

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**  
Pursuant to Section 13 OR 15(d)  
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 4, 2024

**NewAmsterdam Pharma Company N.V.**

(Exact name of registrant as specified in its charter)

The Netherlands  
(State or other jurisdiction  
of incorporation)

001-41562  
(Commission  
File Number)

N/A  
(I.R.S. Employer  
Identification No.)

Gooimeer 2-35  
Naarden  
The Netherlands  
(Address of principal executive offices)

1411 DC  
(Zip Code)

+31 (0) 35 206 2971  
(Registrant's telephone number, including area code)

Not Applicable  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencements communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols	Name of each exchange on which registered
Ordinary Shares, nominal value €0.12 per share	NAMS	The Nasdaq Stock Market LLC
Warrants to purchase Ordinary Shares	NAMSW	The Nasdaq Stock Market LLC

- Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
- If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On January 4, 2024, the board of directors (the "Board") of NewAmsterdam Pharma Company N.V. (the "Company") increased the size of the Board to ten and appointed William H. Lewis, J.D., M.B.A., as Chair of the Board. Mr. Lewis will serve as a temporary non-executive director until his formal appointment at the Company's next general meeting of shareholders. The Board has determined that Mr. Lewis meets the requirements for independence under the applicable listing standards of the Nasdaq Stock Market LLC and the Securities and Exchange Act of 1934, as amended, and has appointed him to serve on the Audit Committee and Compensation Committee of the Board.

Mr. Lewis has served as Chief Executive Officer of Insmid Incorporated, a global commercial-stage biopharmaceutical company, since 2012, and as Chair of Insmid Incorporated's board of directors since 2018. Mr. Lewis succeeds Sander Slootweg, Managing Partner at Forbion, who has served as Chairman of the Board since inception.

As consideration for his service on the Board, Mr. Lewis will be eligible to receive an annual cash retainer of \$40,000, an additional \$30,000 annually for serving as Chair of the Board and an additional \$20,000 annually for serving as lead independent director. Mr. Lewis will also be granted options to subscribe for 100,000 of the Company's ordinary shares under the Company's Long-Term Incentive Plan (the "Initial Grant"). The first 25% of the ordinary shares underlying the Initial Grant will vest on the first anniversary of the vesting start date and the remaining shares will vest in equal monthly installments thereafter for three years, subject to his continued service on the Board. Mr. Lewis will also be entitled to receive an annual retainer of \$7,500 and \$5,000 for serving on the Audit Committee and Compensation Committee, respectively.

There is no arrangement between Mr. Lewis and any person pursuant to which he was selected as a director. Mr. Lewis has no direct or indirect material interest in any existing or currently proposed transaction that would require disclosure under Item 404(a) of Regulation S-K.

**Item 7.01 Regulation FD Disclosure.**

On January 8, 2024, the Company issued a press release announcing Mr. Lewis' appointment to the Board. The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

On January 8, 2024, the Company posted an updated corporate investor presentation on its website (<https://www.newamsterdampharma.com/>). A copy of the corporate investor presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K. The information contained on, or that can be accessed from, the Company's website is not incorporated into, and does not constitute a part of, this Current Report on Form 8-K.

The information contained in this Item 7.01, including Exhibits 99.1 and 99.2, is being "furnished" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 7.01, including Exhibit 99.2, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

<u>EXHIBIT NUMBER</u>	<u>EXHIBIT DESCRIPTION</u>
99.1	<a href="#">Press Release, dated January 8, 2024</a>
99.2	<a href="#">NewAmsterdam Pharma Company N.V. Corporate Presentation</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**NewAmsterdam Pharma Company N.V.**

By: /s/ Michael Davidson

Michael Davidson

Chief Executive Officer

Dated: January 8, 2024

**NewAmsterdam Pharma Appoints William H. Lewis, J.D., M.B.A. as Chair of its Board of Directors**

**Naarden, the Netherlands and Miami, USA; January 8, 2024** – NewAmsterdam Pharma Company N.V. (Nasdaq: NAMS or “NewAmsterdam” or the “Company”), a clinical-stage biopharmaceutical company developing oral, non-statin medicines for patients at high risk of cardiovascular disease with residual elevation of low-density lipoprotein cholesterol (“LDL-C”), for whom existing therapies are not sufficiently effective or well-tolerated, today announced the appointment of William H. Lewis, J.D., M.B.A., as Chair of its Board of Directors. Mr. Lewis has served as Chief Executive Officer of Insmmed Incorporated, a global commercial-stage biopharmaceutical company, since 2012, and as Chair of Insmmed’s Board of Directors since 2018. Mr. Lewis succeeds Sander Slootweg, Managing Partner at Forbion, who has served as Chairman of NewAmsterdam’s Board of Directors since inception.

“Will is a leader in the biotechnology industry, widely recognized for his commitment to putting patients first, championing those who are underserved by existing treatment options, and translating breakthrough science into first-in-disease medicines,” said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. “I have long admired Will for his deep knowledge of the clinical and regulatory landscape, as well as his proven ability to advance new therapies for serious and rare diseases. He will be a tremendous partner, who I have known for many years, and as Chair of our Board I look forward to his contributions as we advance our CETP inhibitor toward market and work to deliver a simple, oral, once-daily option to millions of people living with dyslipidemia. I would also like to thank Sander for his support and contribution as our Chairman over the last several years. His guidance has been invaluable in getting NewAmsterdam to where we are today.”

“Over the past several years, I have had the unique privilege of partnering with Will as both an investor and colleague. He is a remarkable leader, with experience advancing novel molecules through late-stage development, launching into sizeable markets and establishing new standards-of-care,” commented Mr. Slootweg. “I am confident he is the right partner to support NewAmsterdam as it enters its next phase of growth, with multiple pivotal data readouts expected in 2024 and, if approved, its plans to commercialize obicetrapib.”

Mr. Lewis has more than 30 years of executive experience in the pharmaceutical and finance industries both in the U.S. and internationally. Prior to joining Insmmed in 2012, Mr. Lewis served as Co-Founder, President, and Chief Financial Officer of Aegerion Pharmaceuticals, which was acquired by Amryt in 2019. Prior to Aegerion, he spent more than 10 years working in investment banking in the U.S. and Europe. He also previously worked for the U.S. government. Mr. Lewis holds a J.D. with Honors and an M.B.A., both from Case Western Reserve University, and a B.A., *cum laude*, from Oberlin College. He is a member of the Board of Trustees of Case Western Reserve University and of BioNJ, the life sciences association for New Jersey.

“NewAmsterdam was founded in hopes of delivering a new option to high-risk cardiovascular disease patients, many of whom fail to achieve their risk-based LDL-C goals despite treatment with statin therapy,” said Mr. Lewis. “Based on data generated from its five Phase 2 trials to date, it is clear that obicetrapib is designed to be a powerful therapy, with the potential to safely and effectively improve LDL-C, as well as other key markers of cardiovascular disease risk. I am excited to join NewAmsterdam’s Board of Directors and look forward to partnering closely with management to complete the ongoing Phase 3 program and bring obicetrapib forward.”

**About Obicetrapib**

Obicetrapib is a novel, oral, low-dose CETP inhibitor that NewAmsterdam is developing to overcome the limitations of current LDL-lowering treatments. The Company believes that obicetrapib has the potential to be a once-daily oral CETP inhibitor for lowering LDL-C, if approved. In the Company’s Phase 2b ROSE trial, obicetrapib demonstrated a 51% lowering of LDL-C from baseline at a 10 mg dose level on top of high-intensity statins and, in the Company’s Phase 2 ROSE2 trial, the combination of a 10 mg dose of obicetrapib and a 10 mg dose of ezetimibe demonstrated a 63% lowering of LDL-C from baseline. In all five of the Company’s Phase 2 trials, ROSE2, TULIP, ROSE, OCEAN, and TA-8995-203, evaluating obicetrapib as monotherapy or combination therapy, the Company observed statistically significant LDL-lowering combined with a side effect profile similar to that of placebo, including no increase in blood pressure or muscle related side effects. Obicetrapib has demonstrated strong tolerability in more than 800 patients with elevated lipid levels (“dyslipidemia”) in NewAmsterdam’s clinical trials to date. The Company is conducting two Phase 3 pivotal trials, BROADWAY and BROOKLYN, to evaluate obicetrapib

as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to provide additional LDL-lowering for high-risk cardiovascular disease (“CVD”) patients. The Company began enrolling patients in BROADWAY in January 2022 and in BROOKLYN in July 2022 and completed enrollment of BROOKLYN in April 2023 and BROADWAY in July 2023. The Company also commenced the Phase 3 PREVAIL cardiovascular outcomes trial in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of major adverse cardiovascular events, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization.

#### **About NewAmsterdam**

Based in the Netherlands, NewAmsterdam (Nasdaq: NAMS) is a clinical-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where currently approved therapies have not been sufficiently adequate or well tolerated. We seek to fill a significant unmet need for a safe, cost-effective and convenient LDL-lowering therapy as an adjunct to statins, a class of lipid-lowering medications that are the current standard of care for high-risk CVD patients with high cholesterol. NewAmsterdam is investigating obicetrapib, an oral, low-dose and once-daily CETP inhibitor, as the preferred LDL-C lowering therapy to be used as an adjunct to maximally tolerated statin therapy for high-risk cardiovascular disease patients.

#### **Forward-Looking Statements**

Certain statements included in this document that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “position,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding the Company’s business and strategic plans, cash runway, the therapeutic and curative potential of the Company’s product candidate, the Company’s clinical trials and the timing for enrolling patients, the timing and forums for announcing data, the achievement and timing of regulatory approvals and plans for commercialization. These statements are based on various assumptions, whether or not identified in this document, and on the current expectations of the Company’s management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; risks relating to the uncertainty of the projected financial information with respect to the Company; risks relating to the uncertainty of the projected financial information with respect to the Company; risks related to the approval of the Company’s product candidate and the timing of expected regulatory and business milestones, including potential commercialization; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive product candidates; ability to obtain sufficient supply of materials; global economic and political conditions; the effects of competition on the Company’s future business; and those factors described in the Company’s public filings with the U.S. Securities and Exchange Commission. Additional risks related to the Company’s business include, but are not limited to: uncertainty regarding outcomes of the Company’s ongoing clinical trials, particularly as they relate to regulatory review and potential approval for its product candidate; risks associated with the Company’s efforts to commercialize a product candidate; the Company’s ability to negotiate and enter into definitive agreements on favorable terms, if at all; the impact of competing product candidates on the Company’s business; intellectual property related claims; the Company’s ability to attract and retain qualified personnel; ability to continue to source the raw materials for its product candidate. If any of these risks materialize or the Company’s assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that the Company does not presently know or that the Company currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition,

forward-looking statements reflect the Company's expectations, plans, or forecasts of future events and views as of the date of this document and are qualified in their entirety by reference to the cautionary statements herein. The Company anticipates that subsequent events and developments may cause the Company's assessments to change. These forward-looking statements should not be relied upon as representing the Company's assessment as of any date subsequent to the date of this communication. Accordingly, undue reliance should not be placed upon the forward-looking statements. Neither the Company nor any of its affiliates undertakes any obligation to update these forward-looking statements, except as may be required by law.

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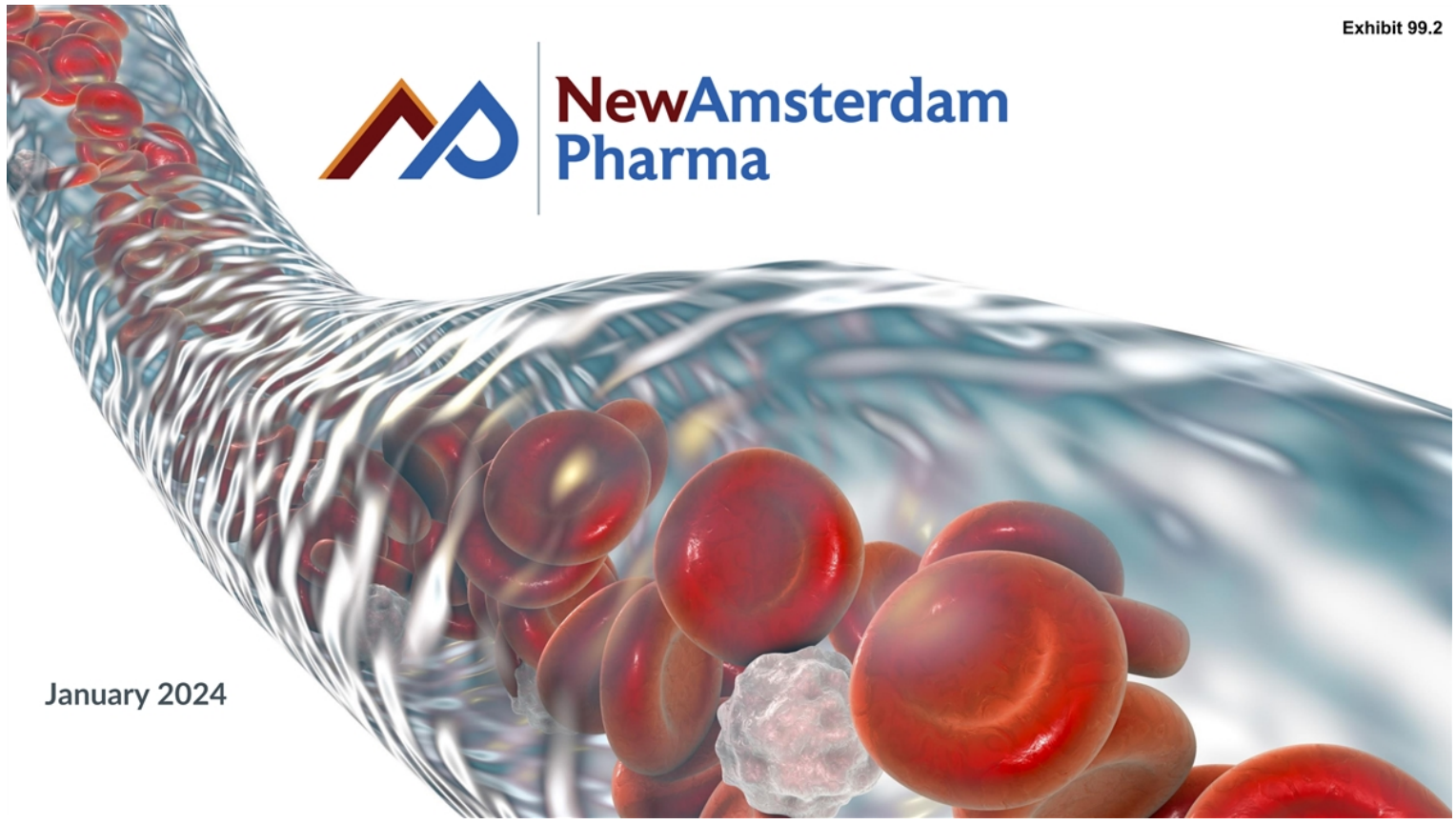
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**NewAmsterdam  
Pharma**

January 2024







# Disclaimer

This presentation (together with oral statements made in connection herewith, this "Presentation") is for informational purposes only. This Presentation shall not constitute an offer to sell, or the solicitation of an offer to buy, any securities, nor shall there be any sale of securities in any states or jurisdictions in which such offer, solicitation or sale would be unlawful.

## Forward Looking Statements

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If any of these risks materialize or NewAmsterdam's assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that are presently unknown by the Company or that NewAmsterdam currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect NewAmsterdam's expectations, plans, or forecasts of future events and views as of the date of this Presentation and are qualified in their entirety by reference to the cautionary statements herein. NewAmsterdam anticipates that subsequent events and developments will cause the Company's assessments to change. These forward-looking statements should not be relied upon as representing NewAmsterdam's assessments as of any date subsequent to the date of this Presentation. Accordingly, undue reliance should not be placed upon the forward-looking statements. Neither NewAmsterdam nor any of its affiliates undertakes any obligation to update these forward-looking statements, except as required by law.

## Market Data

Certain information contained in this Presentation relates to or is based on third-party studies, publications, surveys and NewAmsterdam's own internal estimates and research. In addition, all of the market data included in this Presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while NewAmsterdam believes its internal research is reliable, such research has not been verified by any independent source and NewAmsterdam cannot guarantee and makes no representation or warranty, express or implied, as to its accuracy and completeness.

## Trademarks

This Presentation contains trademarks, service marks, trade names, and copyrights of NewAmsterdam and other companies, which are the property of their respective owners. The use or display of third parties' trademarks, service marks, trade name or products in this Presentation is not intended to, and does not imply, a relationship with NewAmsterdam or an endorsement or sponsorship by or of NewAmsterdam. Solely for convenience, the trademarks, service marks and trade names referred to in this Presentation may appear with the TM or SM symbols, but such references are not intended to indicate, in any way, that NewAmsterdam will not assert, to the fullest extent permitted under applicable law, their rights or the right of the applicable licensor to these trademarks, service marks and trade names.



# 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

## 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

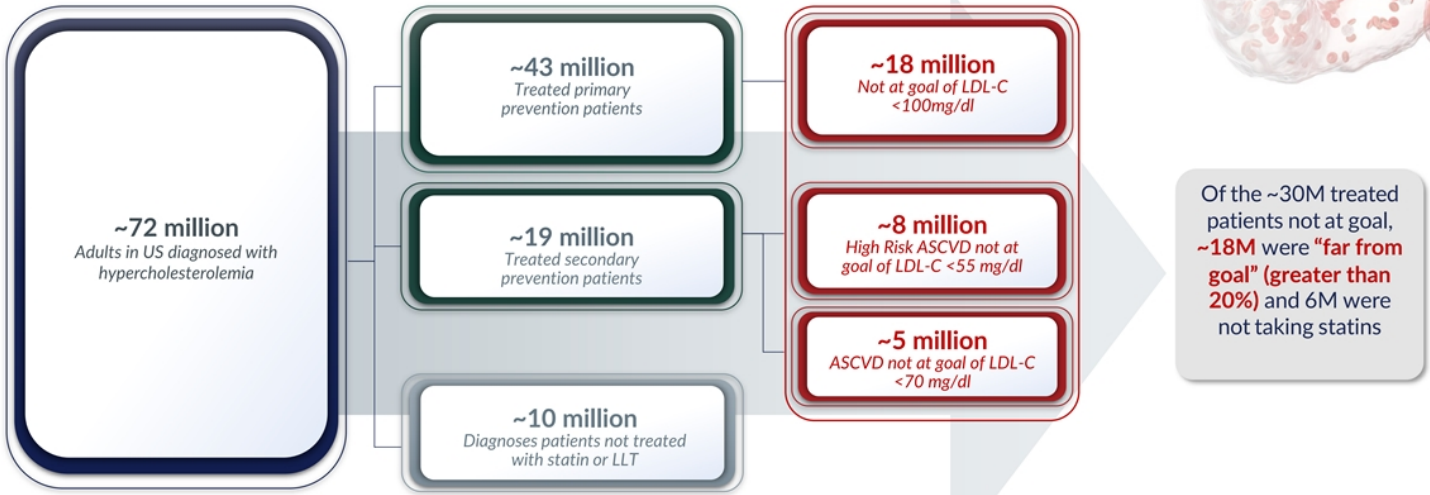
### Upcoming catalysts build on 2023 progress:

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

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



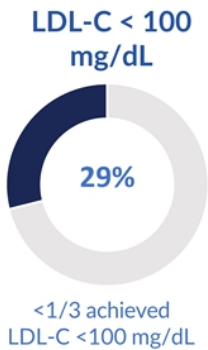
Of the ~30M treated patients not at goal, ~18M were "far from goal" (greater than 20%) and 6M were not taking statins

**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**

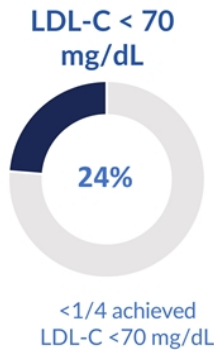
# Majority of ASCVD/HeFH patients are not achieving LDL-C targets



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



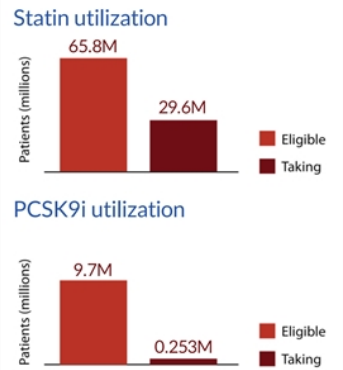
**ASCVD patients** with an LDL-C  
target of LDL<70 or <55 mg/dL  
(2017-2018)<sup>2</sup>



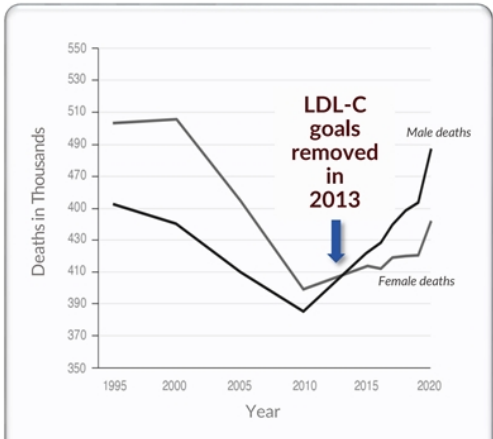
**Very high risk ASCVD patients**  
with an LDL-C target <55  
mg/dL (2020-2021)<sup>3</sup>



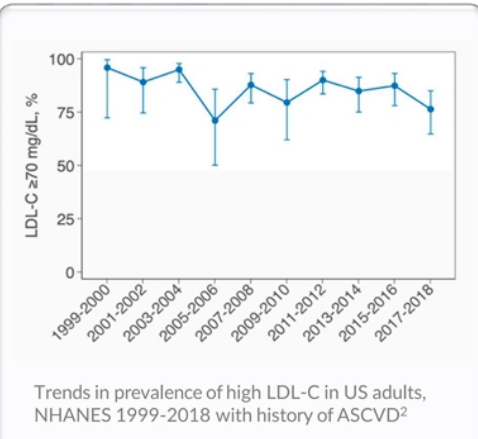
Despite availability of  
treatments continue to see  
minimal uptake, especially  
adjunct to statins<sup>4</sup>



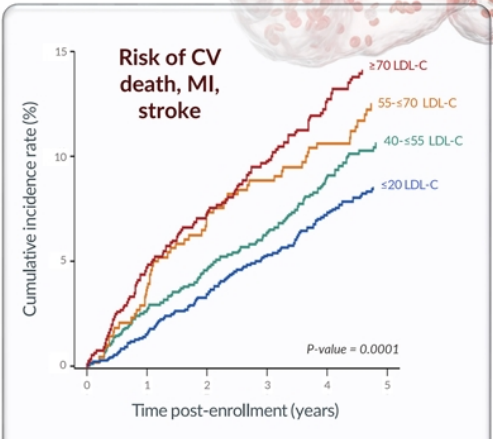
# Increased CV events following removal of LDL-C guidelines in 2013



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



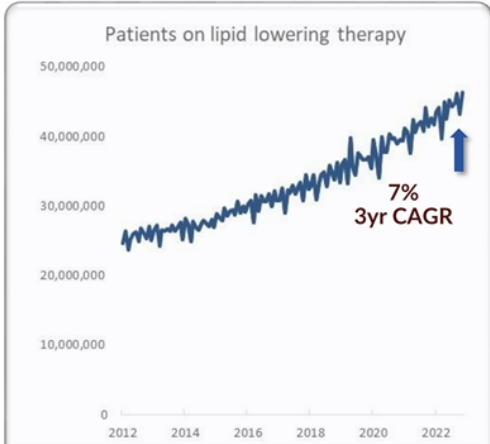
~**75% of ASCVD patients are NOT at their risk-based LDL-C goal**



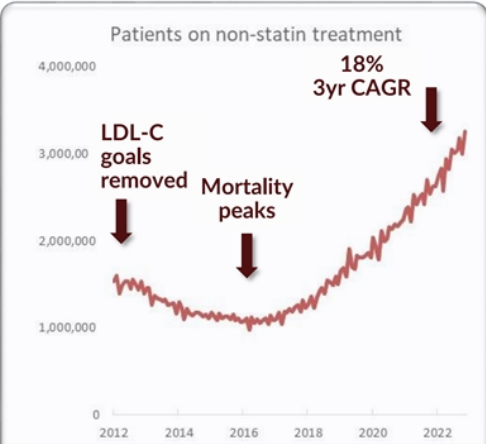
Numerous studies demonstrate resurgence of paradigm **“lower is better”**

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 ~84mm 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.

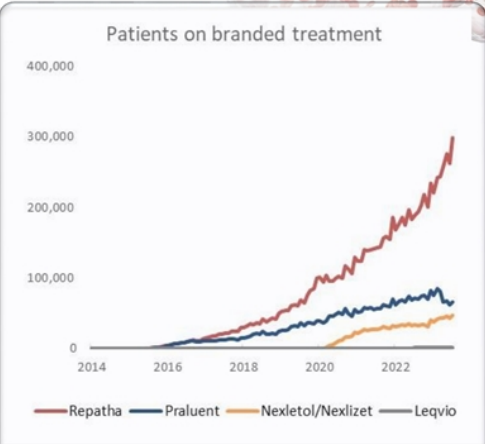
# Resurgence of the “lower is better” paradigm leading to significant US market growth



**7% total market growth in the US**



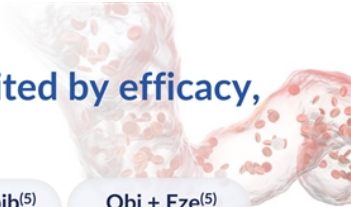
**18% non-statin patient growth**



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

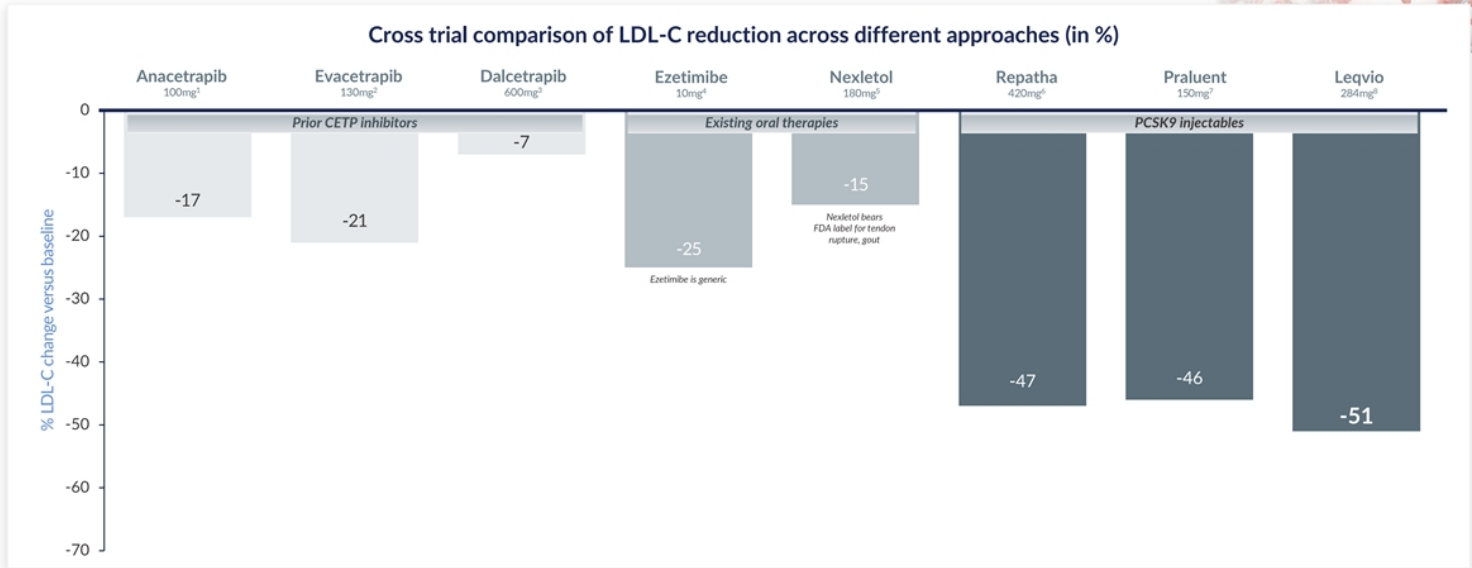


# Few approved post-statin LDL lowering products, which are limited by efficacy, convenience and/or payor access



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



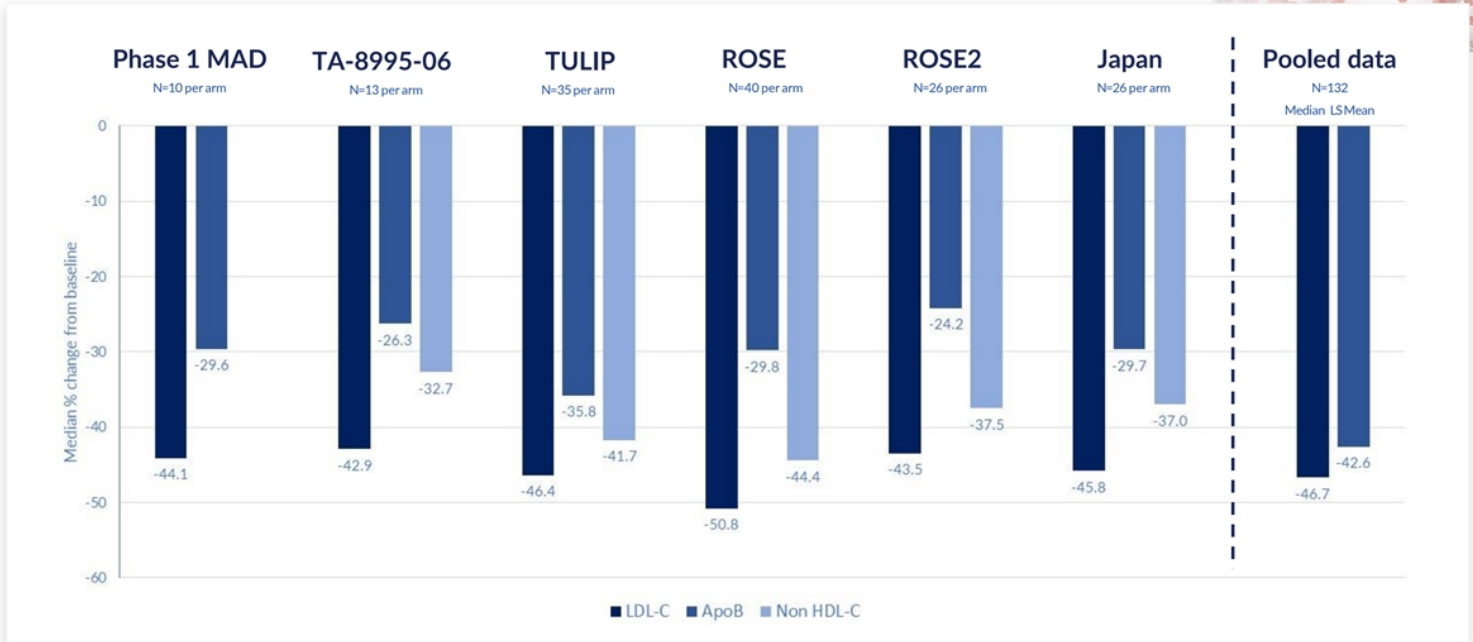
# Obicetrapib program designed to overcome limitations of prior CETP inhibitors



	Torcetrapib <sup>(1)</sup>	Dalcetrapib <sup>(2)</sup>	Evacetrapib <sup>(3)</sup>	Anacetrapib <sup>(4)</sup>	Obicetrapib <sup>(5)</sup>
Observed LDL-C reduction	-20%	-7%	-21%	-17%	-43%
CETP inhibition	80%	40%	65%	90%	98%
Dosing	60mg	600mg	100mg	100mg	10mg
Blood pressure increase	Yes	No	No	No	No
Aldosterone increase	Yes	No	No	No	No
Lp(a) lowering	None	None	30-35%	20-25%	47-57%
<b>OUTCOMES STUDIES</b>					
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	-21%	NS	-31%	-17%	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	As expected, low baseline and LDL reduction	TBD

 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

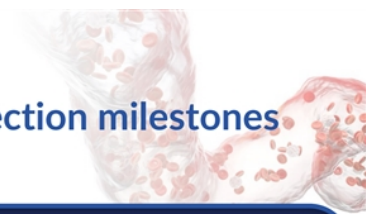
# Obicetrapib Phase 1/2 studies: Consistent benefits observed in lipid biomarkers



# Sufficient cash expected to fund the Company through multiple potential pivotal data readouts 2024-2026



# 2023 achievements pave the way for potential 2024 value inflection milestones



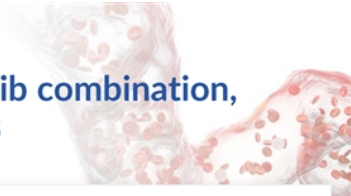


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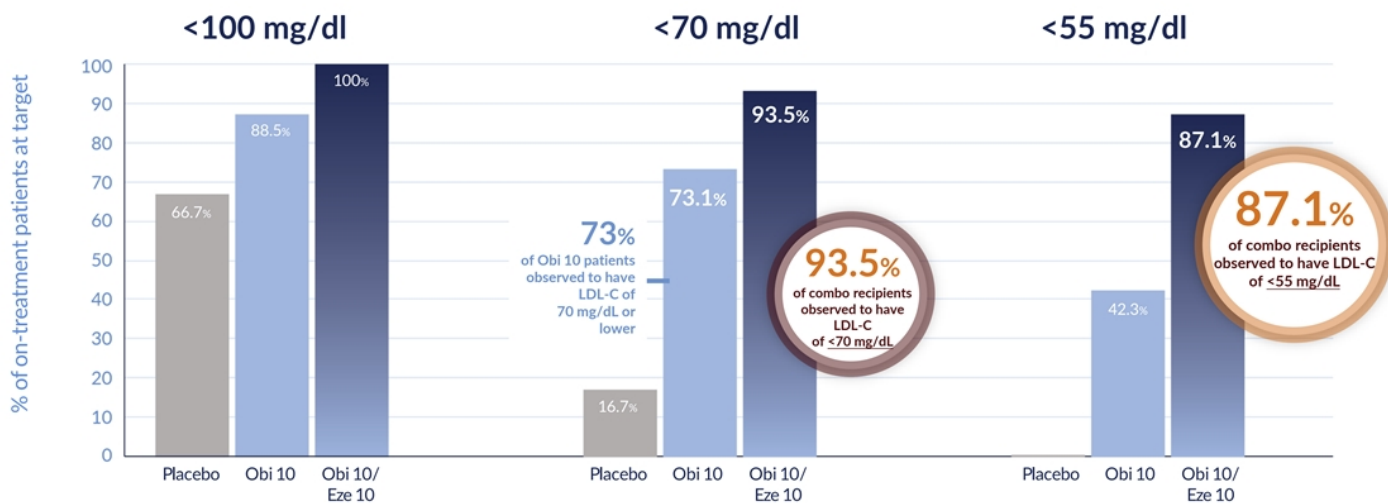
## Obicetrapib for Cardiovascular Disease



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

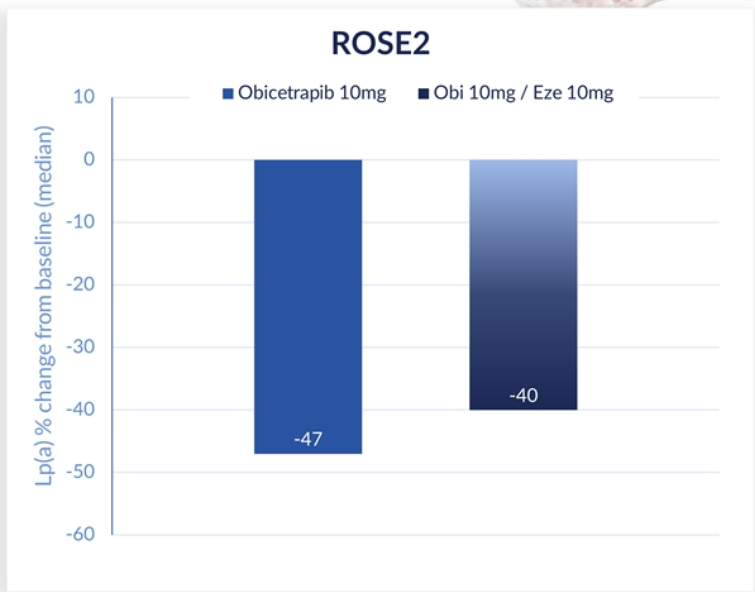
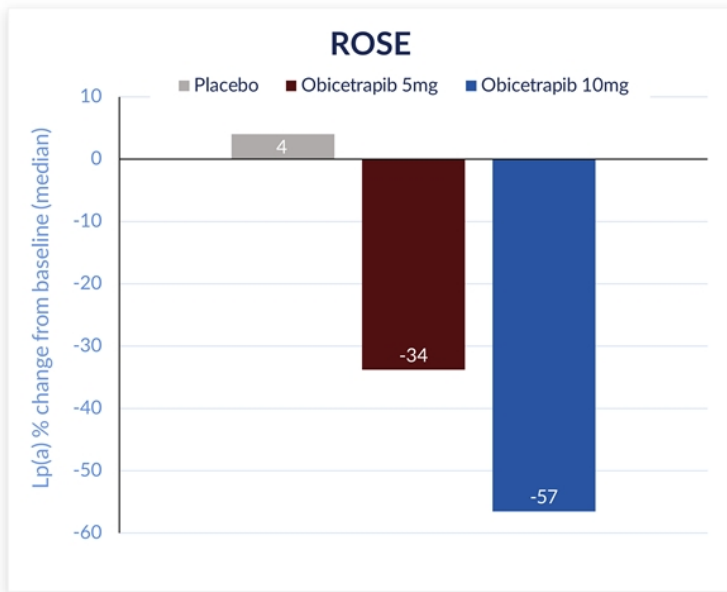
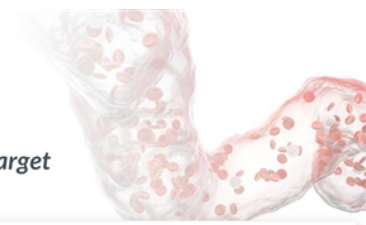


% of patients observed with the following LDL-C levels:

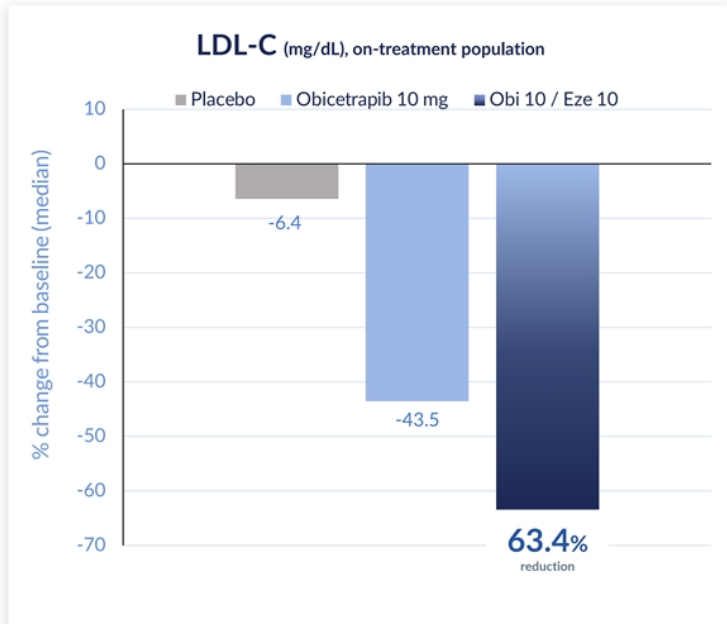


# Lp(a) percent reduction from baseline in ROSE<sup>1</sup> and ROSE2<sup>2</sup>

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



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

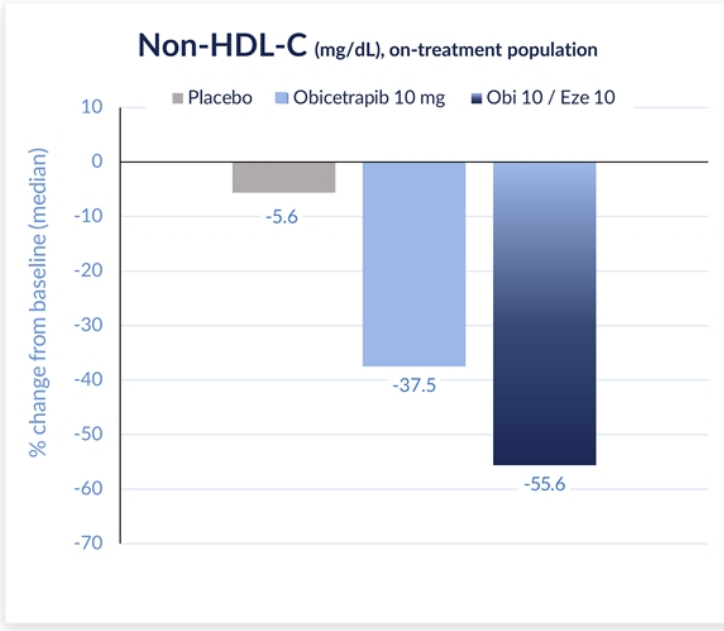


## Median (min, max) LDL-C levels (mg/dL) at baseline & EoT

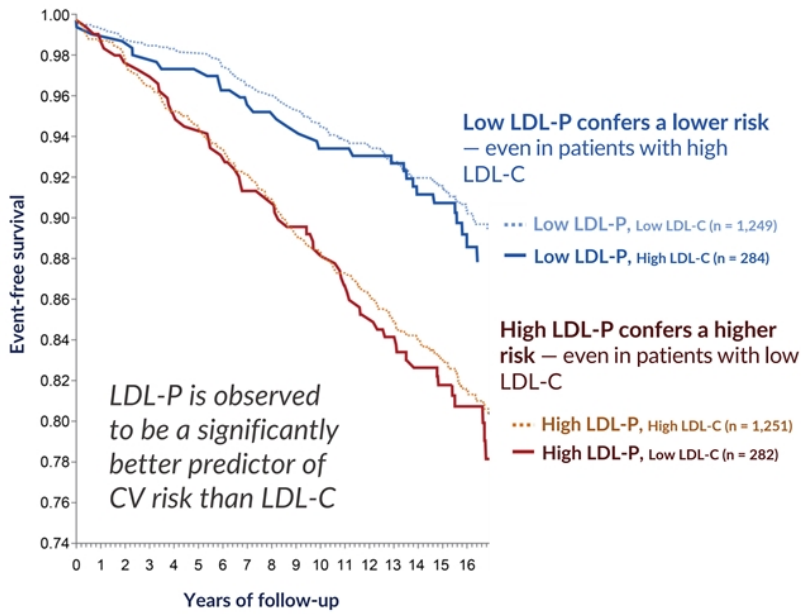
Time	Placebo	Obi 10 mg	Obi 10 / Eze 10
<b>Baseline Median</b>	95.5 (60, 211) (N=40)	100.0 (35, 189) (N=26)	87.0 (62, 152) (N=31)
<b>EoT Median</b>	88.0 (55, 188) (N=36)	55.5 (21, 148) (N=26)	39.0 (15, 96) (N=31)
<b>% Change from Baseline (Median)</b>	-6.4 (-36.4, 96.7) (N=36)	-43.5 (-78.4, 22.6) (N=26)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



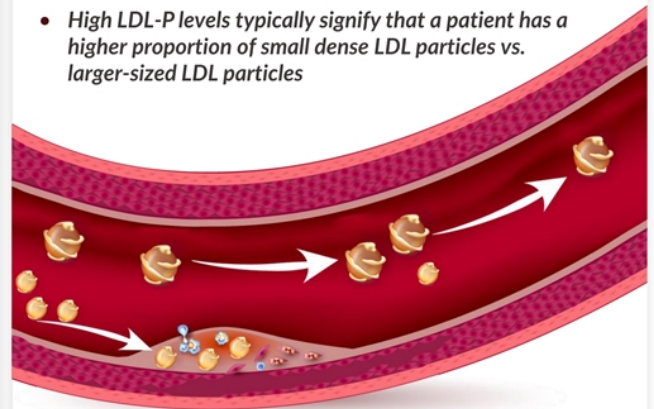
# ROSE2: Non-HDL-C and ApoB percent change from baseline (Day 84)



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



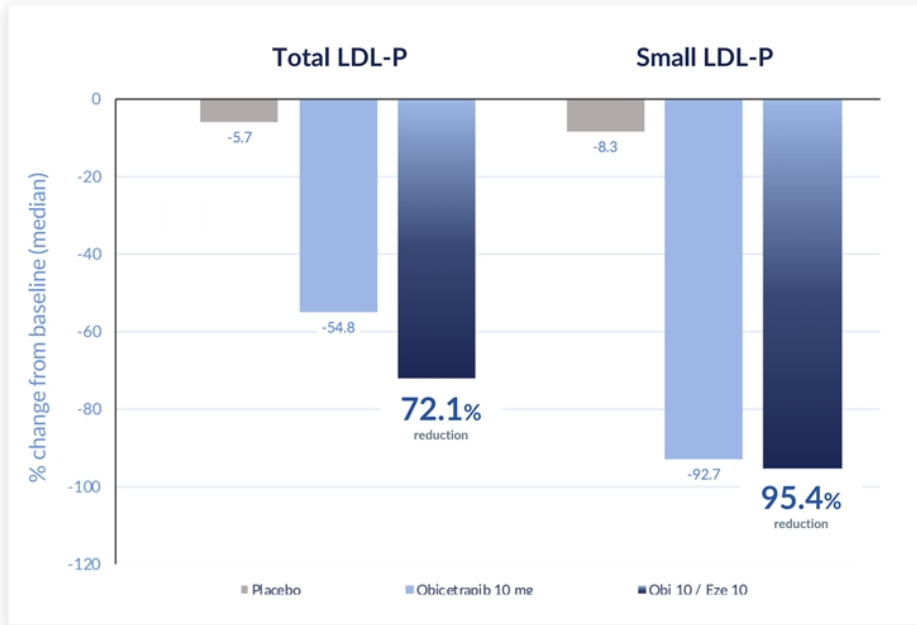
- Small dense LDL particles are more likely to be trapped in arterial wall than larger-sized LDL particles
- High LDL-P levels typically signify that a patient has a higher proportion of small dense LDL particles vs. larger-sized LDL particles



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



**ROSE2 showed significant reduction in total and small LDL particles, bringing patients who had baseline elevated LDL-P to optimal parameters<sup>(1)</sup>**



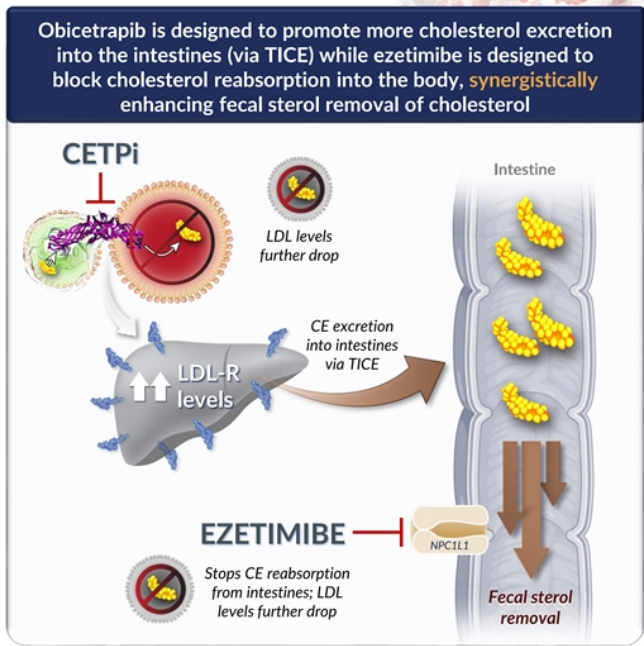
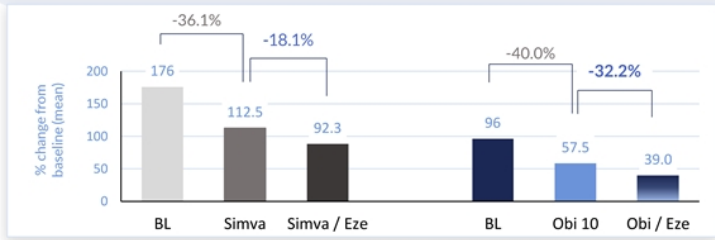
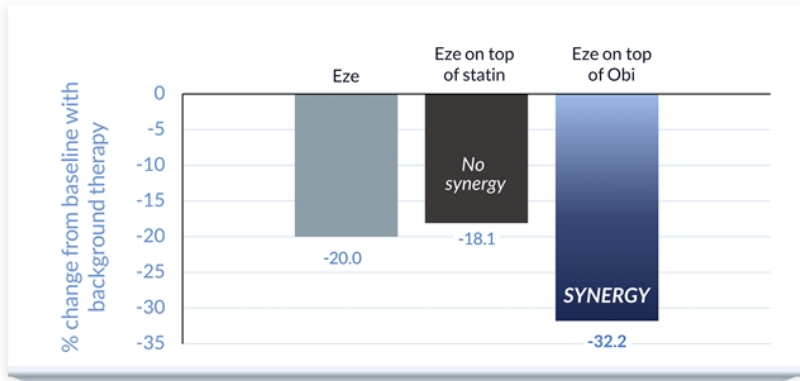
Patients taking the Obi/Eze combo observed to achieve optimal LDL-P profiles

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<sup>(2)</sup>

	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

**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<sup>(1)</sup>**



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



	Comparator <sup>(1)</sup> (N=231)	Pooled Obicetrapib (5, 10mg) <sup>(2)</sup> (N=309)
<b>TEAEs (%)</b>		
TEAEs, total	136 (58.9)	173 (55.9)
TEAEs, related	45 (19.5)	49 (15.8)
TEAEs, severe	5 (2.2)	7 (2.3)
<b>TESAEs</b>		
*TESAEs, total	6 (2.6)	4 (1.3)
TESAEs, related	0	0
Deaths	0	0
<b>Withdrawals study / medication</b>		
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.

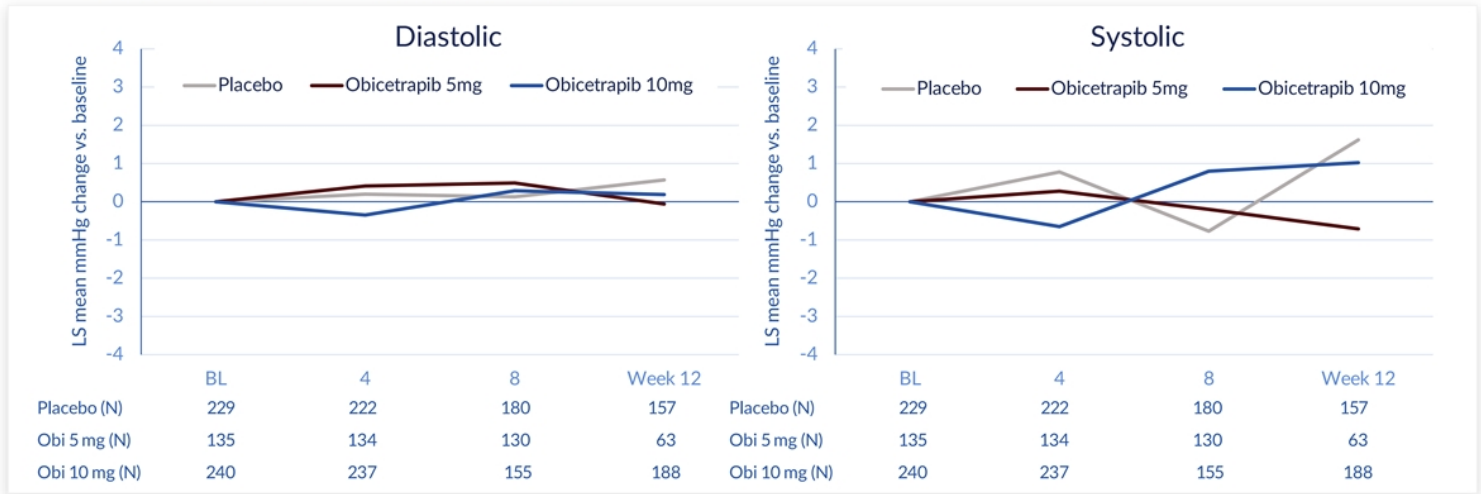
(1) The Comparator group included patients receiving placebo and non-obicetrapib monotherapy.

(2) The pooled obicetrapib group includes patients treated with obicetrapib as a monotherapy and in combination with atorvastatin, rosuvastatin and ezetimibe.



# 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



# PREVAIL trial design & power calculations leverage lessons learned



## Applying lessons from prior CVOTs

- **Study design:**
  - n = 9000
  - Inclusion: ASCVD patients on maximally tolerated statins with risk enhancers and LDL-C > 70mg/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
- **Power assumptions:**
  - 4.4% annual event rate
  - 45mg/dl reduction in LDL-C
  - 90% power to achieve a 20% relative risk reduction ( $p < 0.01$ )

**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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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
<b>TORCETRAPIB<sup>1</sup></b> Suffered from drug-specific toxicity issue (Pfizer)	OFF-TARGET TOXICITY, INCREASED BLOOD PRESSURE, ALDOSTERONE (seen early in Phase 2)	<b>NO LDL-LOWERING</b> ~40% target coverage at CVOT dose	<b>INSUFFICIENT TRIAL DURATION (only 2 years)</b>  Sufficient duration (4.1 years, with 6.3 year follow up)  Baseline LDL too low (60 mg/dL)	<b>COMMERCIAL VIABILITY</b>  COMMERCIALLY UNVIABLE - HIGH LIPOPHILICITY AND FAT TISSUE ACCUMULATION LED TO 4+ YEAR HALF-LIFE
<b>DALCETRAPIB<sup>2</sup></b> Drug showed no LDL-lowering efficacy (Roche)	Safe & well-tolerated	Modest LDL-lowering ~80% target coverage at CVOT dose		
<b>EVACETRAPIB<sup>3</sup></b> Overall mortality benefit (P = .04) - but CVOT was too short to demonstrate MACE benefit (Lilly)	Safe & well-tolerated Strong safety profile across ~59k patients	Modest LDL-lowering ~80% target coverage at CVOT dose		
<b>ANACETRAPIB<sup>4</sup></b> Meaningful MACE benefit observed - but drug accumulated in fat tissue (Merck)	Safe & well-tolerated	Modest LDL-lowering ~80% target coverage at CVOT dose		
<b>OBICETRAPIB<sup>5</sup></b> 	✓ 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) <sup>(1)</sup> = PREVAIL CVOT design expected to translate into 15-20% MACE benefit	

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/TIMISS-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

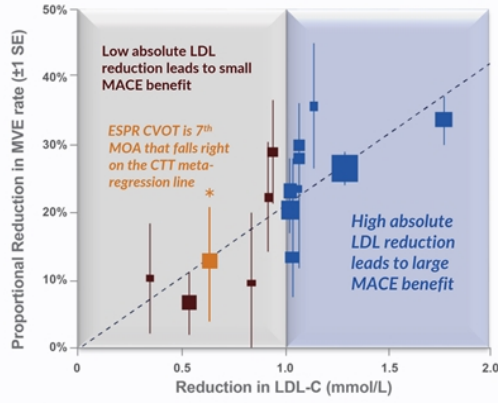
MACE benefits impacted by 2 key factors:

ABSOLUTE REDUCTION

STUDY DURATION

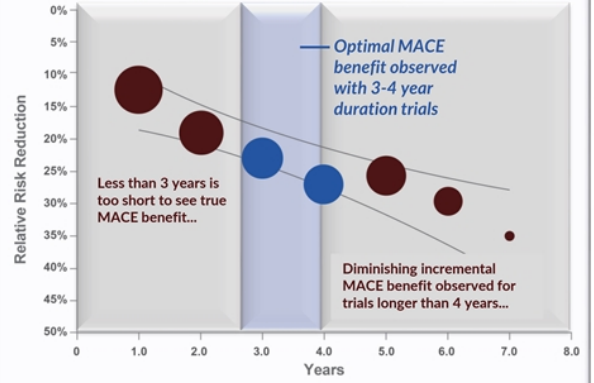
## Key factor 1: Absolute reduction

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





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

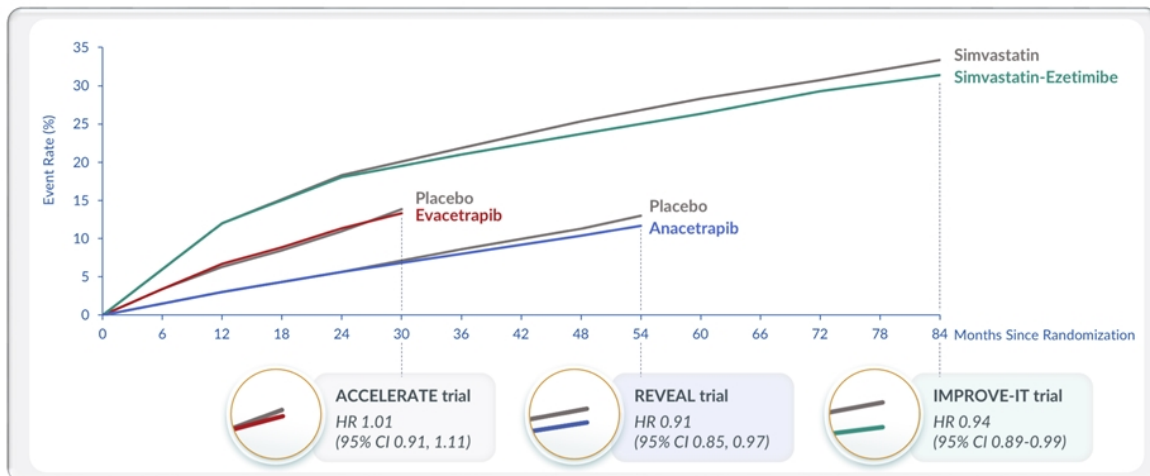
Kaplan-Meier curves for these trial, with very similar absolute ApoB reductions, show separation later than 2 years, which is the point in time that ACCELERATE stopped



MACE benefits impacted by 2 key factors:

ABSOLUTE REDUCTION

STUDY DURATION

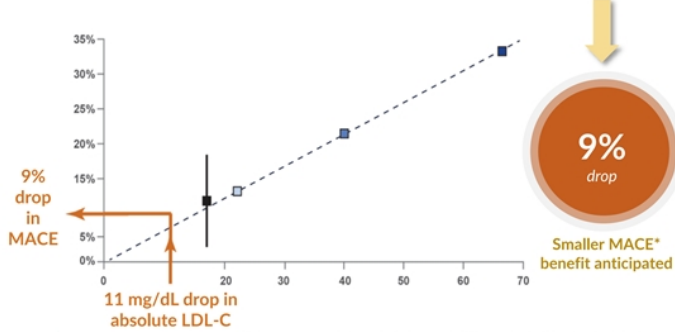
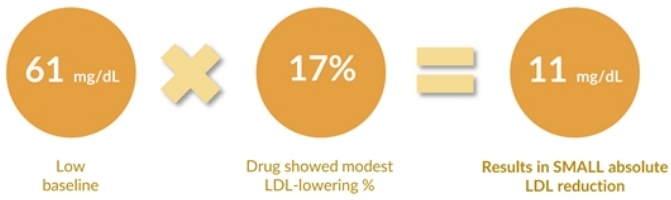


Curves are for the primary efficacy endpoint, which in IMPROVE-IT was defined as the composite of death from cardiovascular disease, a major coronary event (nonfatal myocardial infarction, documented unstable angina requiring hospital admission, or coronary revascularization occurring at least 30 days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

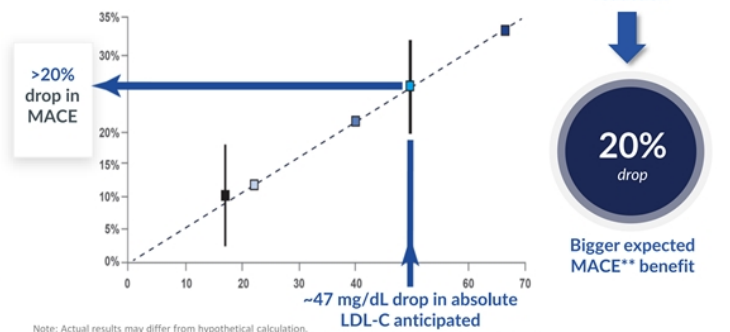
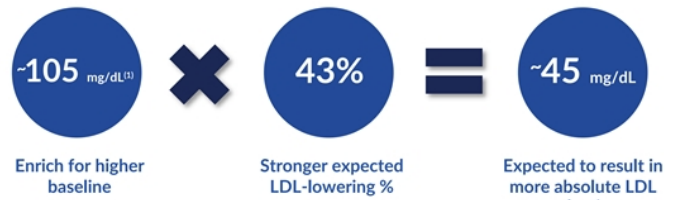
Cannon CP, et al. N Engl J Med 2015;372:2387-2397. Lincoff AM, et al. N Engl J Med 2017;376:1933-1942. Bowman L, et al. N Engl J Med 2017;377:1217-1227.

# REVEAL data supports translation from absolute LDL reduction to MACE benefit

## EXPERIENCE: REVEAL (anacetrapib)



## Hypothetical: PREVAIL (obicetrapib)



\* 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.

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

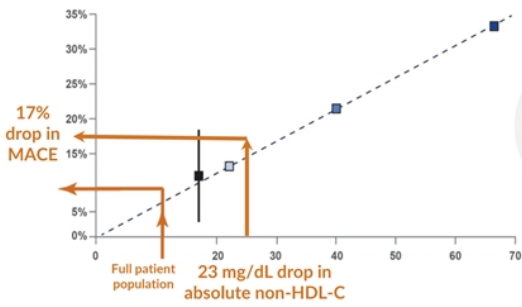
## EXPERIENCE: REVEAL (anacetrapib)



non-HDL-C high tercile baseline

Drug showed modest Non-HDL-C lowering %

Results in **SMALL** absolute non-HDL-C reduction



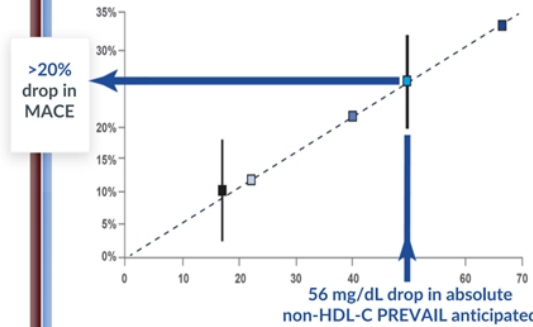
## Hypothetical: Obicetrapib (Phase 2 Studies)



Non-HDL-C PREVAIL baseline

Non-HDL-C lowering in Obi P2s

absolute non-HDL-C reduction



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, Dittmarsch 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

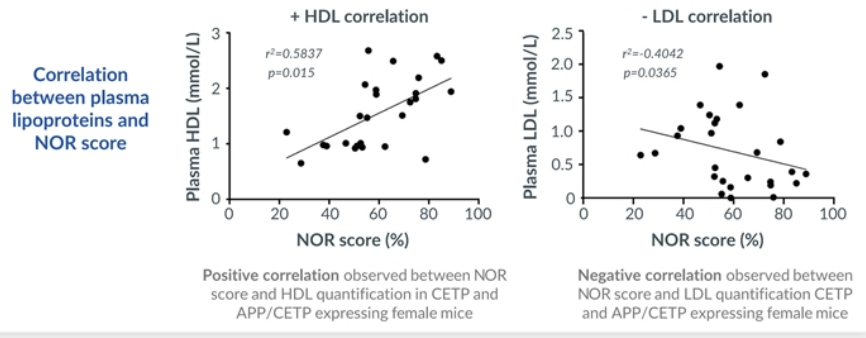
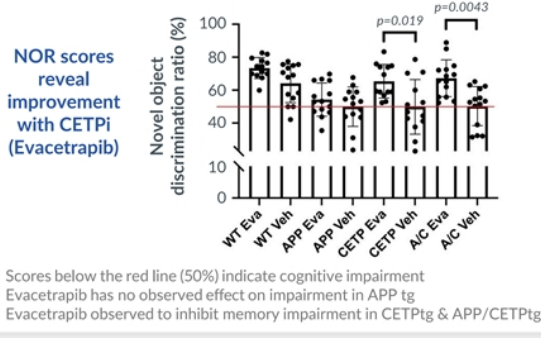
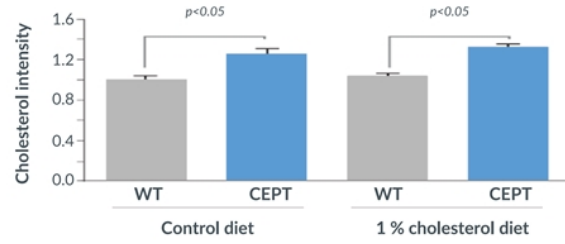
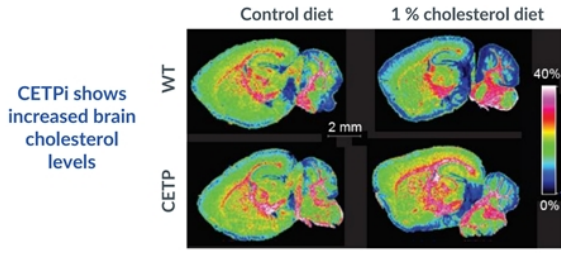


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## Obicetrapib and Alzheimer's Disease



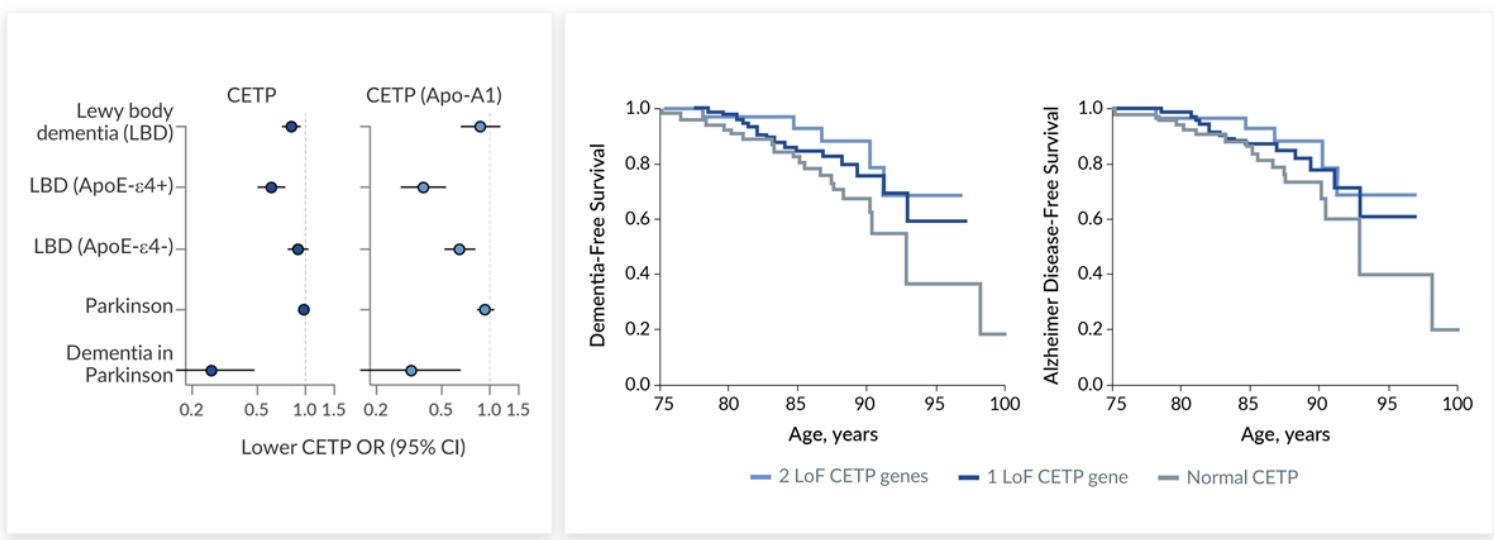
# CETP knock-in mice observed to increase brain cholesterol levels and CETPi rescues cognition in preclinical models of CETP-induced AD





## 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

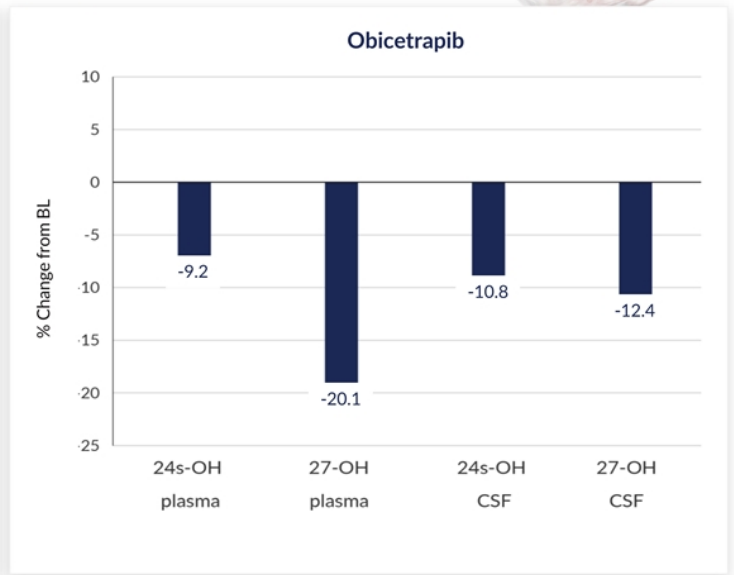
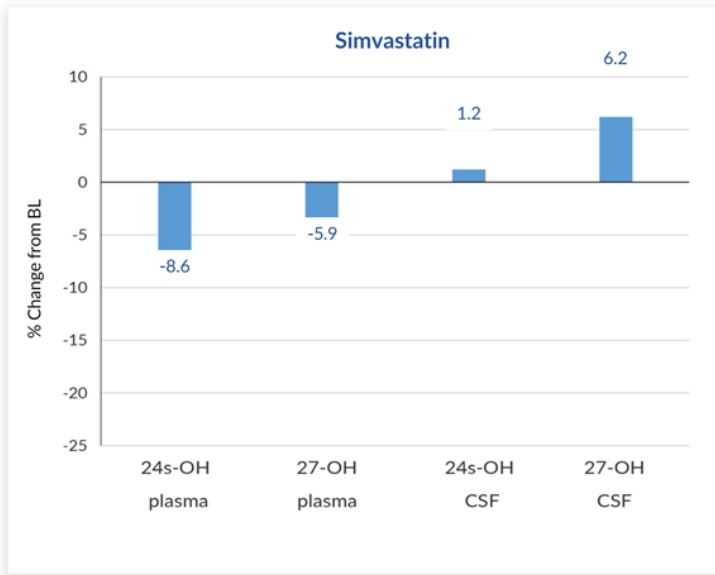
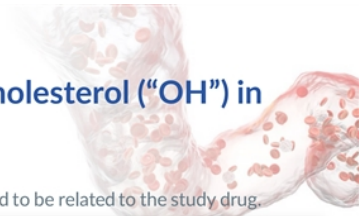






## Initial data for Obicetrapib 10mg observed to decrease 24s- & 27-hydroxycholesterol (“OH”) in both plasma and cerebrospinal fluid (“CSF”)

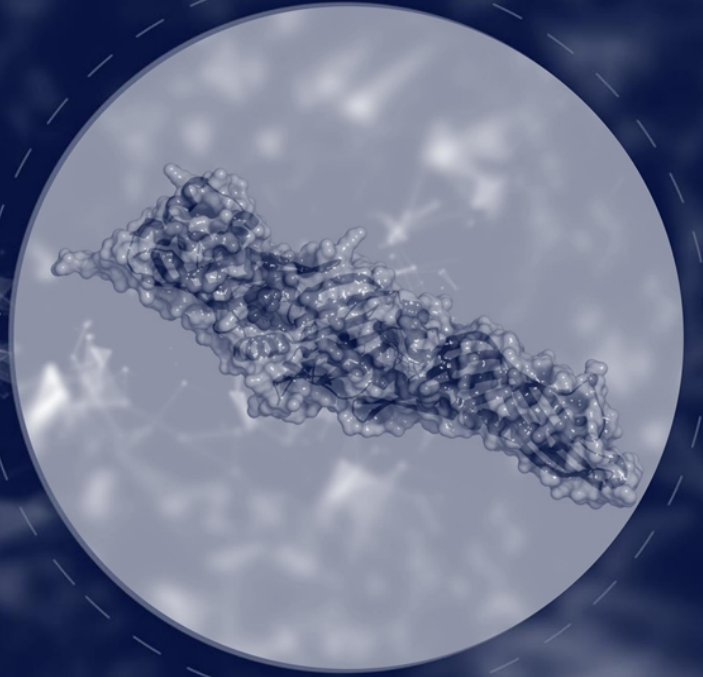
- In separate trials with different protocols and endpoints, Simvastatin was observed to only reduce 24s- and 27-OH in plasma
- Obicetrapib was observed to be well-tolerated. No serious adverse events were reported, nor were any adverse events considered to be related to the study drug.





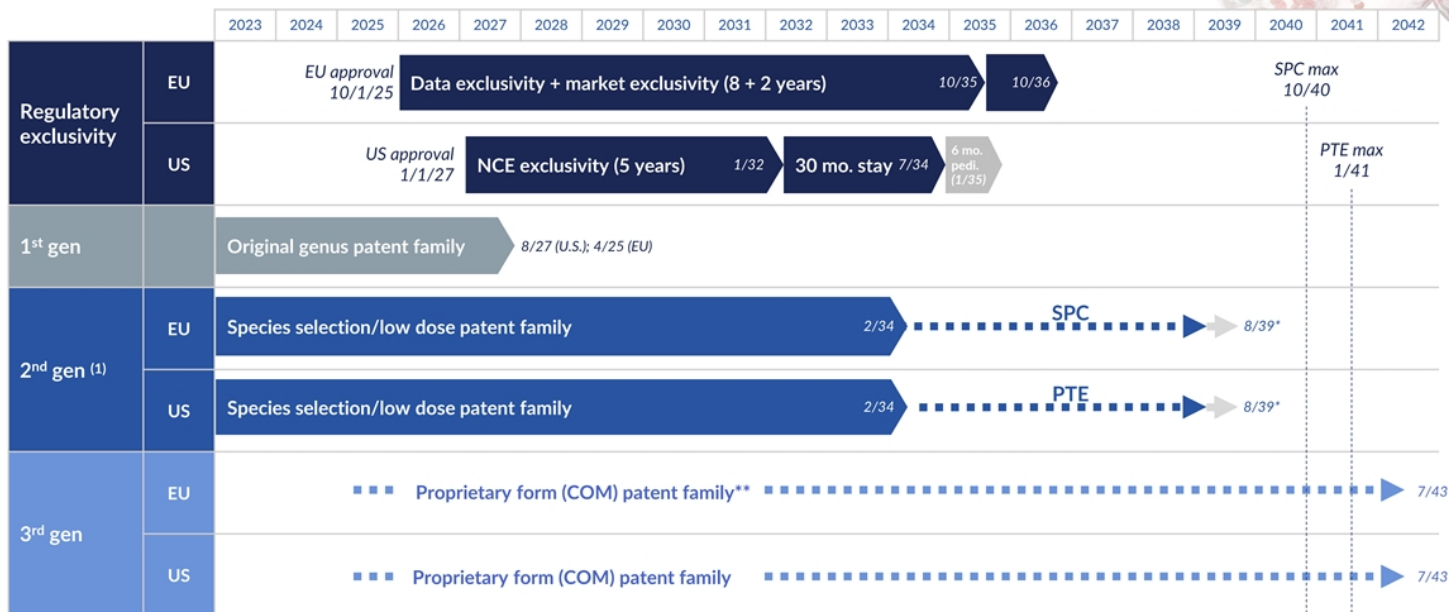
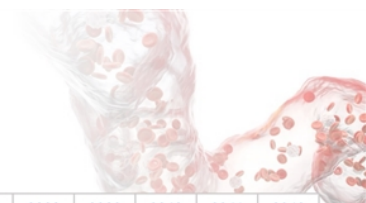
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## Clinical events and exclusivity timelines

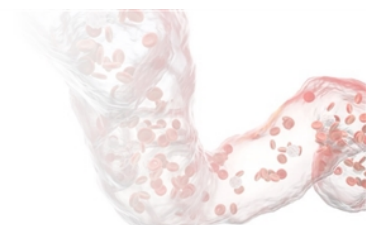


# Projected exclusivity timelines in the EU and US

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



# Expert cardiometabolic leadership supported by top investors



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