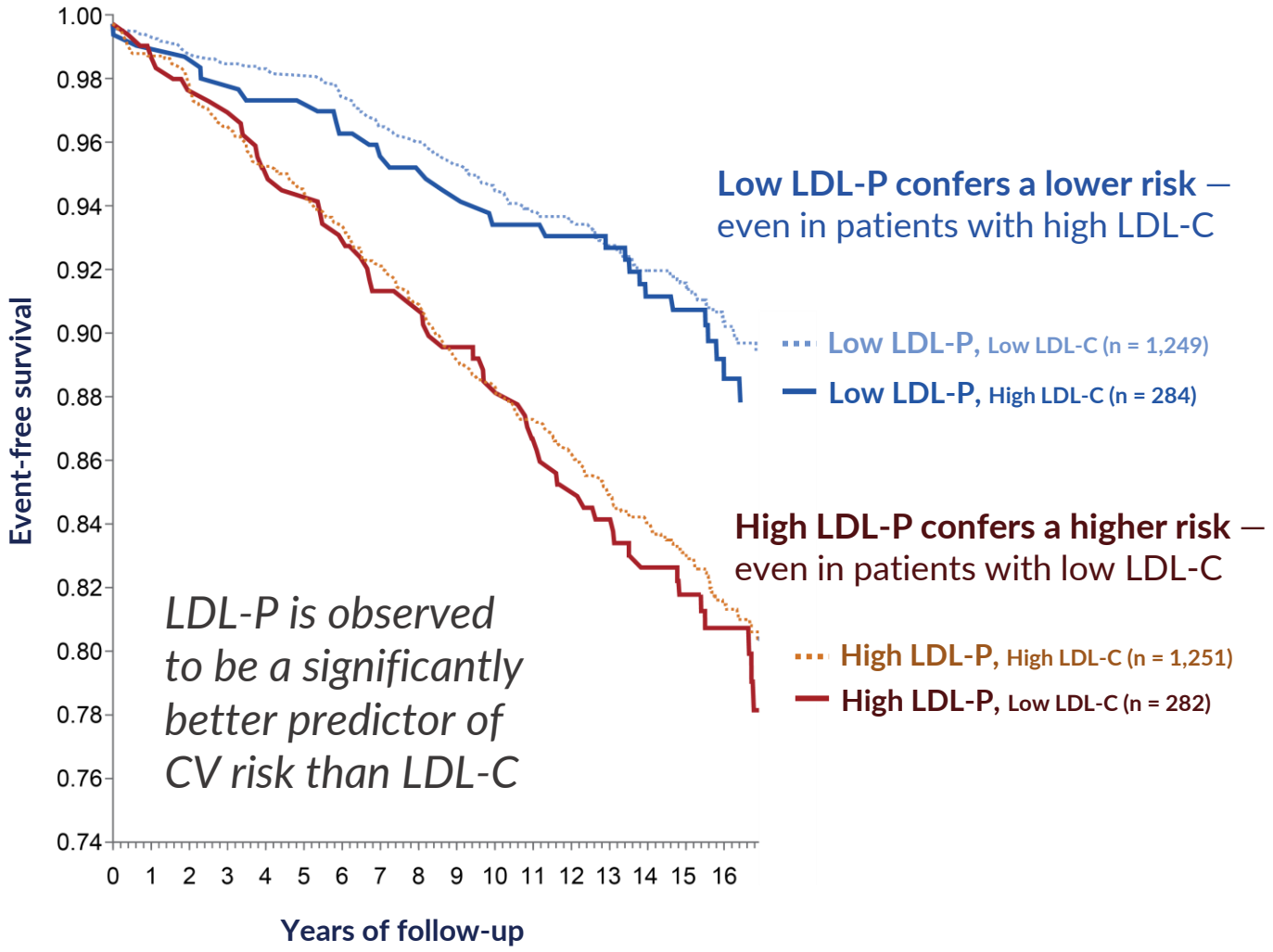
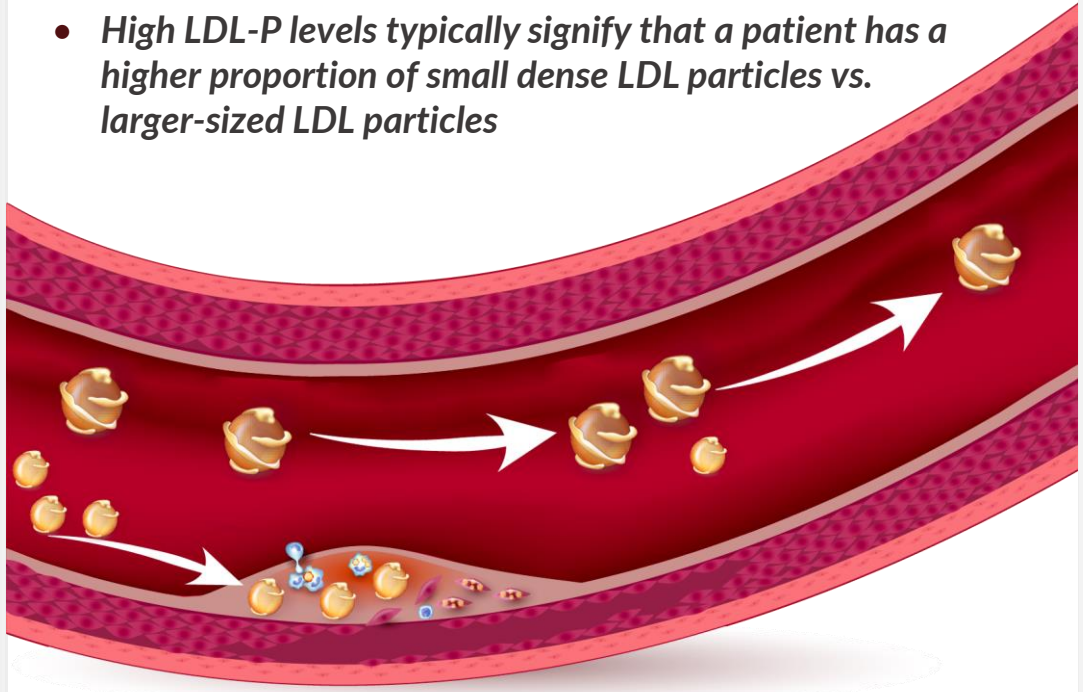
Source: Ballantyne CM, et al. J. of Clinical Lipidology 2023

LDL-P believed to be one of the most robust predictors of cardiovascular risk



- *Small dense LDL particles are more likely to be trapped in arterial wall than larger-sized LDL particles*
- *High LDL-P levels typically signify that a patient has a higher proportion of small dense LDL particles vs. larger-sized LDL particles*



Even though all LDL particles contain only one ApoB protein, small dense LDL particles have a less massive ApoB protein

= Larger-sized LDL

= Small dense LDL

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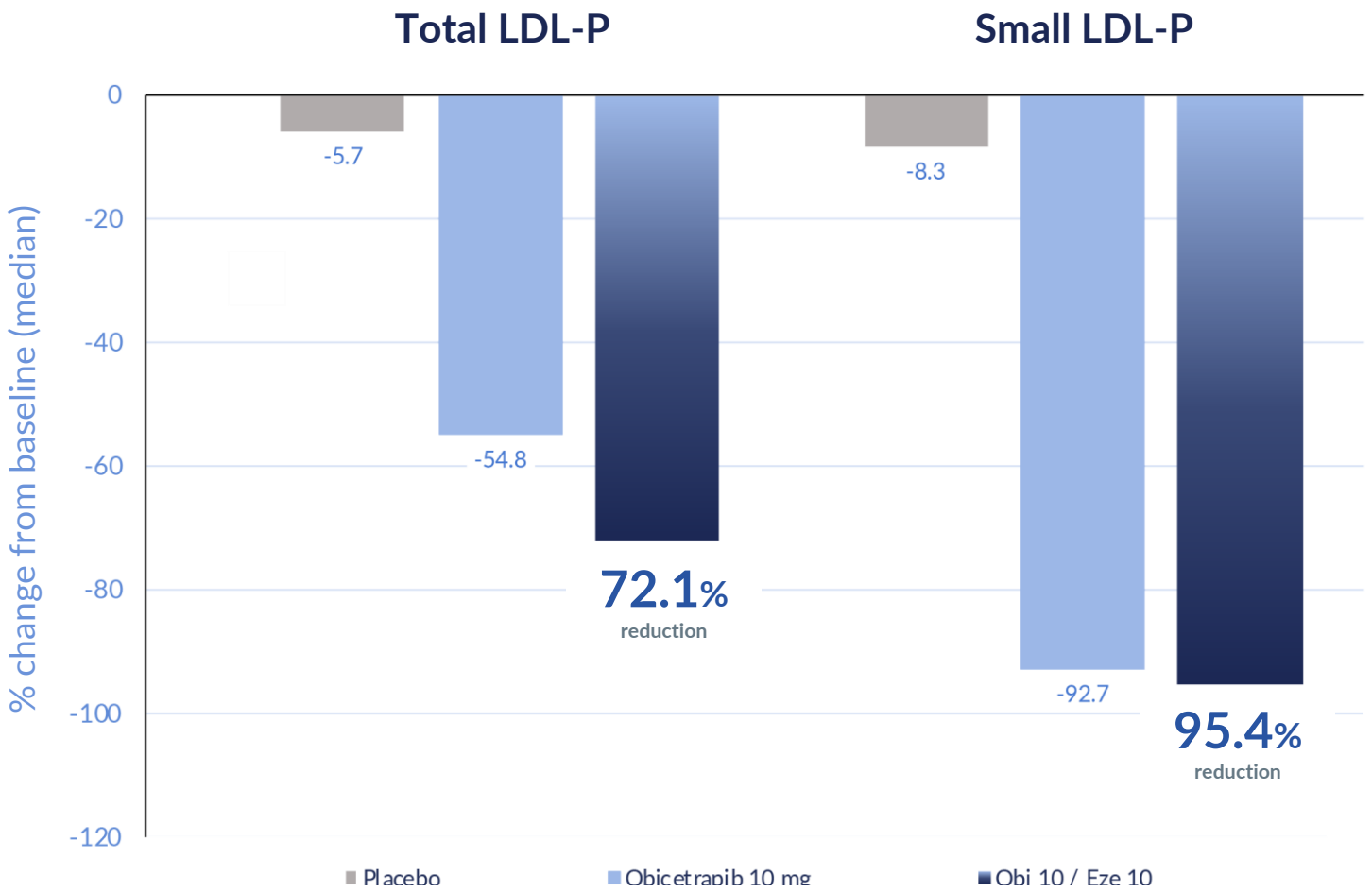
Source: Cromwell WC, et al. Clin Lipidol. 2007 December 1; 1(6): 583–592

ROSE2 showed significant reduction in total and small LDL particles, bringing patients who had baseline elevated LDL-P to optimal parameters[1]



Patients taking the Obi/Eze combo observed to achieve optimal LDL-P profiles

Lipoprotein fractionation 1	ROSE2 placebo	ROSE2 Obi / Obi + Eze
LDL-P (nmol/L)	1012.8	495 / 300
Small LDL-P (nmol/L)	717.5	73.4 / 47.5
LDL size (nm)	20.26	21.0 / 21.0

Key[2]

	High	Moderate	Optimal
LDL-P (nmol/L)	>1816	935-1816	<935
Small LDL-P (nmol/L)	>820	467-820	<467
LDL size (nm)	≤20.5	N/A	>20.5

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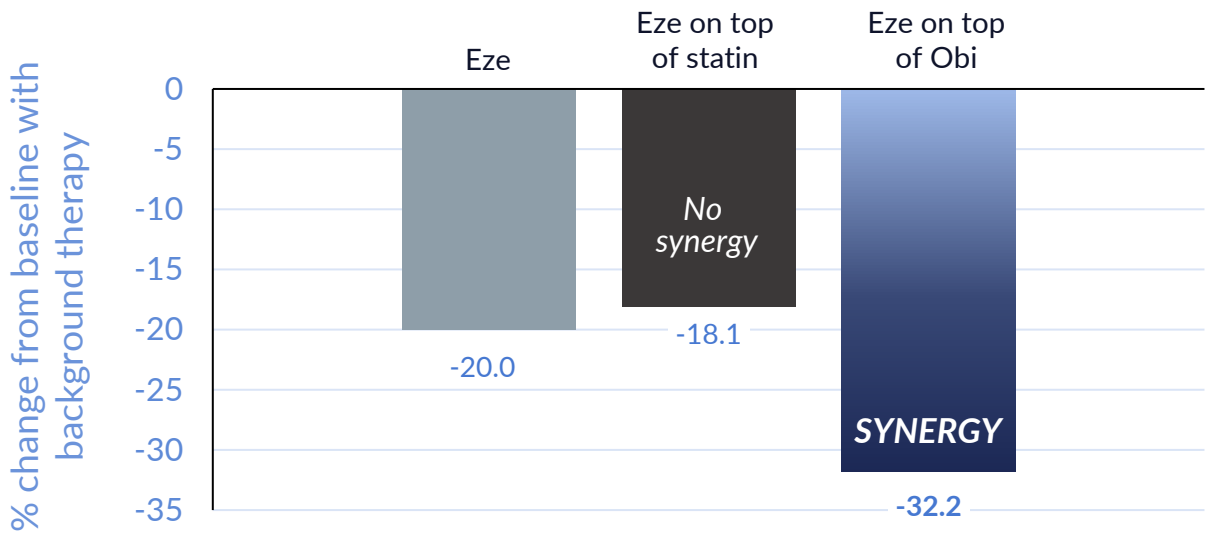
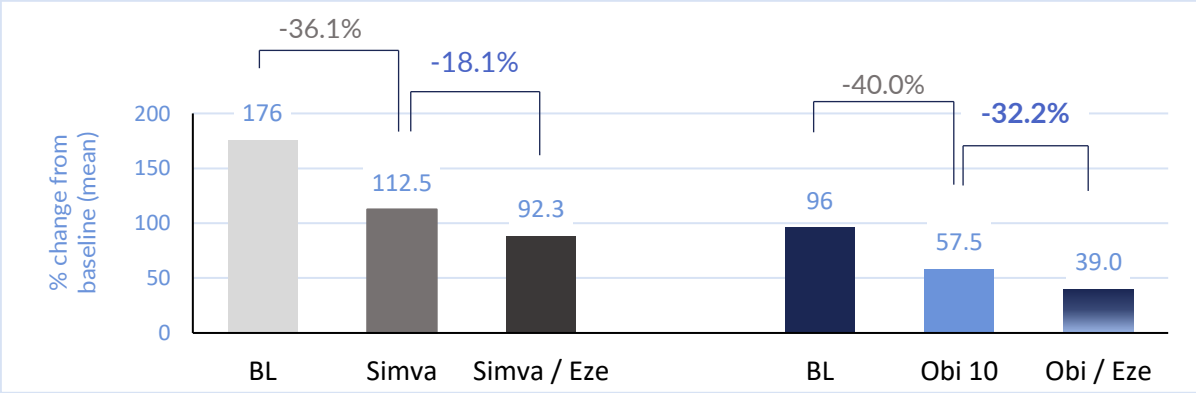
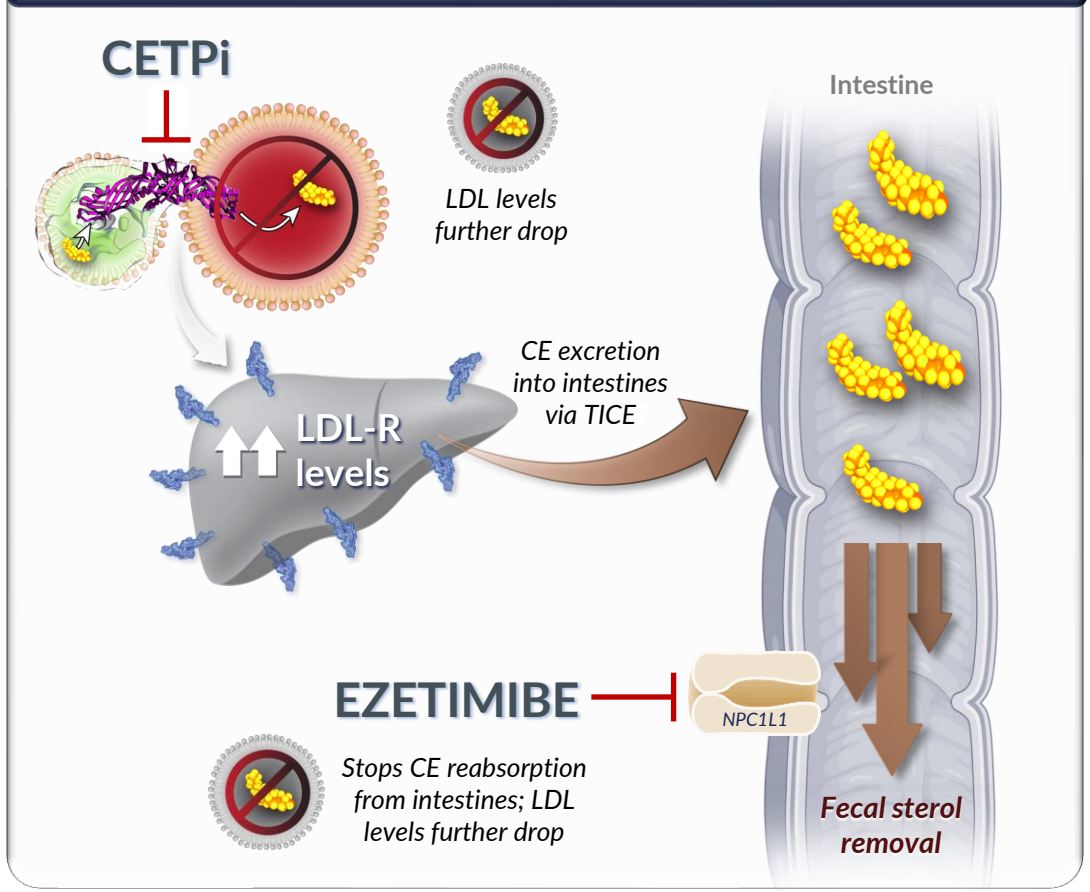
Sources: 1. Ballantyne CM, et al. J. of Clinical Lipidology 2023, 2. LipoFraction NMR practitioner Guidelines

Stronger LDL-lowering observed with ezetimibe in obicetrapib combo vs. ezetimibe with statins, potentially due to a synergistic mechanism of action for obi/eze combo(1)





Obicetrapib is designed to promote more cholesterol excretion into the intestines (via TICE) while ezetimibe is designed to block cholesterol reabsorption into the body, synergistically enhancing fecal sterol removal of cholesterol



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Source: Ballantyne CM, et al. J. of Clinical Lipidology 2023
Note: The calculations included in the graphs here represent the Company's hypothetical calculation assuming one patient was treated with each drug independently.

Favorable safety profile observed in all LDL Phase 1 & 2 clinical studies

	Comparator[1] (N=231)	Pooled Obicetrapib (5, 10mg)[2] (N=309)
TEAEs (%)		
TEAEs, total	136 (58.9)	173 (55.9)
TEAEs, related	45 (19.5)	49 (15.8)
TEAEs, severe	5 (2.2)	7 (2.3)
TESAEs		
*TESAEs, total	6 (2.6)	4 (1.3)
TESAEs, related	0	0
Deaths	0	0
Withdrawals study / medication		
TEAEs leading to discontinuation of study drug	13 (5.6)	13 (4.2)

* There were three additional TESAEs in other obicetrapib dose arms: two in the TULIP 2.5mg arm, and one in the Lp(a) 2.5mg arm; none were considered to be related to study drug.
(1) The Comparator group included patients receiving placebo and non-obicetrapib monotherapy.
(2) The pooled obicetrapib group includes patients treated with obicetrapib as a monotherapy and in combination with atorvastatin, rosuvastatin and ezetimibe.

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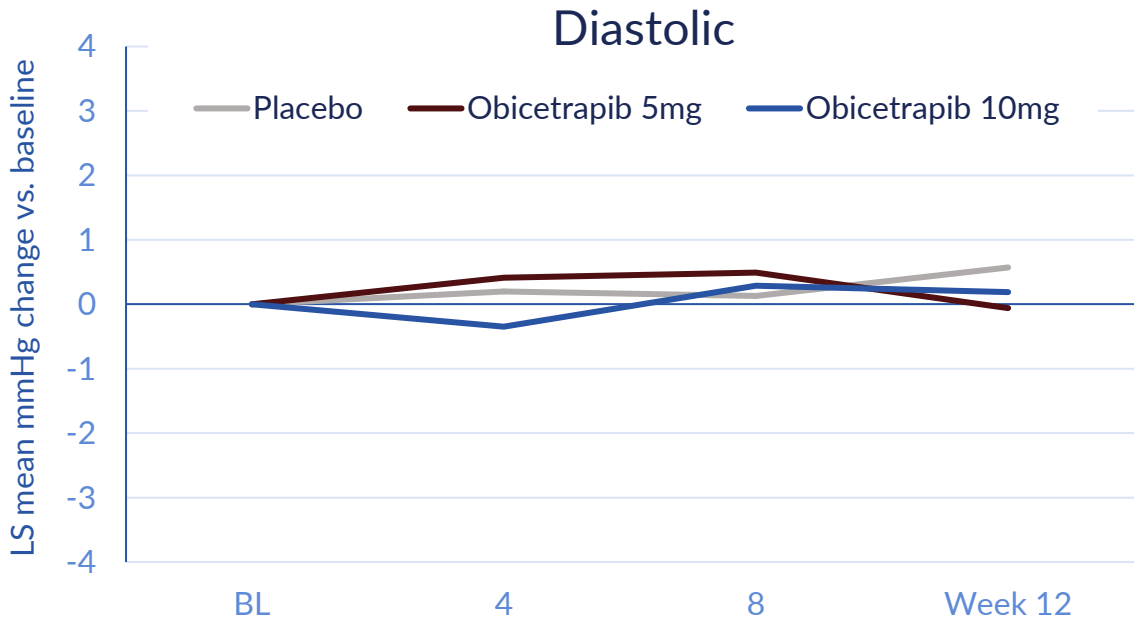
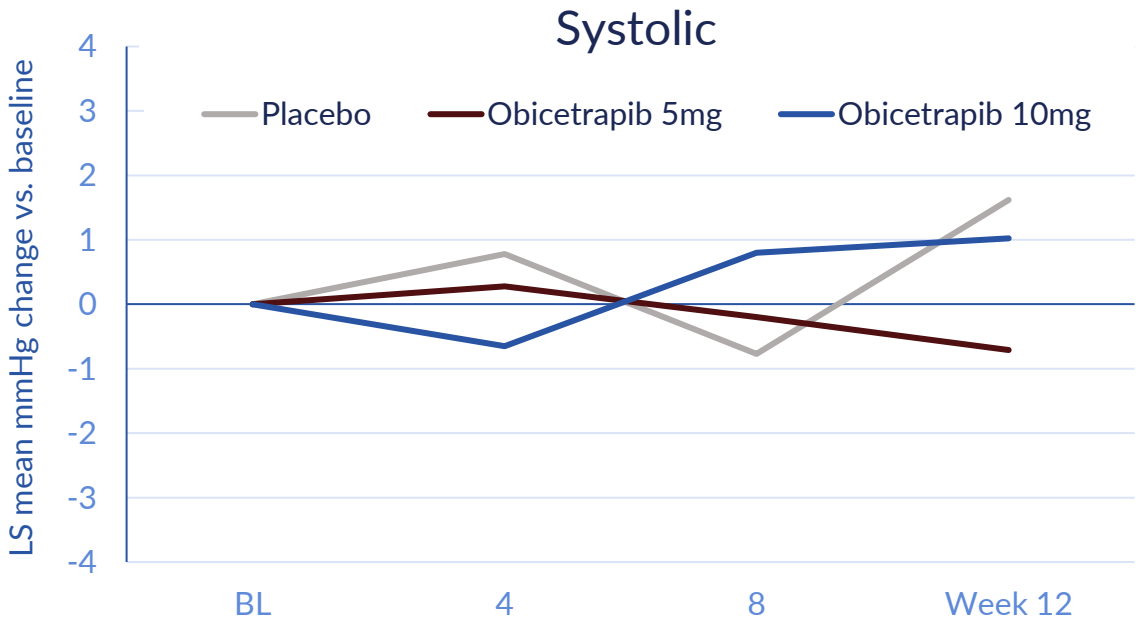
Obicetrapib does not show an effect on systolic and diastolic blood pressure

- A dedicated meta-analysis of the obicetrapib ROSE2, ROSE, TULIP, OCEAN, and TA-8995-203 study did not reveal any signal in systolic and diastolic blood pressure
- By contrast, in the cardiovascular outcome trial ILLUMINATE, torcetrapib showed a significant 5.4 and 2.0mm Hg increase in systolic blood and diastolic pressure and was associated with a significant decrease in serum potassium, and increases in serum sodium, bicarbonate and aldosterone



	BL	4	8	Week 12
Placebo (N)	229	222	180	157
Obi 5 mg (N)	135	134	130	63
Obi 10 mg (N)	240	237	155	188



	BL	4	8	Week 12
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Obi 10 mg (N)	240	237	155	188

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Sources: Circulation 2021;144:e564–e593 17065: Obicetrapib Lowers LDL-C in Patients Taking High Intensity Statins: Results From Rose Clinical Trial.
*Represents pooled data from the ROSE, TULIP and OCEAN clinical trials.

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Target biology and class overview:
Key lessons learned

Obicetrapib program designed to overcome limitations of all prior CETP inhibitors

We believe that all prior CETPi were developed with a misguided focus on HDL increase (rather than LDL decrease) as the primary MoA for CVD risk reduction, leading to inappropriate compound selection or inappropriate CVOT design

	SAFETY	LDL-LOWERING POTENCY	CVOT DESIGN (DURATION & BASELINE LDL)	COMMERCIAL VIABILITY
TORCETRAPIB[1] Suffered from drug-specific toxicity issue (Pfizer)	OFF-TARGET TOXICITY, INCREASED BLOOD PRESSURE, ALDOSTERONE *(seen early in Phase 2)*	NO LDL-LOWERING *~40% target coverage at CVOT dose*	INSUFFICIENT TRIAL DURATION *(only 2 years)*	COMMERCIALLY UNVIABLE - HIGH LIPOPHILICITY AND FAT TISSUE ACCUMULATION LED TO 4+ YEAR HALF-LIFE
DALCETRAPIB[2] Drug showed no LDL-lowering efficacy (Roche)	Safe & well-tolerated	Modest LDL-lowering *~80% target coverage at CVOT dose*	Sufficient duration *(4.1 years, with 6.3 year follow up)* Baseline LDL too low *(60 mg/dL)*	
EVACETRAPIB[3] *Overall mortality benefit (P =.04)* – but CVOT was too short to demonstrate MACE benefit (Lilly)	Safe & well-tolerated			
ANACETRAPIB[4] *Meaningful MACE benefit observed* - but drug accumulated in fat tissue (Merck)	Safe & well-tolerated	Modest LDL-lowering *~80% target coverage at CVOT dose*		

Strong safety profile across ~59k patients

OBICETRAPIB[5]

- ✓ Tolerability profile observed in >800 patients through Phase 2b
- ✓ No concerns seen in biomarker safety data, including blood pressure-associated biomarkers

- ✓ ~43% LDL-LOWERING OBSERVED IN PHASE 2B
- ✓ ~59% LDL-LOWERING OBSERVED IN FDC PHASE 2

~97% target coverage

- ✓ Longer trial duration *(4 yrs)*
+
- ✓ High baseline LDL *(100 mg/dL)*[(1)]

= PREVAIL CVOT design expected to translate into 15-20% MACE benefit

- ✓ Favorable PK/PD profile
- ✓ No accumulation in fat tissue observed

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Note: The above trials and data do not represent head-to-head comparisons. Obicetrapib has not been approved for marketing by any regulatory authority.
(1) Represents estimated average baseline LDL to be enrolled, not entry criteria.

Sources: 1. Barter PJ, et al. N Engl J Med 2007;357:2109-2122; 2. Schwartz GG, et al. N Engl J Med 2012;367:2089-2099; 3. Lincoff AM, et al. N Engl J Med 2017;376:1933-1942; 4. The HPS3/TIMI55–REVEAL Collaborative Group. N Engl J Med 2017; 377:1217-1227; 5. Data on file

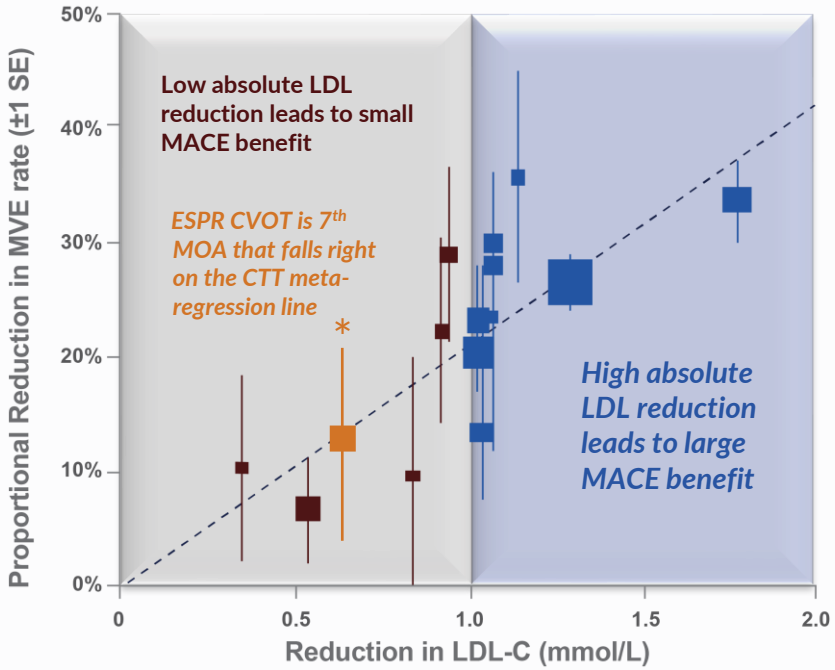
Absolute reduction of LDL-C and ApoB, and *duration* of that reduction are believed to be key to reducing cardiovascular risk

MACE benefits impacted by 2 key factors:

- ABSOLUTE REDUCTION
- STUDY DURATION

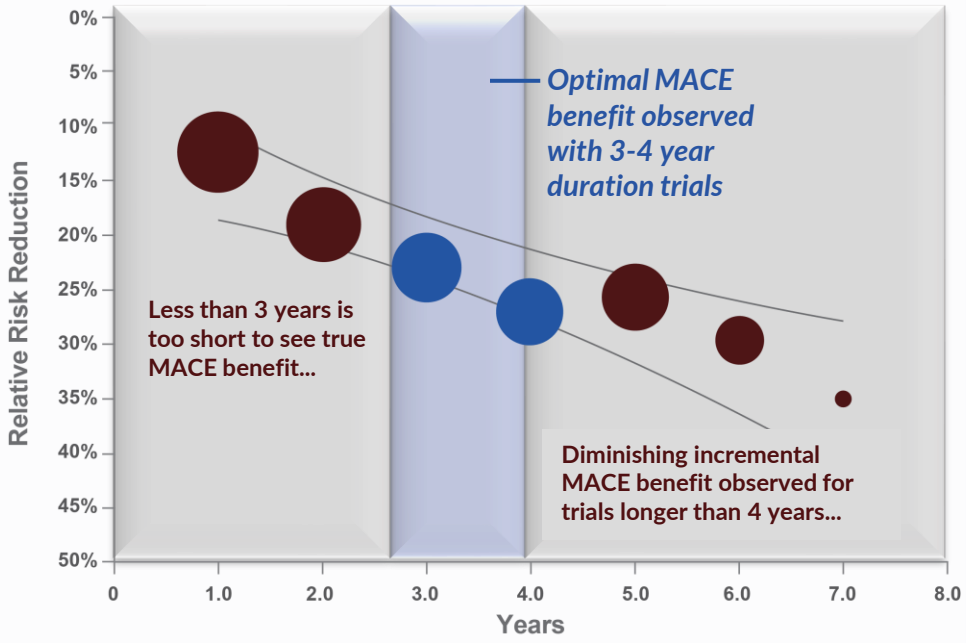
Key factor 1: Absolute reduction

CTT meta-regression line shows a *linear and predictable* relationship between absolute LDL-C lowering and MACE reduction



Key factor 2: Study duration

Meta-analysis of CVOT duration shows that *~3.5 year median* follow up optimizes the probability of seeing *maximal MACE reduction benefit*



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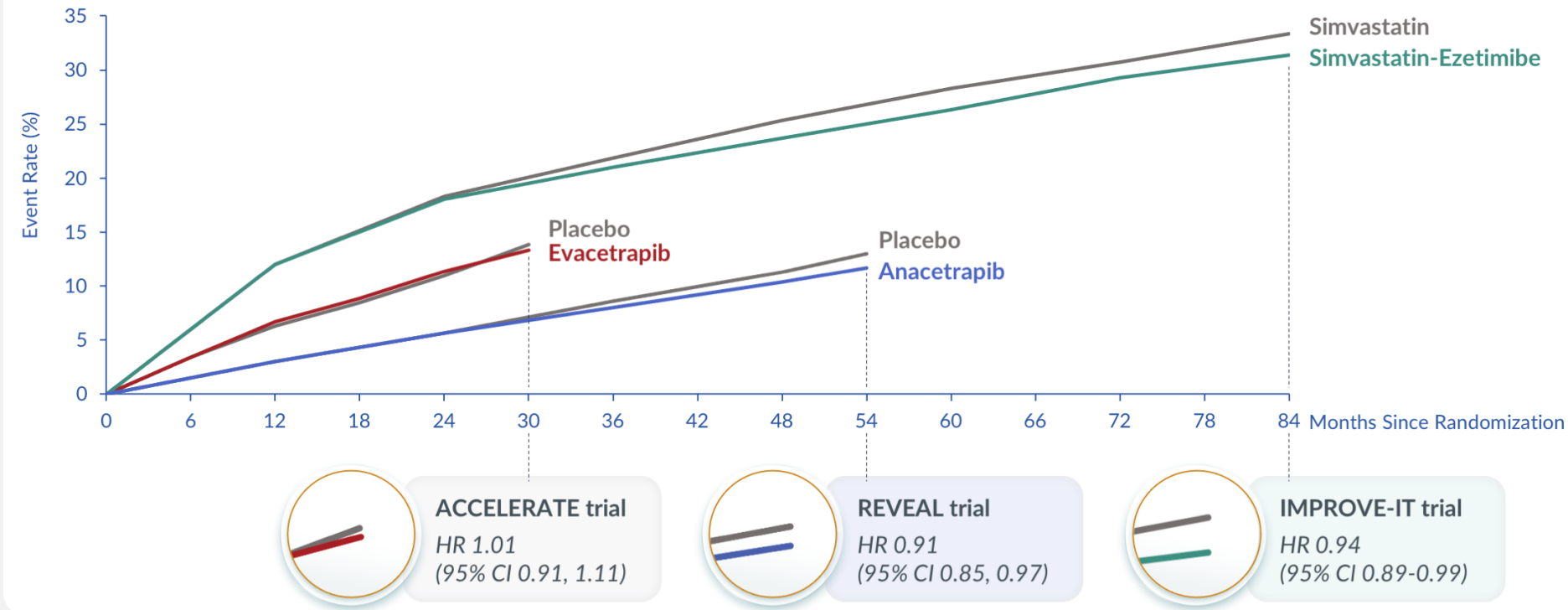
Sources: American Heart Association, CDC, Mayo clinic, Global Health estimates 2016: Deaths by Cause, Age, Sex, by Country and by Regio, 2000-2016, Geneva, WHO; 2018. Lancet 2005;366:1267-78; Silverman MG, et al. JAMA 2016;27:1289-1297. * ESPR CVOT depiction based on ACC 2023 presentation, drawn as approximation to existing meta-regression figure.

ACCELERATE, REVEAL and IMPROVE-IT support our belief that CVOT study duration should be long enough to see optimal MACE benefit

Kaplan-Meier curves for these trial, with very similar absolute ApoB reductions, show separation later than 2 years, which is the point in time that ACCELERATE stopped

MACE benefits impacted by 2 key factors:

- ABSOLUTE REDUCTION
- STUDY DURATION



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.

REVEAL data supports translation from absolute LDL reduction to MACE benefit

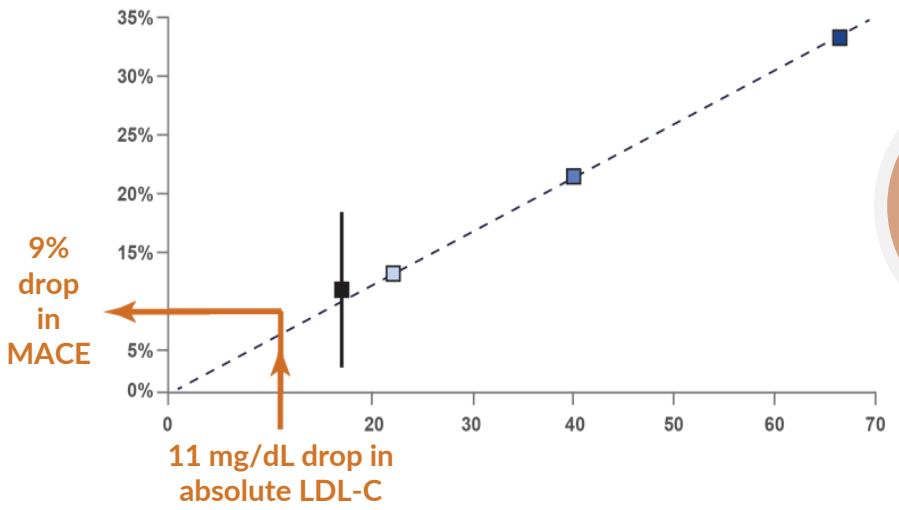
EXPERIENCE: *REVEAL (anacetrapib)*

61 mg/dL × 17% = 11 mg/dL

Low baseline

Drug showed modest LDL-lowering %

Results in SMALL absolute LDL reduction



9% drop

Smaller MACE* benefit anticipated

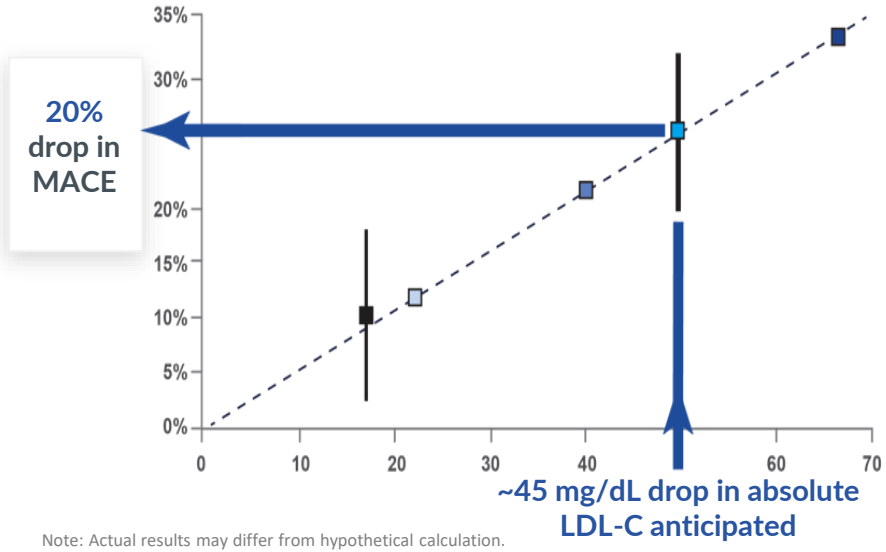
Hypothetical: *PREVAIL (obicetrapib)*

~105 mg/dL[1] × 43% = ~45 mg/dL

Enrich for higher baseline

Stronger expected LDL-lowering %

Expected to result in more absolute LDL reduction



20% drop

Bigger expected MACE** benefit

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* Composites of MACE included in this analysis were coronary death, myocardial infarction or coronary revascularization.

Source: The HPS3/TIMI55–REVEAL Collaborative Group. N Engl J Med 2017; 377:1217-1227
Cholesterol Treatment Trialists Collaboration. Lancet. 2010 376:1670-81.

Note: Actual results may differ from hypothetical calculation.
Source: Cholesterol Treatment Trialists Collaboration. Lancet. 2010 376:1670-81 Circulation. 2021;144:e564–e593 17065: Obicetrapib Lowers LDL-C in Patients Taking High Intensity Statins.
(1) Represents estimated average baseline LDL to be enrolled, not entry criteria.
** MACE includes cardiovascular death, myocardial infarction, stroke and non-elective coronary revascularization in adults.

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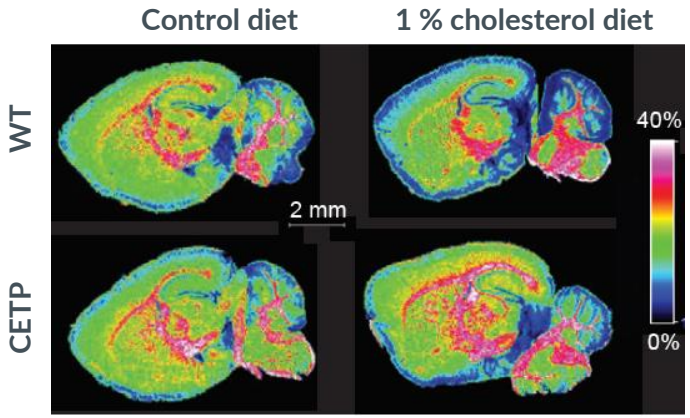
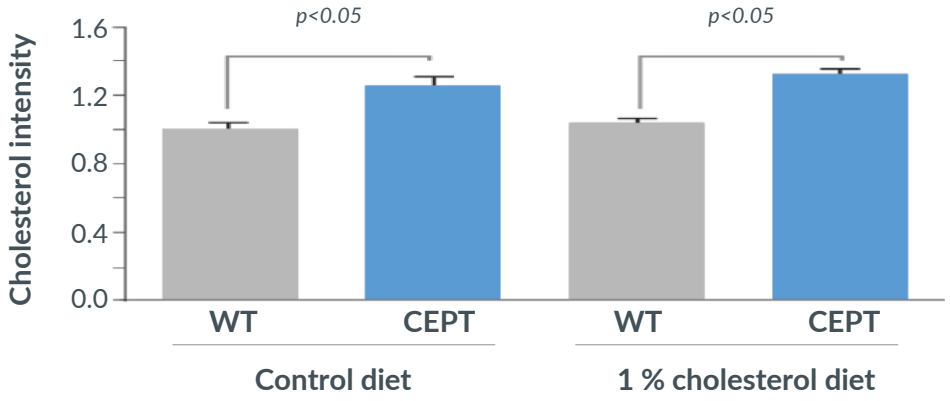
Obicetrapib and Alzheimer's Disease

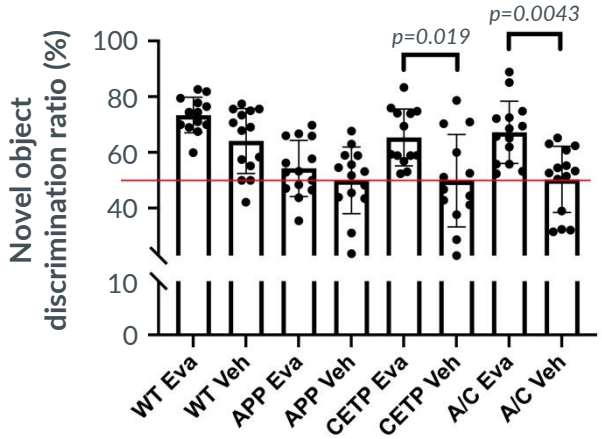
CETP knock-in mice observed to increase brain cholesterol levels and CETPi rescues cognition in preclinical models of CETP-induced AD

CETPi shows increased brain cholesterol levels



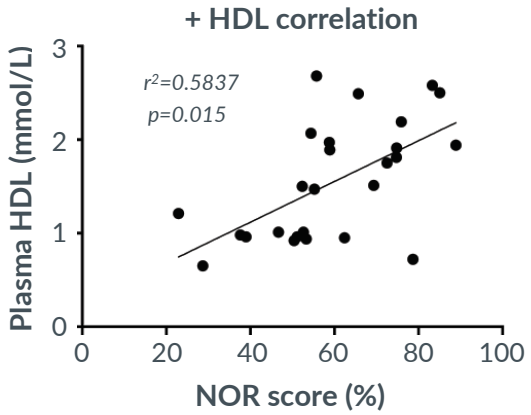


NOR scores reveal improvement with CETPi (Evacetrapib)

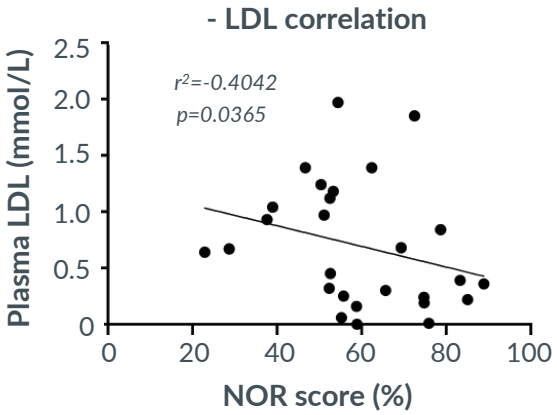


- Scores below the red line (50%) indicate cognitive impairment
- Evacetrapib has no observed effect on impairment in APP tg
- Evacetrapib observed to inhibit memory impairment in CETPtg & APP/CETPtg

Correlation between plasma lipoproteins and NOR score



Positive correlation observed between NOR score and HDL quantification in CETP and APP/CETP expressing female mice



Negative correlation observed between NOR score and LDL quantification CETP and APP/CETP expressing female mice

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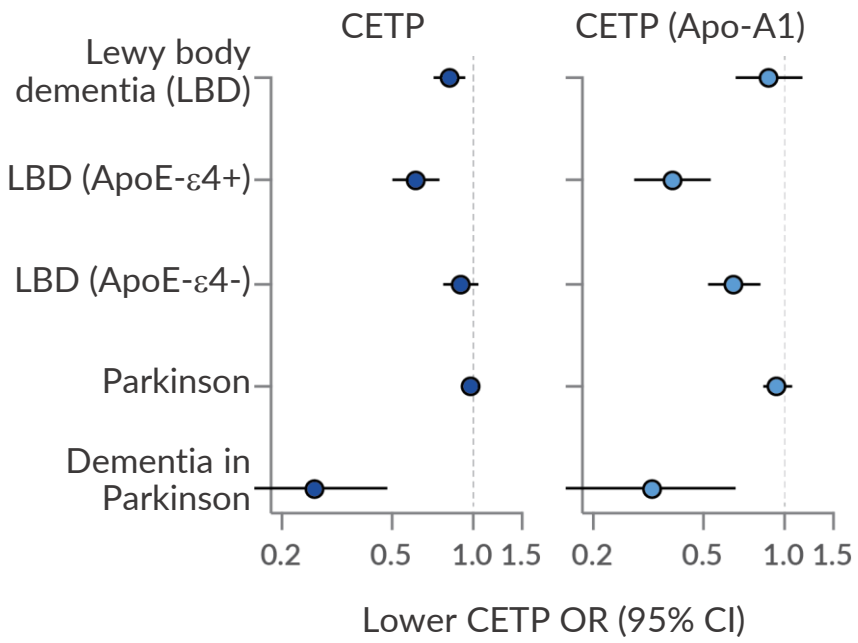
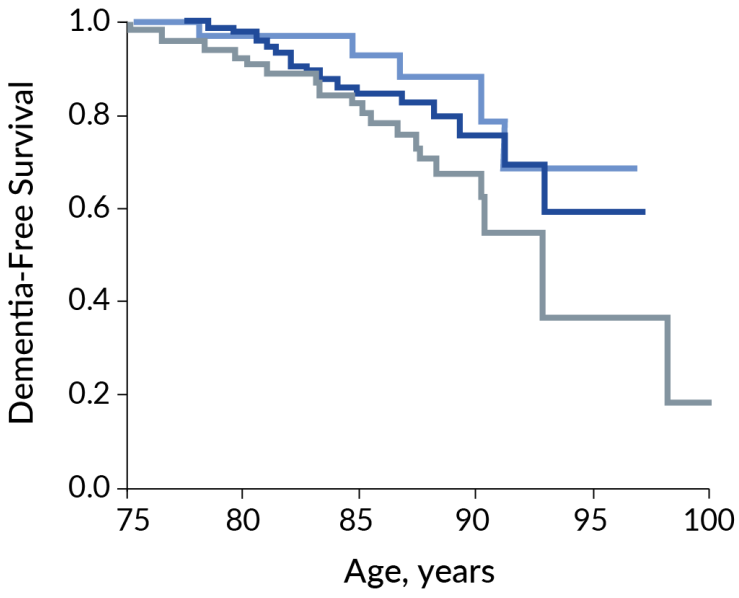
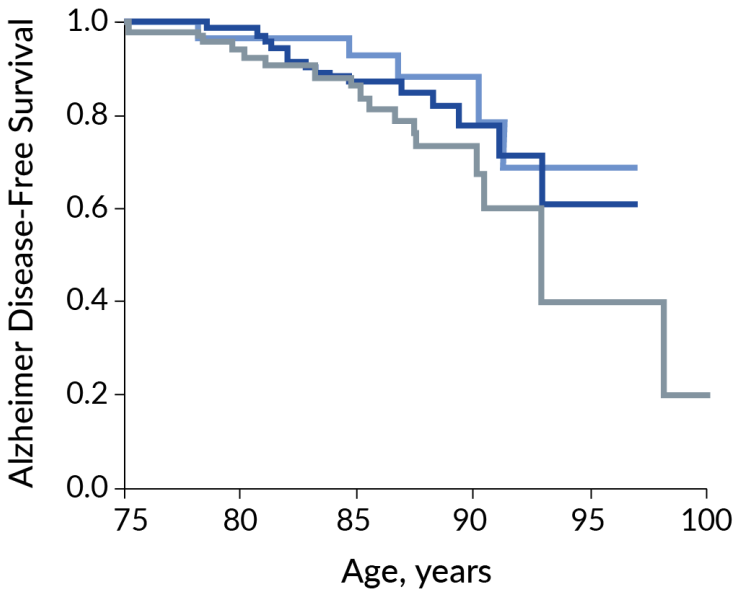
Source: Felix Oestereich, et al., The Cholesteryl Ester Transfer Protein (CETP) raises Cholesterol Levels in the Brain and affects Presenilin-mediated Gene Regulation, Journal of Lipid Research, vol. 63, no.9, 2022.

CETP loss-of-function (LoF) genotype may be associated with slower memory decline and lower AD risk

- CETP's potential involvement in CNS cholesterol homeostasis is supported by genetic data
- CETP LoF genotype may be associated with lower CETP activity & a corresponding increase in HDL levels







2 LoF CETP genes — 1 LoF CETP gene — Normal CETP

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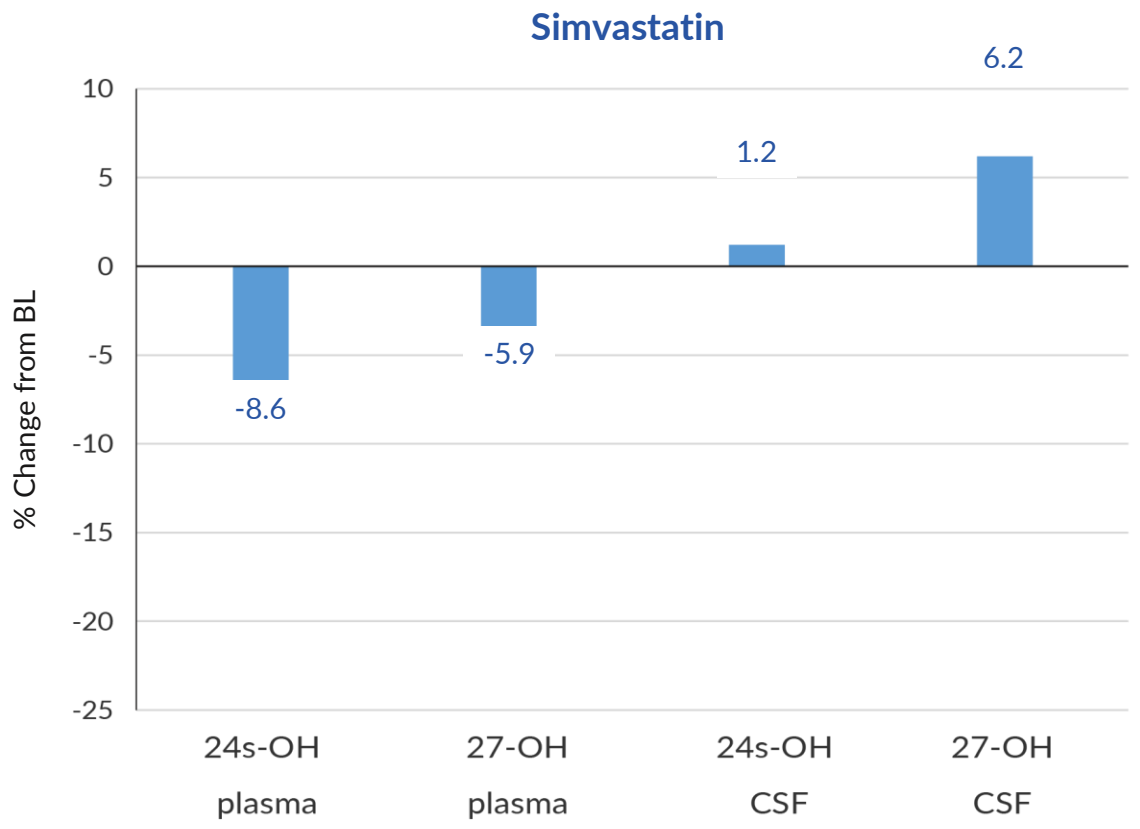
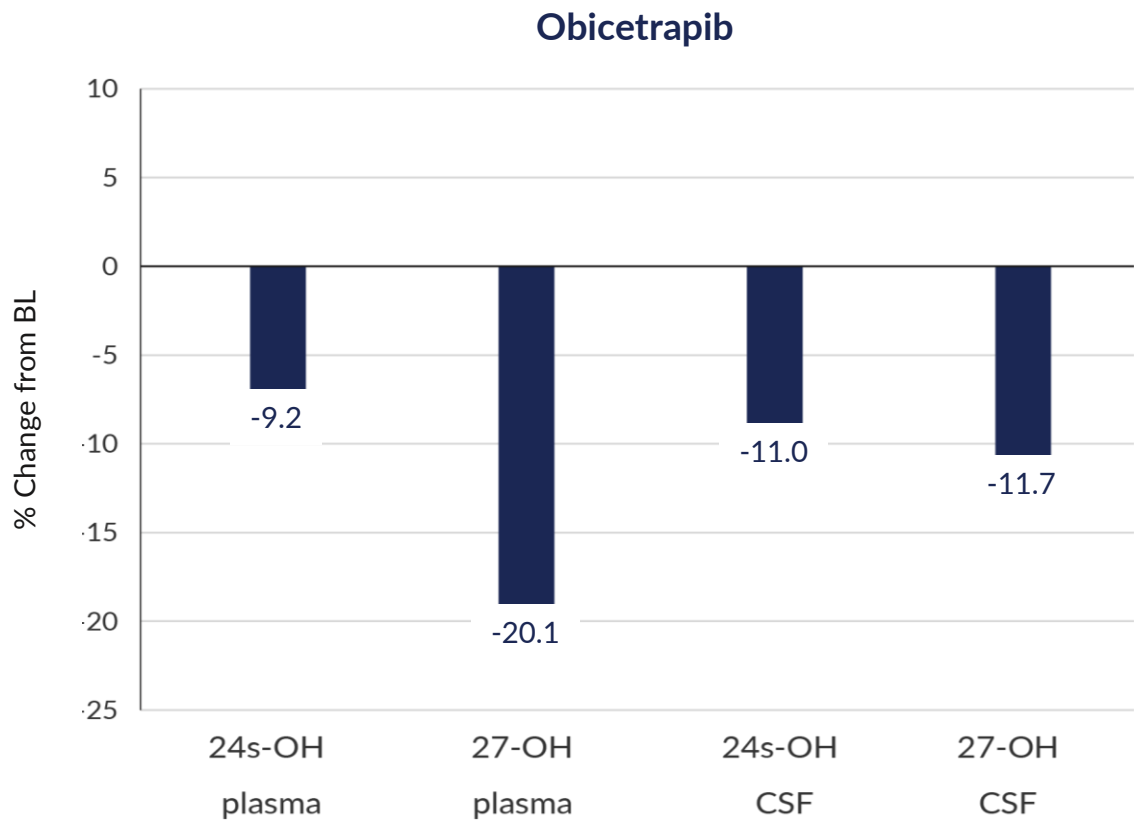
Source: *JAMA, January 13, 2010—Vol 303, No. 2*

Initial data for Obicetrapib 10mg observed to decrease 24s- & 27-hydroxycholesterol ("OH") in both plasma and cerebrospinal fluid ("CSF")

- In separate trials with different protocols and endpoints, Simvastatin was observed to only reduce 24s- and 27-OH in plasma
- Obicetrapib was observed to be well-tolerated. No serious adverse events were reported, nor were any adverse events considered to be related to the study drug.





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Source: Alzheimer Dis Assoc Disord. 2010; 24(3): 220–226 and Company data
Note: The results shown above do not represent head-to-head comparisons. The data was obtained from clinical trials with different objectives, designs and patients. Actual results may differ from expectations.

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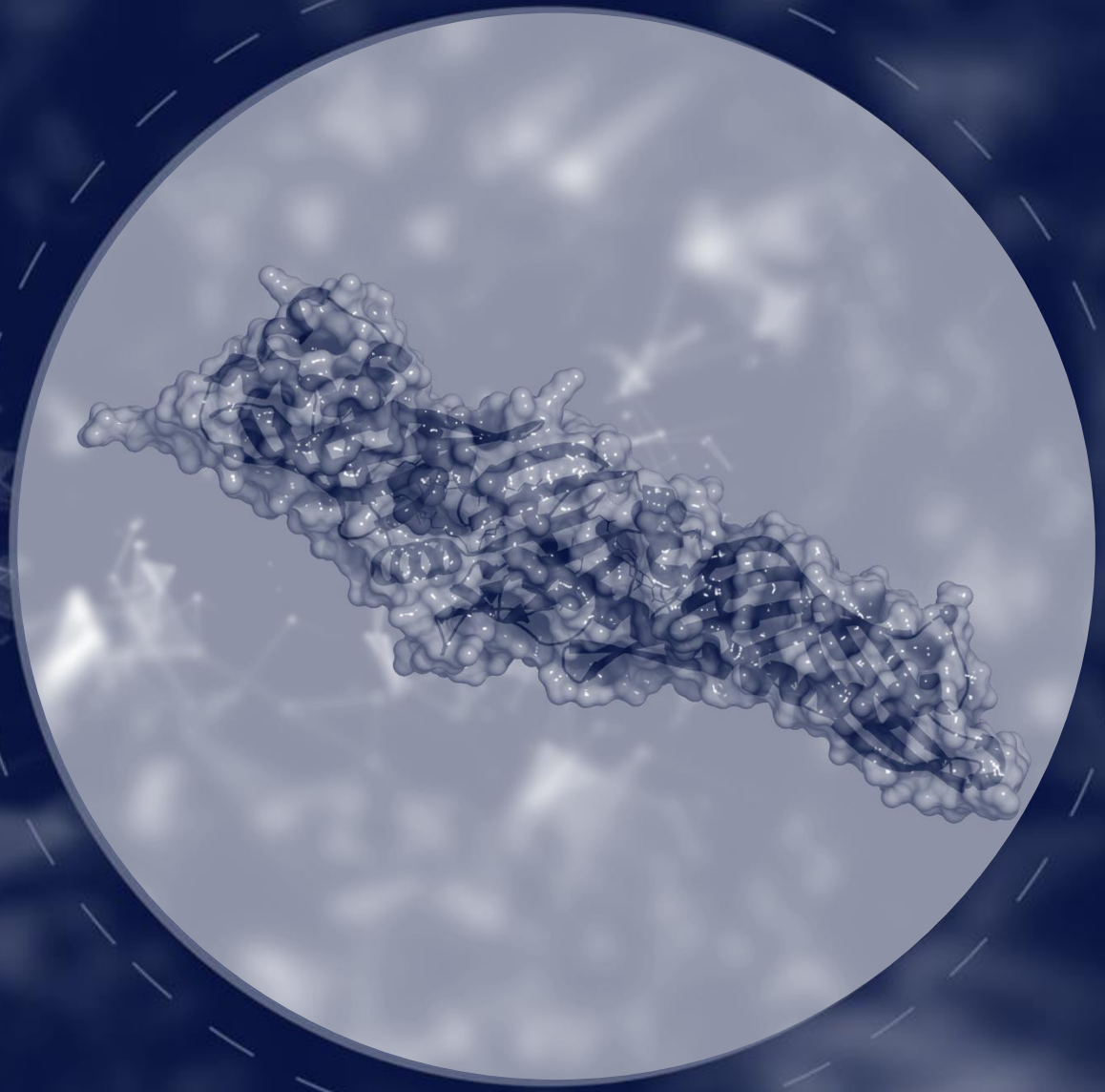
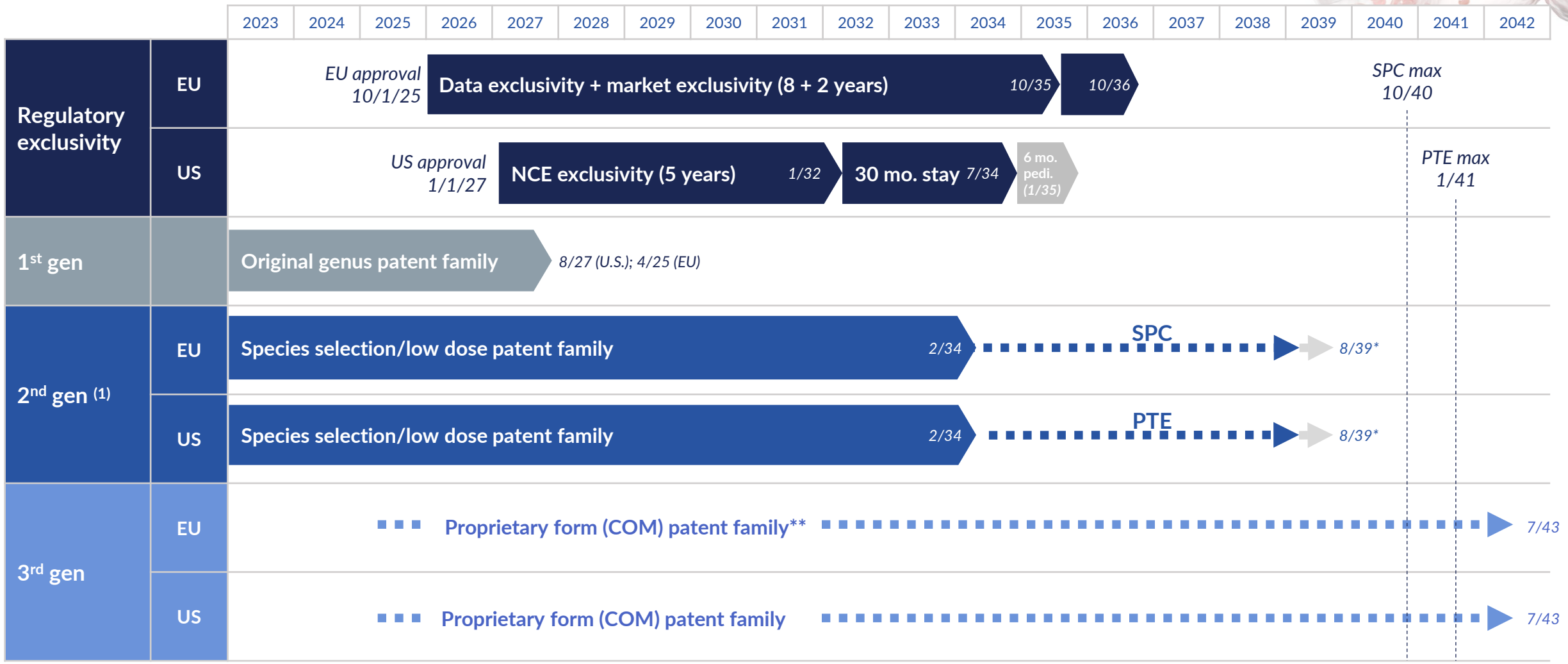
Clinical events and exclusivity timelines



Projected exclusivity timelines in the EU and US

Assumes EU approval 4Q 2025 and US approval 1Q 2027



Note: Dates for information purposes only, Filled colors = granted patents & dotted lines = pending patents; one patent only to be selected for SPC/PTE; an earlier US approval leads to earlier regulatory expiry & shorter PTE; *including pediatric extension 6m; ** will be pending once a PCT application is filed; actual results may differ from expectations. 1. Low dose/ species selection patents US 10,653,692, US 11,013,742, US 11,642,344; statin combo patent US 10,300,059

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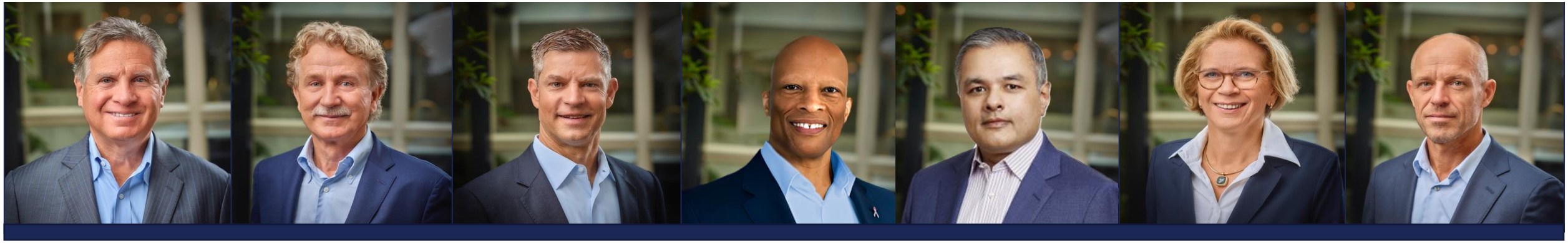
Expert cardiometabolic leadership supported by top investors



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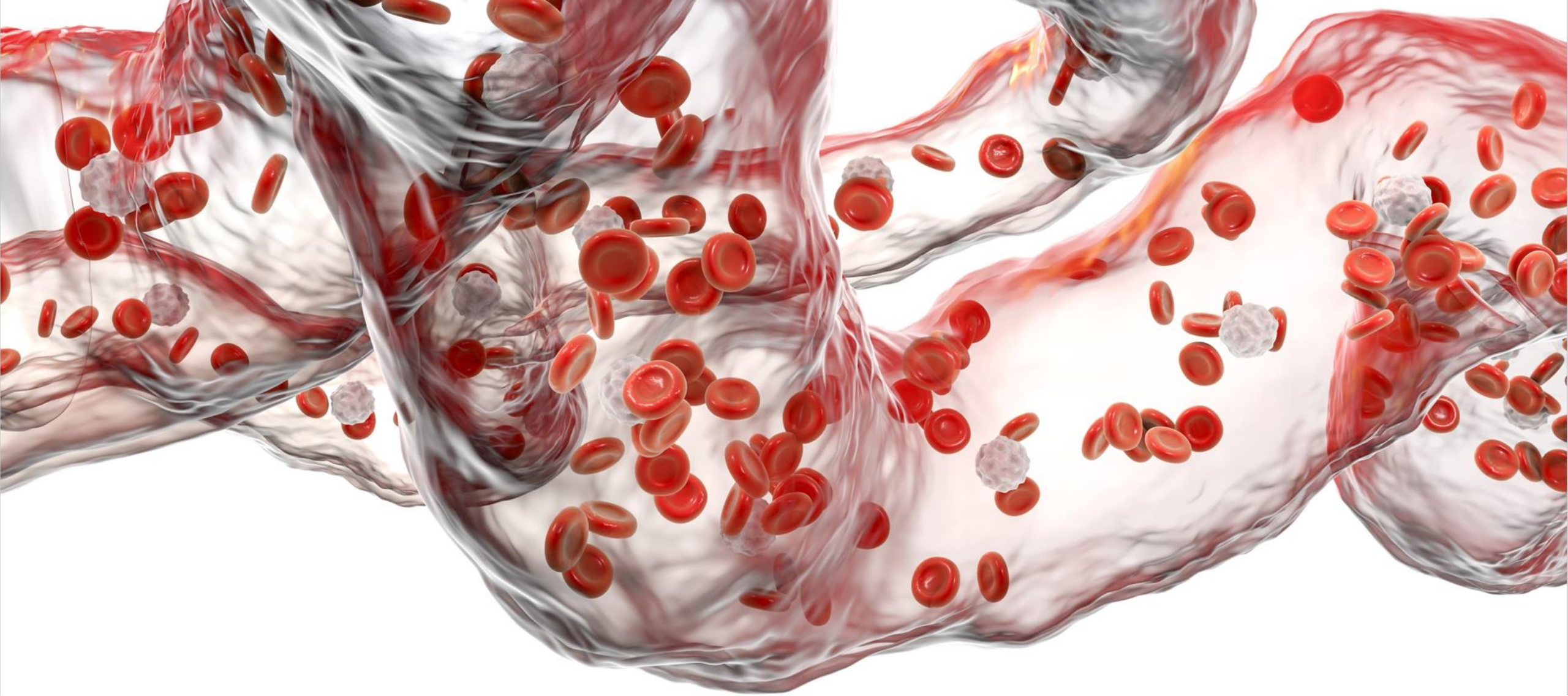

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