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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of August 2023

Commission File Number: 001-41562

NewAmsterdam Pharma Company N.V.
(Exact name of registrant as specified in its charter)

Gooimeer 2-35
1411 DC Naarden
The Netherlands
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

On August 14, 2023, the Company issued a press release announcing it has appointed William “BJ” Jones as Chief Commercial Officer. A copy of the press release is furnished as Exhibit 99.1 to this Report on Form 6-K.

On August 14, 2023, NewAmsterdam Pharma Company N.V. (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 Report on Form 6-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 Report on Form 6-K.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated August 14, 2023.
99.2	NewAmsterdam Pharma Company N.V. Corporate Presentation

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, thereunto duly authorized.

NewAmsterdam Pharma Company N.V.

August 14, 2023

By: /s/ Michael Davidson
Name: Michael Davidson
Title: Chief Executive Officer

NewAmsterdam Pharma Announces Appointment of William "BJ" Jones, formerly of Biohaven Pharmaceuticals, as Chief Commercial Officer

Naarden, the Netherlands and Miami, USA; August 14, 2023 – 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 "BJ" Jones as the company's first Chief Commercial Officer ("CCO"), effective August 14, 2023. Mr. Jones brings 30 years of commercial and launch experience in the U.S. and globally, with particular experience in driving mass market product launch strategies for industry-leading brands. At NewAmsterdam, he will build and lead all commercial functions, including, marketing, market access, sales, medical science engagement and commercial operations.

"We are delighted to welcome BJ to our team. With obicetrapib progressing through pivotal Phase 3 development, now is the right time to begin building a powerful commercial organization, with the potential to deliver our oral, low-dose, once-daily CETP inhibitor, if approved, to the millions of dyslipidemia patients globally in need of better options," said Dr. Michael Davidson, M.D., President & Chief Executive Officer. "BJ is an exceptional leader with a proven track record of building commercial organizations, developing strategic and creative go-to-market strategies, and launching industry-leading products in mass markets, including in the cardiovascular disease space. We believe BJ's expertise uniquely complements our existing team, and we look forward to his leadership as we mature NewAmsterdam into a fully integrated company and work to ultimately deliver on the promise of CETP inhibition to address major unmet needs across cardiometabolic diseases."

Mr. Jones joins NewAmsterdam with three decades of commercial and launch experience in both large pharmaceutical and small biotech companies. Most recently, he served as CCO, Migraine & Common Diseases at Biohaven Pharmaceuticals, which was acquired by Pfizer for $11.6B. During his tenure, Mr. Jones led the commercial enterprise that launched Biohaven's Nurtec® ODT. Earlier in his career, Mr. Jones held leadership roles of increasing responsibility at Takeda Pharmaceuticals, AstraZeneca, Bristol-Myers Squibb, Boehringer Ingelheim and NitroMed, during which time he supported mass market product launches for notable brands including Excedrin Migraine®, Farxiga®, Pradaxa®, BiDil®, and Abilify®. Mr. Jones is a graduate of the United Air Force Academy and attained the rank of Major through his active duty and reserve service. He holds an M.B.A from Stanford Graduate School of Business and an M.S. in Industrial Engineering from Texas A&M University.

"I am excited to be a part of NewAmsterdam Pharma, a company that I believe is uniquely positioned in the quest to alleviate the impact of the world's leading cause of mortality—cardiovascular disease. Based on data reported to-date, I believe obicetrapib, if approved, has the potential to solve a substantial challenge in cardiovascular disease, helping many more patients achieve their risk-based LDL-C goals, while positively impacting a number of other lipid and lipoprotein parameters associated with cardiovascular disease risk," said Mr. Jones. "I look forward to leveraging my experience to build NewAmsterdam's commercial team and operations and to partnering with the management team to unlock obicetrapib's value as a potentially safe and effective oral therapy that could change the treatment paradigm for patients worldwide."

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,” “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, the Company’s commercial opportunity, 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 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, including the Russia-Ukraine conflict; the effects of competition on the Company’s future business; and those factors described in the Company’s public filings with the Securities 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.

Company Contact

Matthew Philippe
matthew.philippe@newamsterdampharma.com

Media Contact

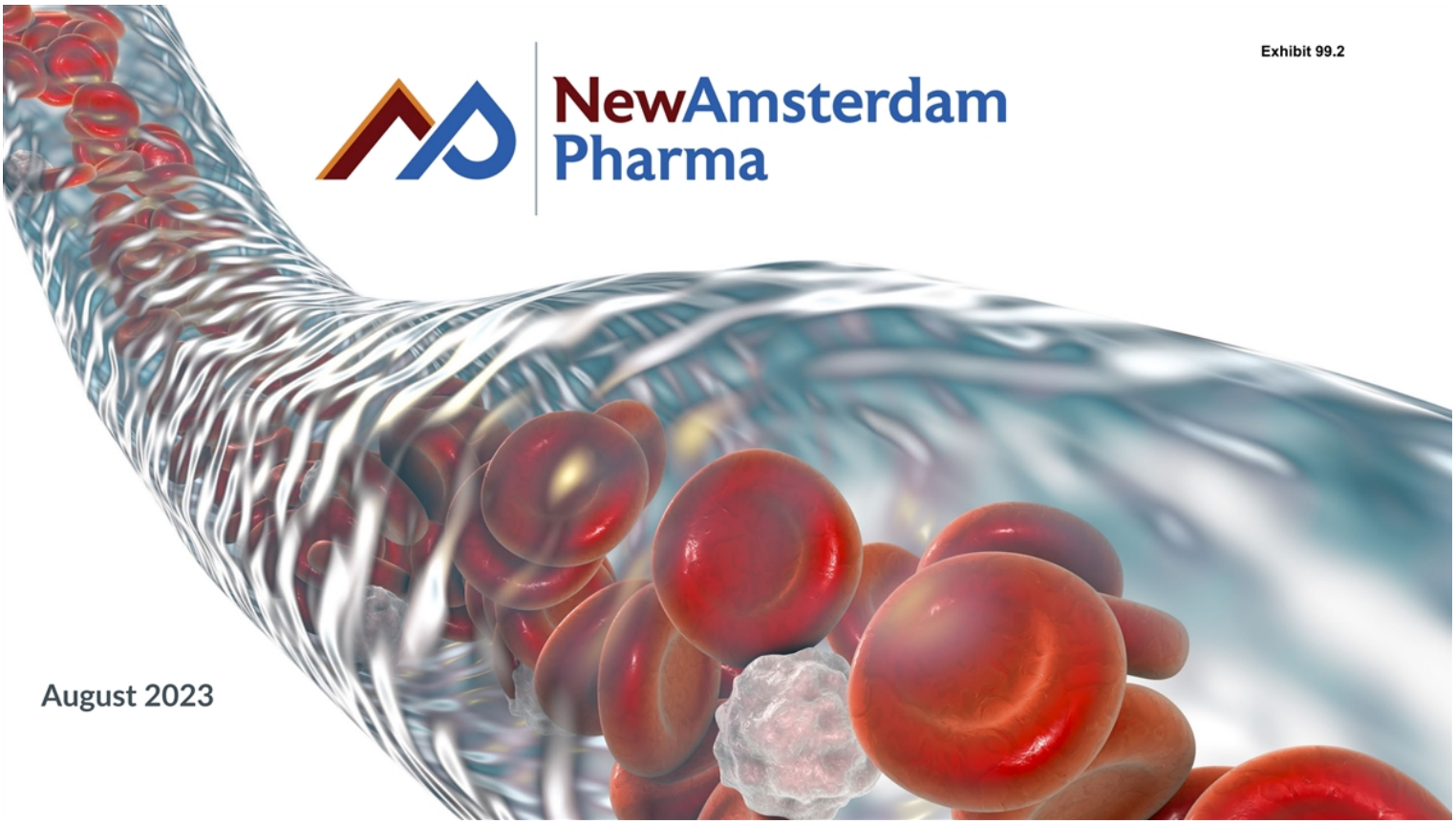
Spectrum Science on behalf of NewAmsterdam
Jenn Gordon
P: 1-202-957-7795
jgordon@spectrumscience.com

Investor Contact

Stern Investor Relations on behalf of NewAmsterdam
Hannah Deresiewicz
P: 1 212-362-1200
hannah.deresiewicz@sternir.com

Exhibit 99.2

NewAmsterdam Pharma



August 2023

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.

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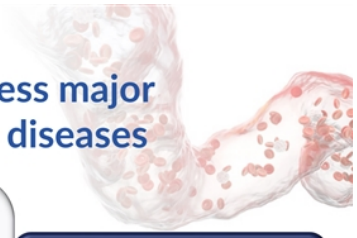
Market Data

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.

NewAmsterdam is developing oral obicetrapib as CETPi to address major unmet need in hypercholesterolemia and other cardiometabolic diseases



Company history:

- Mid-'20: **Founded** after spin-out from Amgen
- Jan '21: **~$196M Series A**
- June '22: **>$1B European license** with Menarini Group (including €142.5M committed capital + significant back-end economics, 1st milestone achieved in 2023)
- Nov '22: **Nasdaq listing** (*NAMS*) with **$328M total proceeds** ($93M from FLAC trust in deSPAC, plus $235M PIPE co-lead by Frazier and Bain)
- Jun '23: **~$1B market cap** and **$424M cash**

OBICETRAPIB

- **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
- **Simple, oral, once-daily, low dose** CETP inhibitor with strong LDL-lowering observed through Phase 2b:
  - **~50%** LDL-lowering as monotherapy, **~63%** in combination with ezetimibe, observed on top of high-intensity statins
  - Tolerability data in **>800 pts**
  - Robust effects on **ApoB, non-HDL-C, HDL-C and Lp(a)**
- **Convenient oral format + expected low cost of goods sold** (COGS) potentially enables broad market access strategy to address existing unmet need

>35M addressable patient population

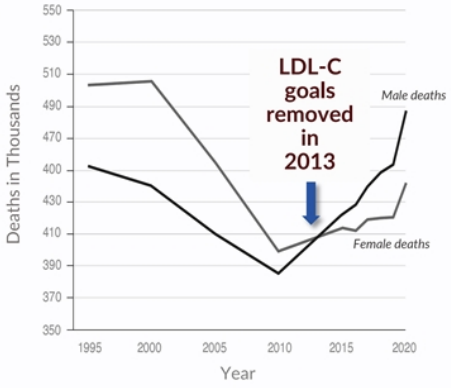
~63% LDL-lowering observed in Phase 2b

$4B+ global market opportunity

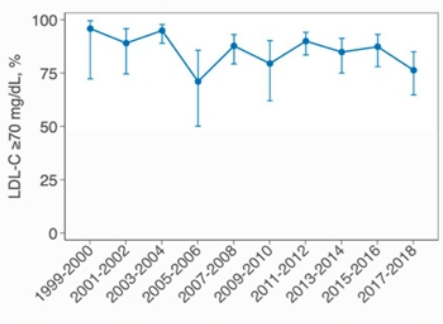
Achievements and milestones:

- **Expected funding through 2026** including CVOT readout
- **Ph3 enrollment completed** for BROOKLYN in 2Q23 (ahead of schedule); other studies on track
- **Late-stage inflection points** expected from 2023-2025 (including Phase 2 & 3 clinical readouts and registrational filings)
- **Pipeline expansion** potential in Alzheimer's disease and diabetes

Despite availability of statins, tremendous unmet need remains – with resurgance of the "lower-is better" paradigm

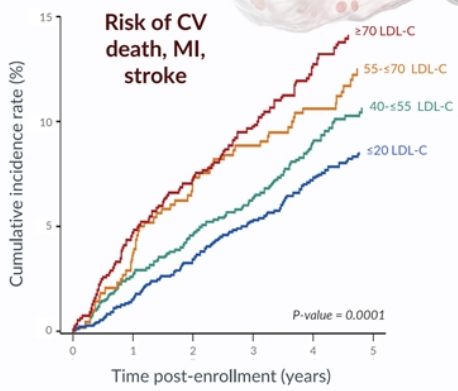


Despite statins, **CVD deaths are on the rise**



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

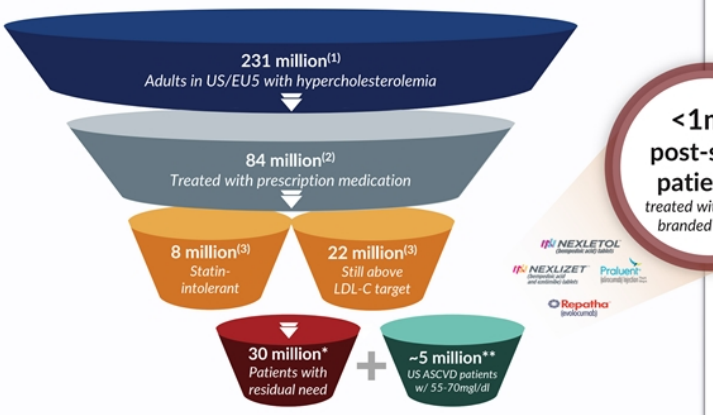
~75% of ASCVD patients are NOT at their **risk-based LDL-C goal**



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

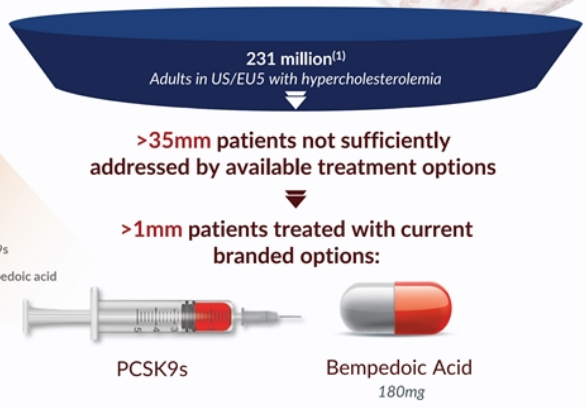
Sources: Trinity NewAmsterdam Market Research Summary; Trinity quantitative market research with N = 100 PCPs and Cardiologists; Bloomberg Prescription Data; IQVIA Rx Tracker. (1) Literature review suggesting hypercholesterolemia prevalence of ~94mm in the US (average of He et al. 2020, Mercado et al. 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.

Obicetrapib has potential to solve a substantial unmet medical need in dyslipidemia



Key factors limiting penetration include **product limitations** and **market access** hurdles

***Based on estimated from Company's analysis of in new U.S. guidance lowering LDL-C goals to 55 mg/dL for very high-risk patients, which could potentially grow addressable patient population*



THE PROBLEM

- **Payors highly restrict access**
- **Low prescriber enthusiasm for existing TPPs**

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Sources: (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). (2) Value derived from top-down epidemiology-based market model for obicetrapib; assumptions derived from secondary research / literature and primary market research with US and EU5 physicians and payers.

Currently approved post-statin LDL-lowering products all fall short of the profile patients need

	Nexletol	PCSK9i	Oral PCSK9	Patients need a drug that fits the following profile:
Efficacy	Modest[1]	Strong	Potentially strong, but significant food effect	Strong[1]
Administration/ Dose	Oral, High Dose 180mg	Injectable, High Dose ~140-150mg	Oral, Large Pill 30mg API + >100mg snac	Oral, Low Dose
Market Access/ Price	Branded Price, Limited Access	Very High Price, Highly Restricted Access (High COGS)	High COGS, likely high price	Disruptive Price, Broad Access (Low COGS)
Safety & Tolerability	FDA Label: Tendon rupture & gout warning	Safe Painful injection site reactions	SNAC technology has previously been observed to have tolerability concerns [2]	Safe, Well-Tolerated
Ancillary Benefit(s)	None	Modest Lp(a) Lowering	Potentially modest Lp(a) Lowering	Strong Lp(a) lowering, HDL raising has potential benefits in Alzheimer's and diabetes

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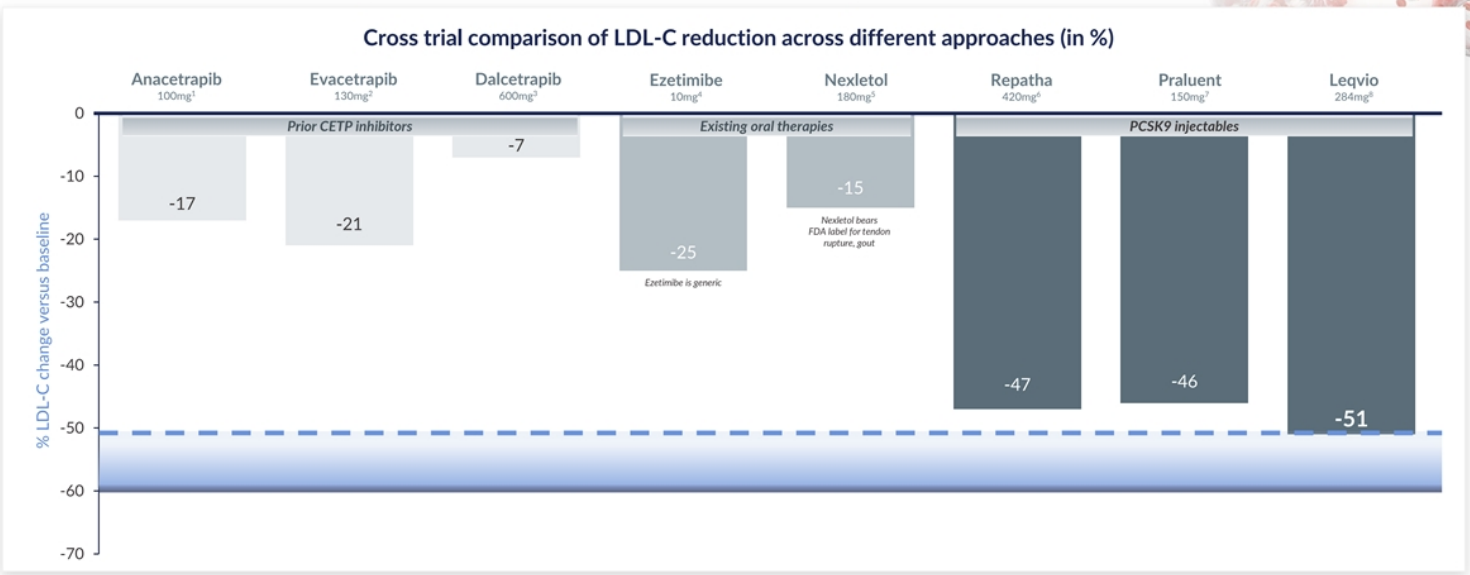
Note: Novartis' stated price of Inclisiran to be approximate to net prices of PCSK9 mAbs.
(1) Lighter shaded region of bar chart represents the additional potential efficacy for fixed dose combinations with ezetimibe. (2) MK-0616 was observed to have AEs comparable to placebo Phase2b trials

~50% LDL-C reduction efficacy would be virtually identical to PCSK9 injectables and is substantially better than other oral therapies



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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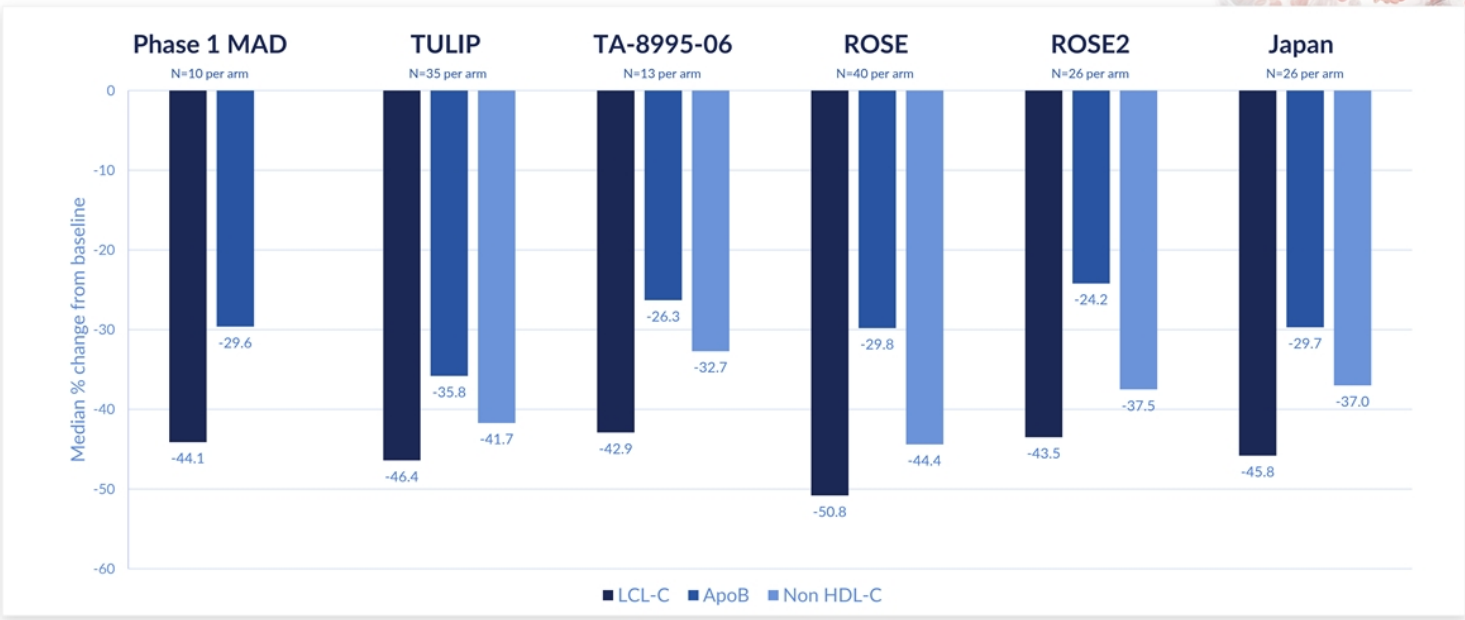
Changes in lipid biomarkers for obicetrapib 10mg monotherapy across phase 1/2 studies



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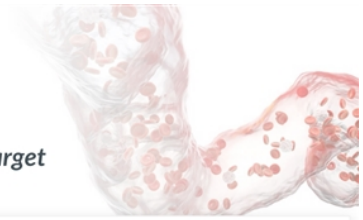
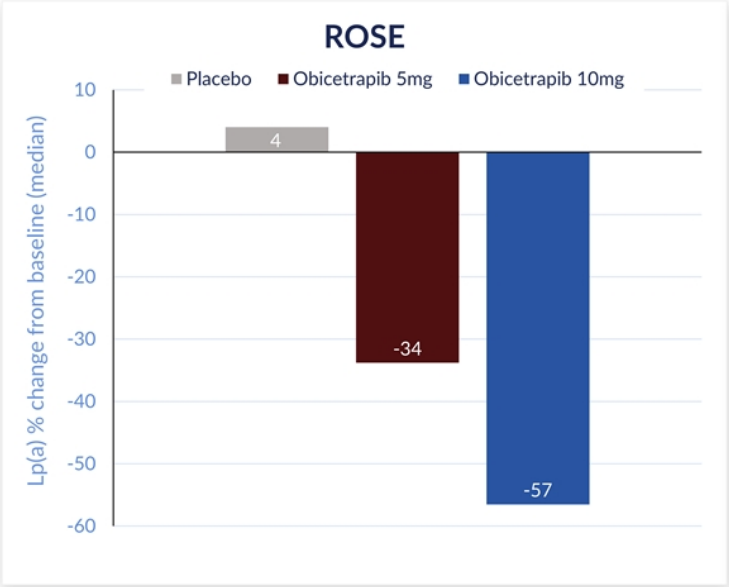
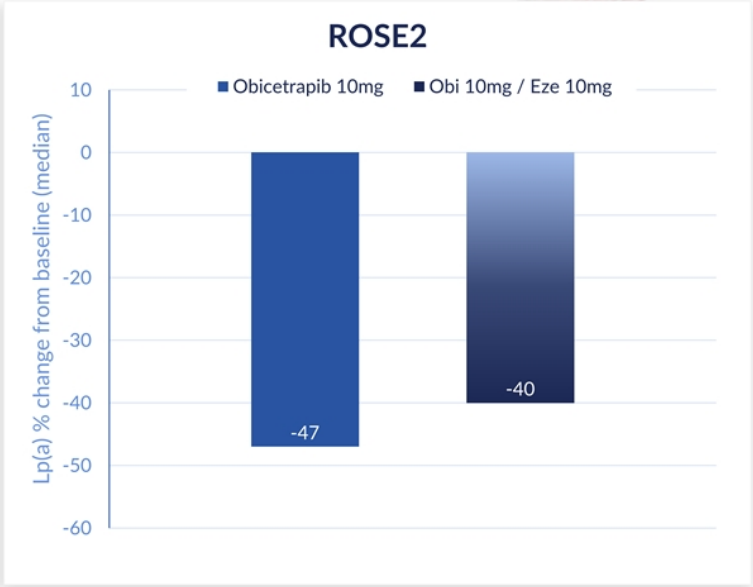
Lp(a) percent reduction from baseline in ROSE[1] and ROSE2[2]

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







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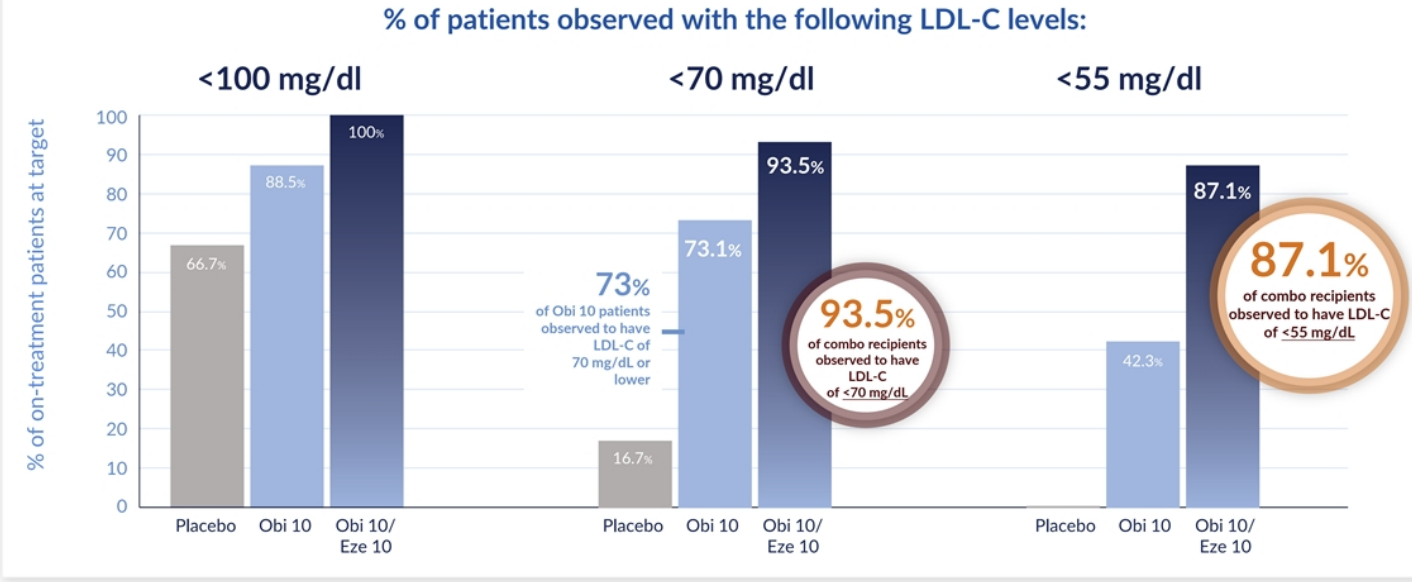
Source: 1. Nicholls SJ, et al. Nat Med 2022;28:1672-1678. 2. Ballantyne CM, et al. J. of Clinical Lipidology 2023 (to be published June 3, 2023)

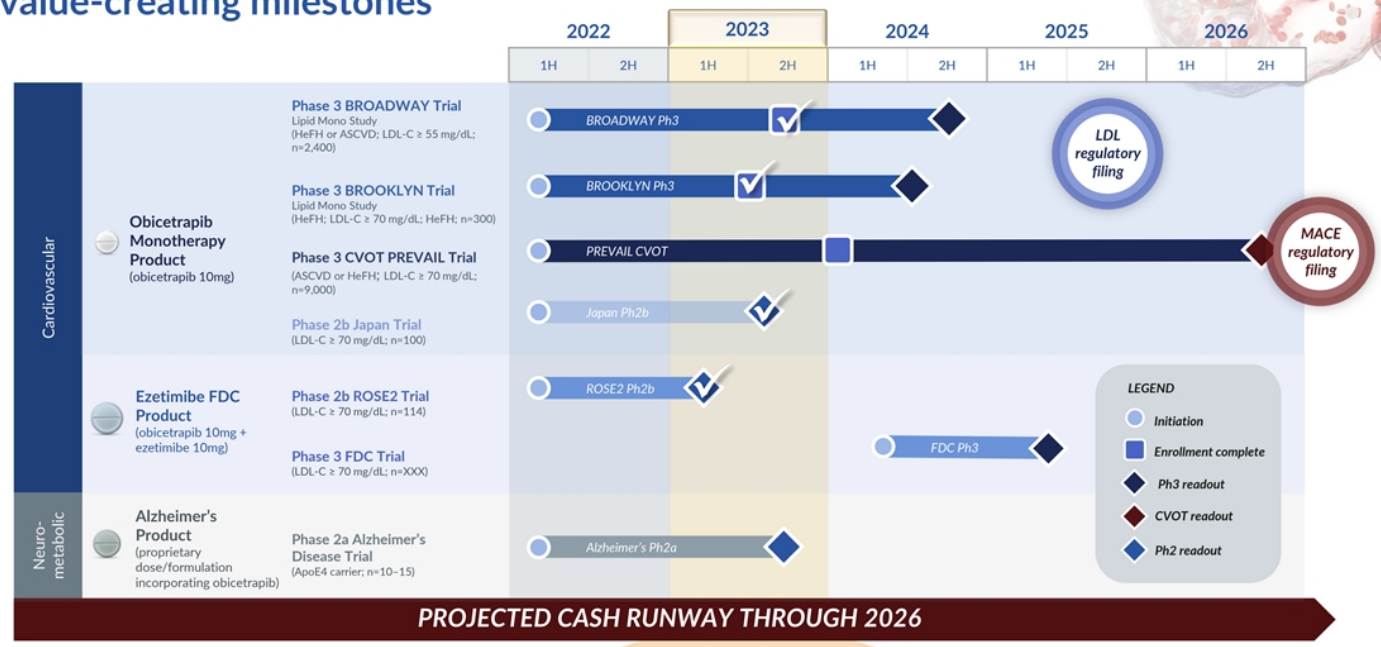
Exceptional LDL goal attainment observed with ezetimibe + obicetrapib combination, including >87% of patients observed to attain <55 mg/dl LDL-C levels



NewAmsterdam Pharma

Source: Ballantyne CM, et al. J. of Clinical Lipidology 2023 (to be published June 3, 2023)

Current cash expected to fund obicetrapib development through several value-creating milestones



NewAmsterdam Pharma

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.

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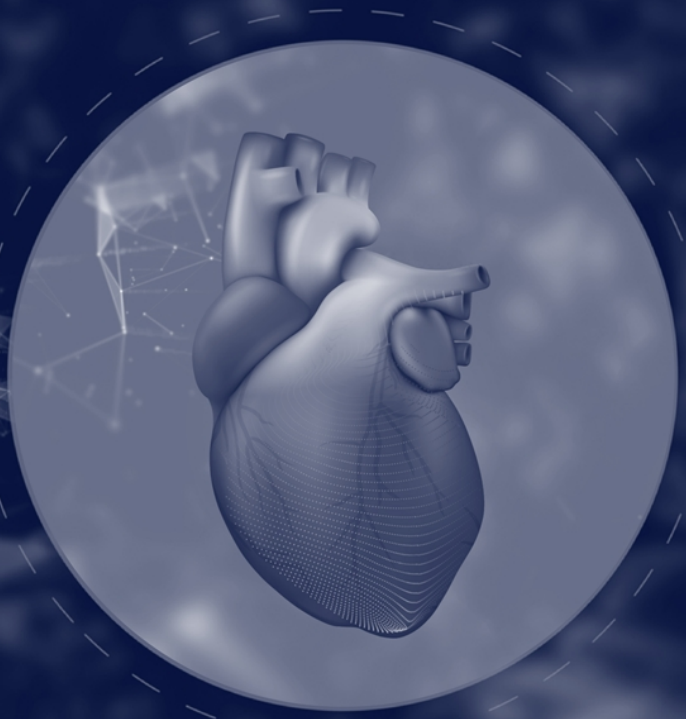
Obicetrapib for Cardiovascular Disease



ROSE2 study: Obicetrapib and high intensity statin (HIS) therapy

Objective: To evaluate the effect of obicetrapib 10 mg in combination with ezetimibe 10 mg on top of HIS on LDL-C

Inclusion criteria

- A stable dose of High Intensity Statins (A 40 / 80; R 20 / 40) 8 weeks prior to screening
- Fasting LDL-C levels >70 mg/dL (1.8 mmol/L)

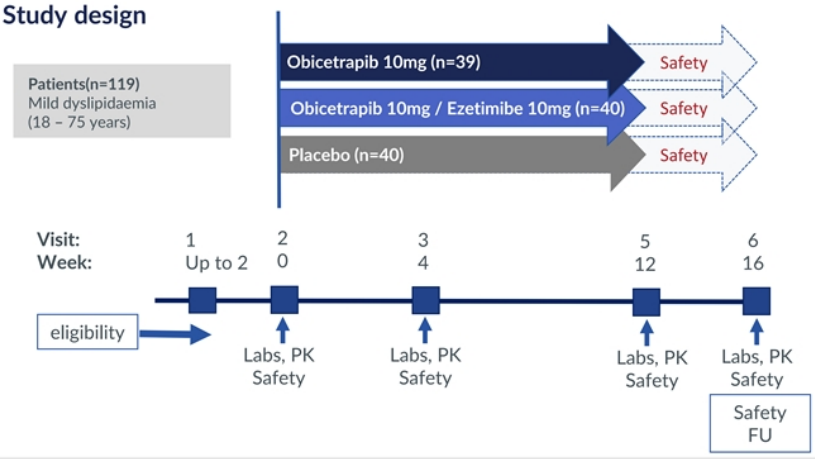
Exclusion criteria

- Current significant CV disease
- HbA1c ≥10%
- Uncontrolled hypertension

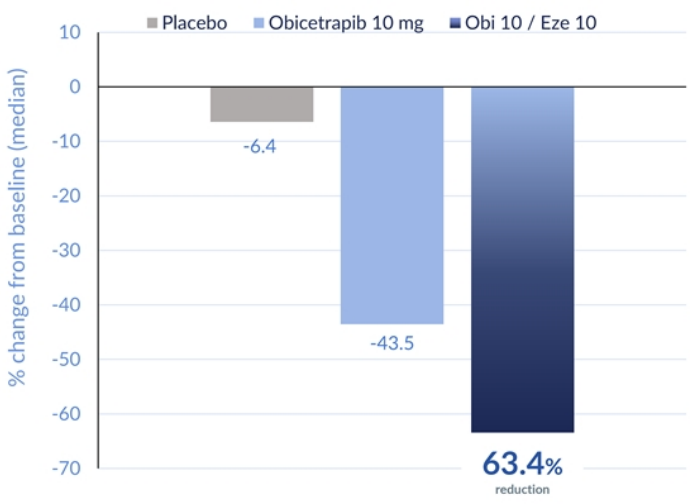
Primary efficacy endpoint

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

Study design



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

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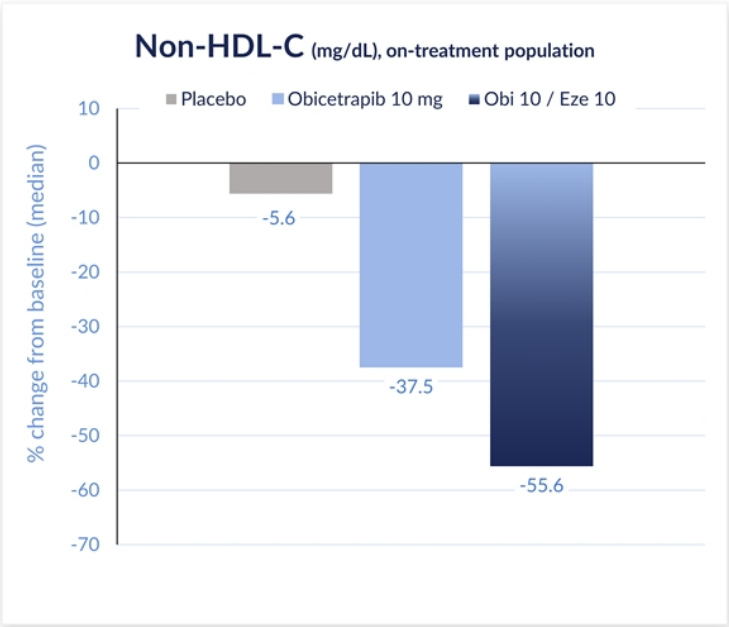
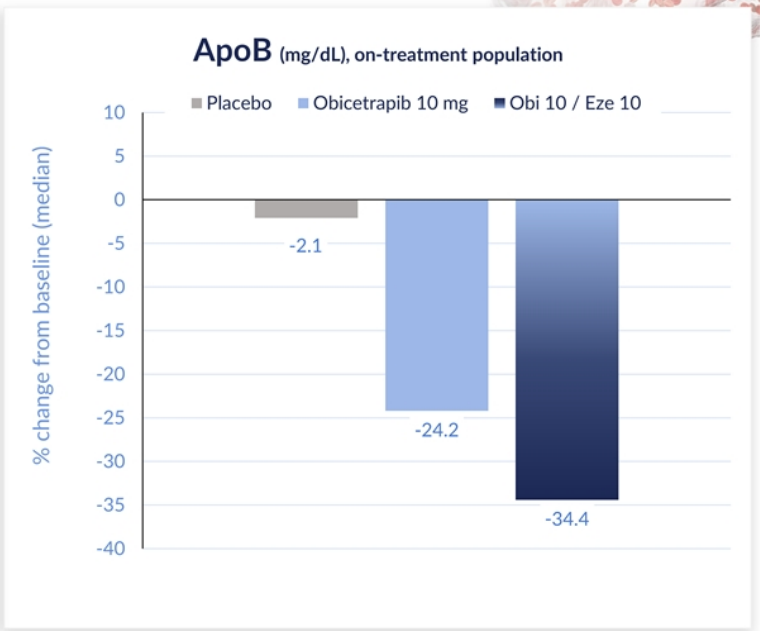
Source: Ballantyne CM, et al. J. of Clinical Lipidology 2023 (to be published June 3, 2023)

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

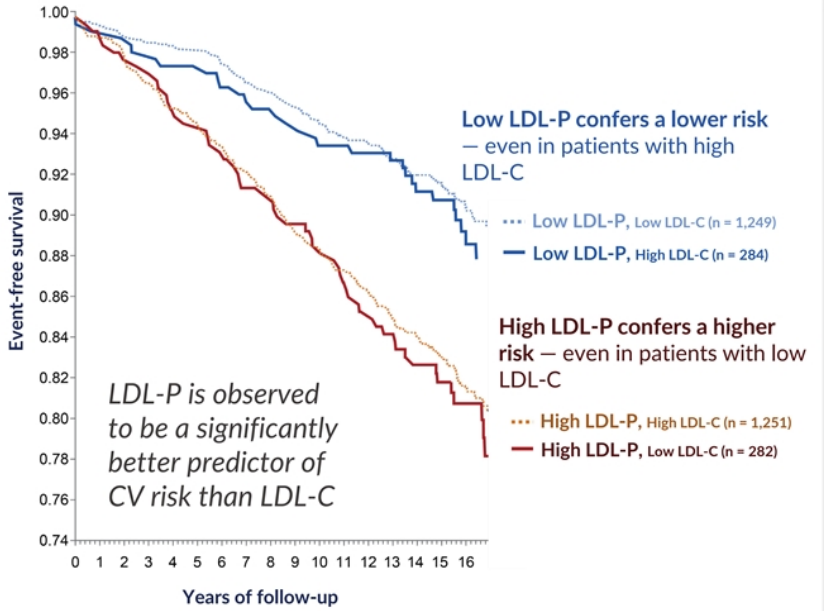




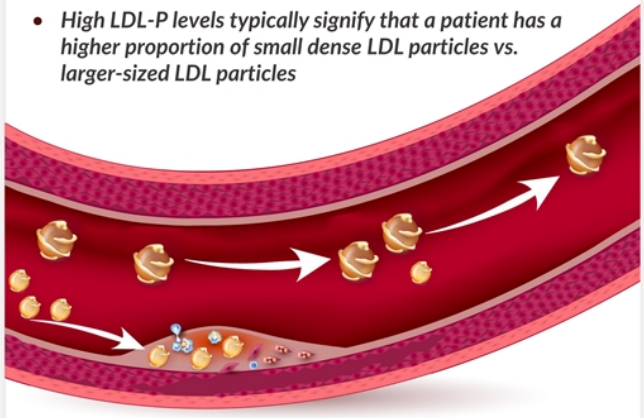
NewAmsterdam Pharma

Source: Ballantyne CM, et al. J. of Clinical Lipidology 2023 (to be published June 3, 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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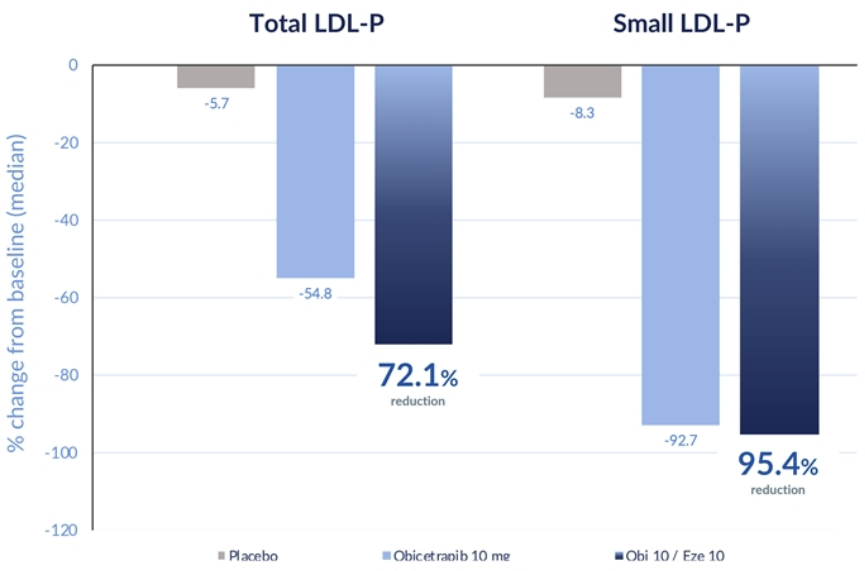
Source: Cromwell WC, et al. Clin Lipidol. 2007 December 1; 1(6): 583–592

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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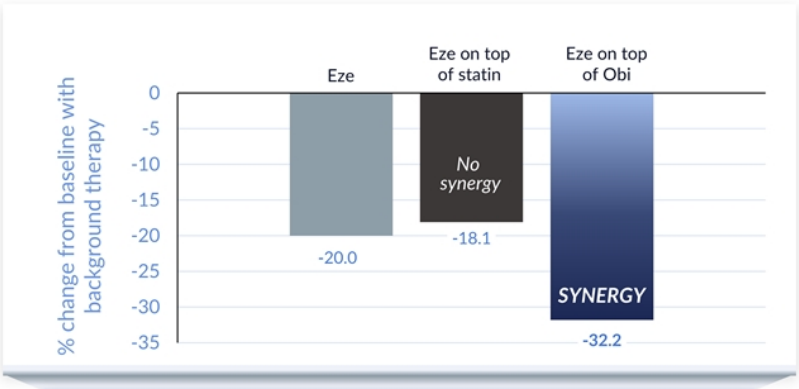
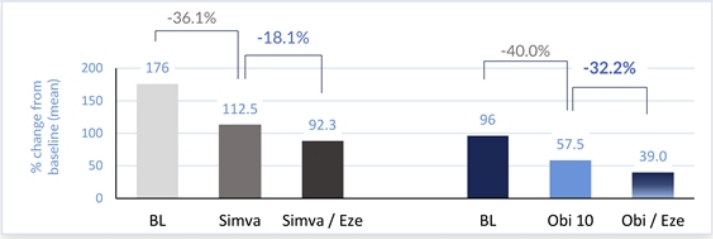
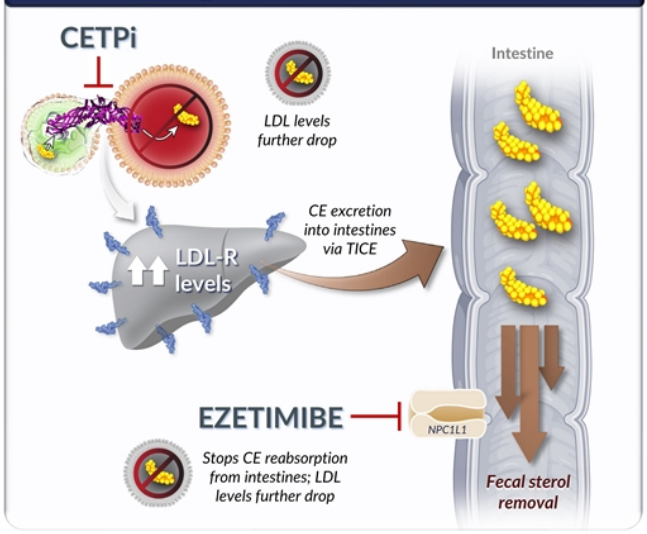
Sources: 1. Ballantyne CM, et al. J. of Clinical Lipidology 2023 (to be published June 3, 2023), 2. LipoFraction NMR practitioner Guidelines

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 (to be published June 3, 2023)
Note: The calculations included in the graphs here represent the Company's hypothetical calculation assuming one patient was treated with each drug independently.

ROSE2 Safety: TEAEs, TESAEs, and withdrawal overview (safety population)

	Placebo N= 40, N (%)	Obicetrapib 10 mg N= 39, N (%)	Obi 10 mg / Eze 10 mg N= 40, N (%)
TEAEs (%)			
TEAEs	16 (40)	8 (20.5)	11 (27.5)
Related TEAEs	2 (5.0)	4 (10.3)	5 (12.5)
Severe TEAEs	2 (5.0)	1 (2.6)	0 (0)
TESAEs			
TESAEs, total	1 (2.5)	1 (2.6)	0 (0)
Deaths	0	0	0
Withdrawal's study / medication			
TEAEs leading to discontinuation of study drug	2 (5.0)	2 (5.1)	1 (2.5)

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Source: Ballantyne CM, et al. J. of Clinical Lipidology 2023 (to be published June 3, 2023)

Obicetrapib safety profile in ROSE and across multiple studies: overview of AEs, SAEs and withdrawals

Clean safety profile; Similar rates of drug discontinuation were observed for obicetrapib and placebo

ROSE Safety	Placebo (N=40)	Obicetrapib, 5mg (N=40)	Obicetrapib, 10mg (N=40)
TEAEs (%)			
TEAEs, total	19 (47.5)	15 (37.5)	8 (20.0)
TEAEs, related	4 (10.0)	2 (5.0)	1 (2.5)
TEAEs, severe	1 (2.5)	0	0
TESAEs			
TESAEs, total	2 (5.0)	0	0
TESAEs, related	0	0	0
Deaths	0	0	0
Withdrawals study / medication			
TEAEs leading to discontinuation of study drug	1 (2.5)	0	0

Pooled Safety	Comparator[1] (N=231)	Obicetrapib Pooled 5mg + 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)

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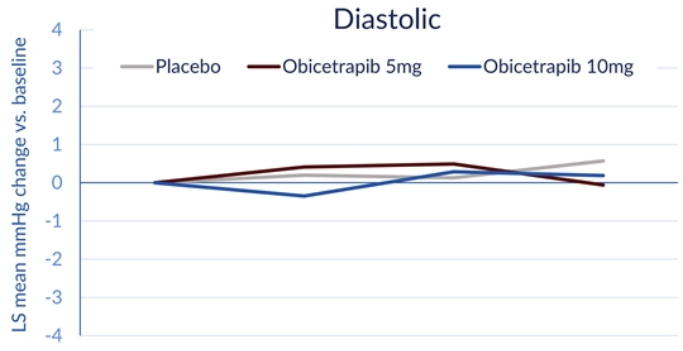
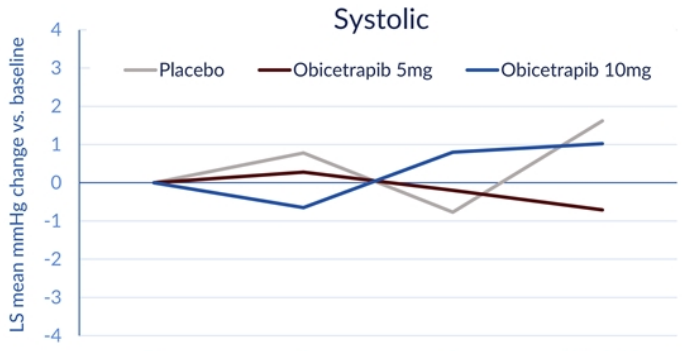
* There were three additional TESAEs in other obicetrapib dose arms: two in the TULIP 2.5mg arm, and one in the Lp(a) 2.5mg arm; none were considered to be related to study drug.
(1) The Comparator group included patients receiving placebo and non-obicetrapib monotherapy.
(2) The pooled obicetrapib group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





	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
Placebo (N)	229	222	180	157
Obi 5 mg (N)	135	134	130	63
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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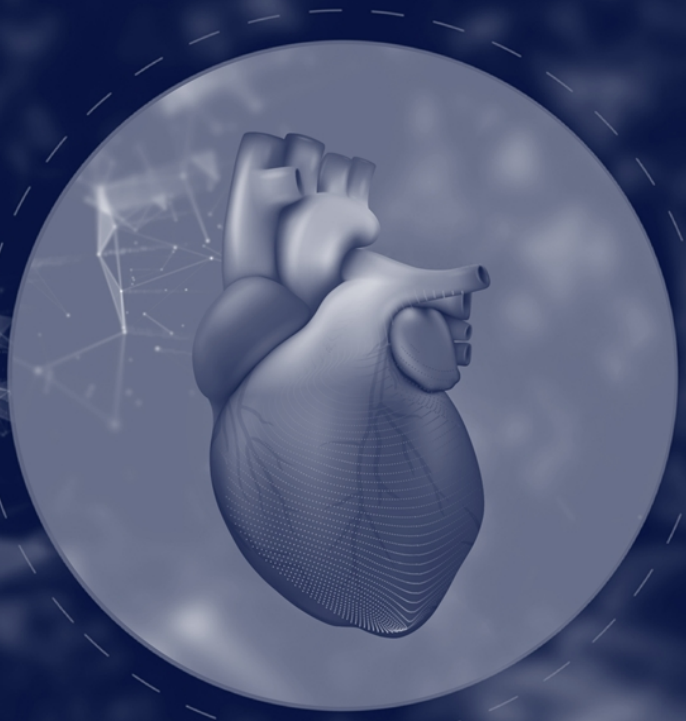
Target biology and class overview:
Key lessons learned



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 6.4 year follow up)*	
EVACETRAPIB[3] *Overall mortality benefit (P =.04)* – but CVOT was too short to demonstrate MACE benefit (Lilly)	Safe & well-tolerated		Baseline LDL too low *(60 mg/dL)*	
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

- ✓ **~50% LDL-LOWERING OBSERVED IN PHASE 2B**
- ✓ **~63% 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 >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.
(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

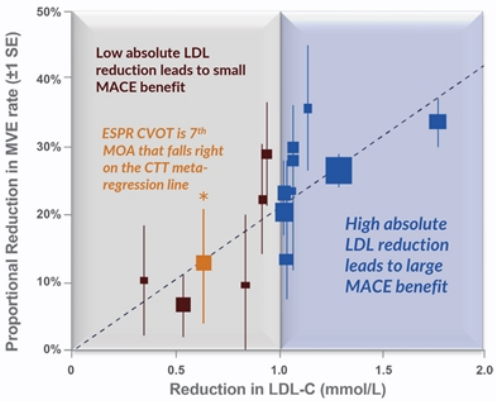
Absolute reduction of LDL-C and ApoB, and *duration* of that reduction are believed to be key to reducing cardiovascular risk

MACE benefits impacted by 2 key factors:

- ABSOLUTE REDUCTION
- STUDY DURATION

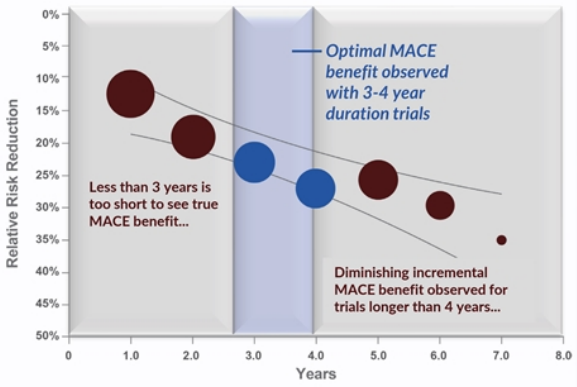
Key factor 1: Absolute reduction

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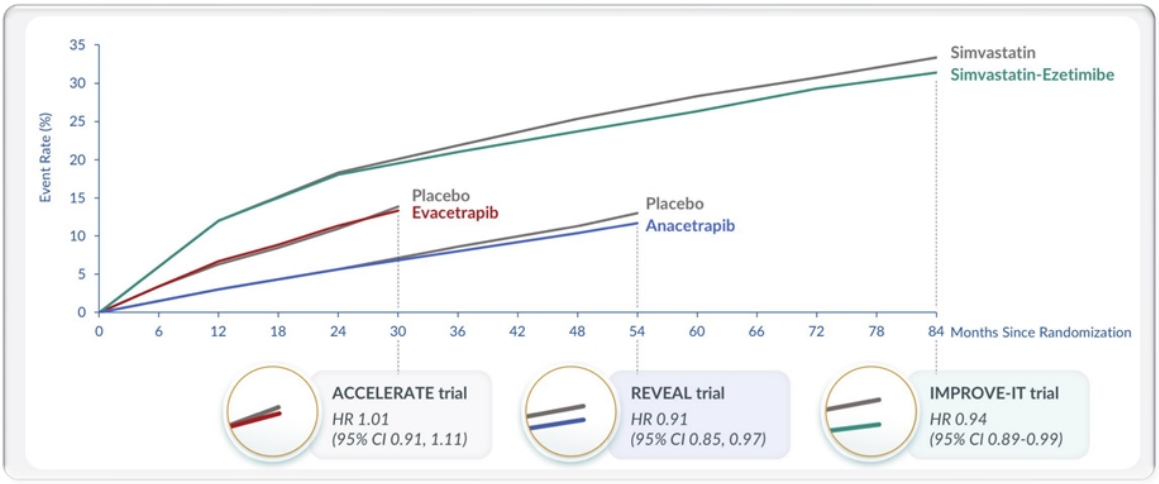
Sources: American Heart Association, CDC, Mayo clinic, Global Health estimates 2016: Deaths by Cause, Age, Sex, by Country and by Regio, 2000-2016, Geneva, WHO; 2018. Lancet 2005;366:1267-78; Silverman MG, et al. JAMA 2016;27:1289-1297. * ESPR CVOT depiction based on ACC 2023 presentation, drawn as approximation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

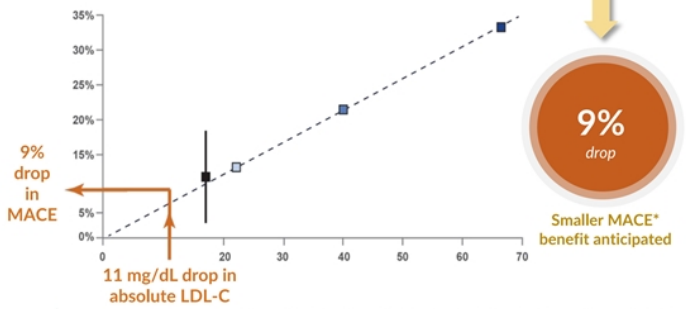
EXPERIENCE: *REVEAL (anacetrapib)*

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

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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.

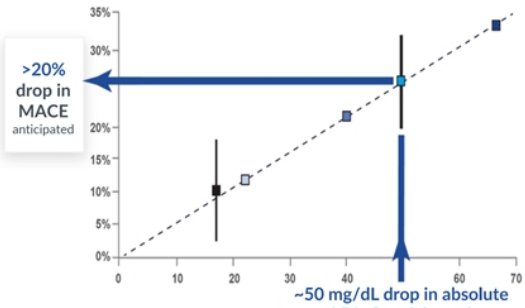
PREDICTION: *PREVAIL (obicetrapib)*

~110 mg/dL(1) × 45% *anticipated* = ~50 mg/dL

Enrich for higher baseline

Stronger expected LDL-lowering %

Expected to result in more absolute LDL reduction



>20% *drop anticipated*

Bigger expected MACE** benefit

Note: Actual results may differ from expectations.

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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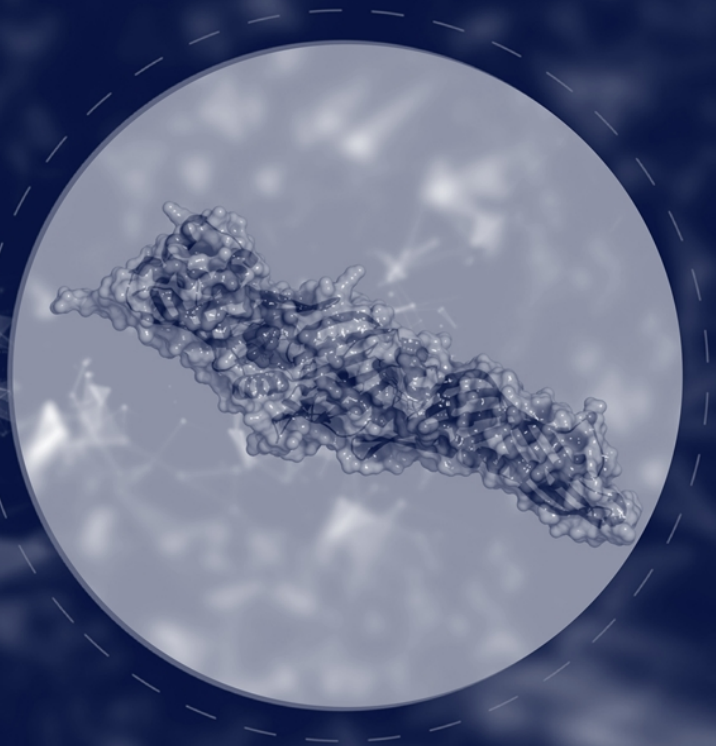
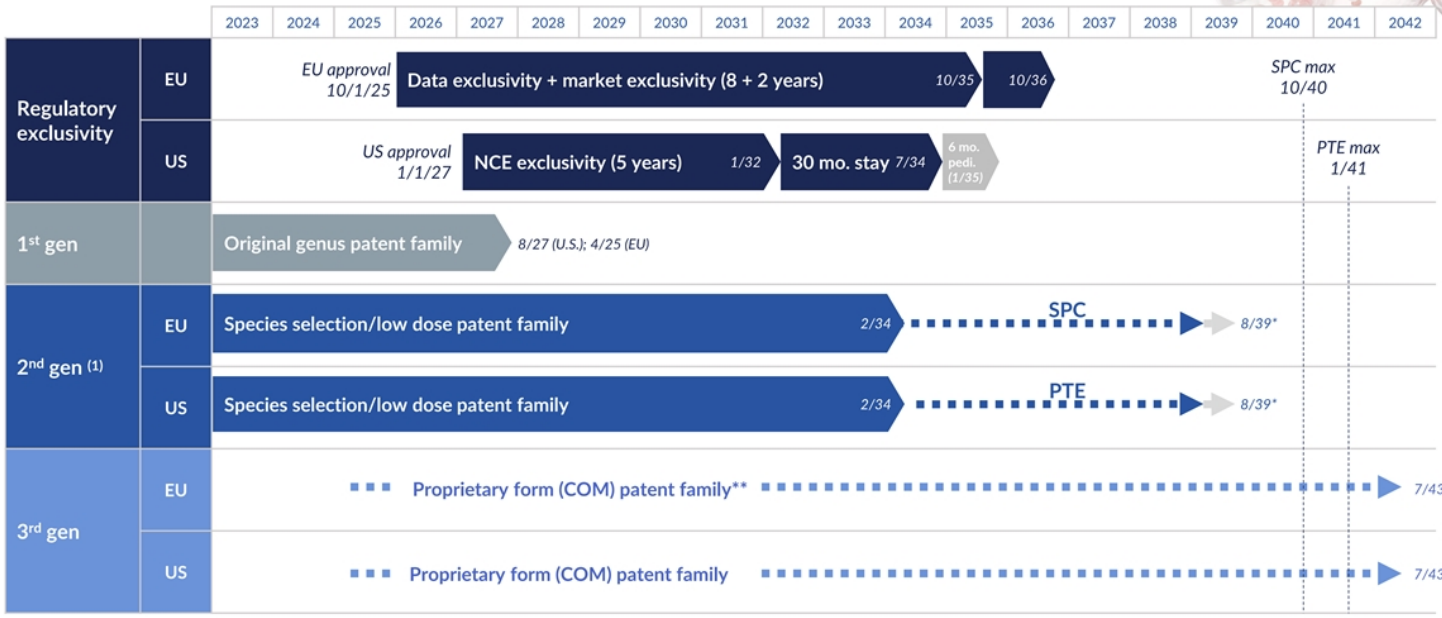
Clinical events and exclusivity timelines



Projected exclusivity timelines in the EU and US

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



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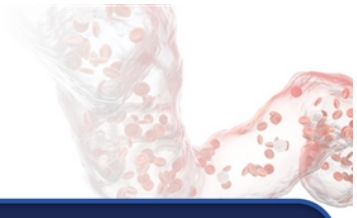
Note: Dates for information purposes only, Filled colors = granted patents & dotted lines = pending patents; one patent only to be selected for SPC/PTE; an earlier US approval leads to earlier regulatory expiry & shorter PTE; *including pediatric extension 6m; ** will be pending once a PCT application 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

Achieved and anticipated upcoming 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[1]
- Topline Japan Phase 2b results ✓
- Topline Alzheimer's Phase 2 results ✓
- Select formulation for FDC Phase 3 trial ✓

2024

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

2H 2024[1]
- Announce BROOKLYN Phase 3 topline ✓
- Announce BROADWAY Phase 3 topline ✓

1 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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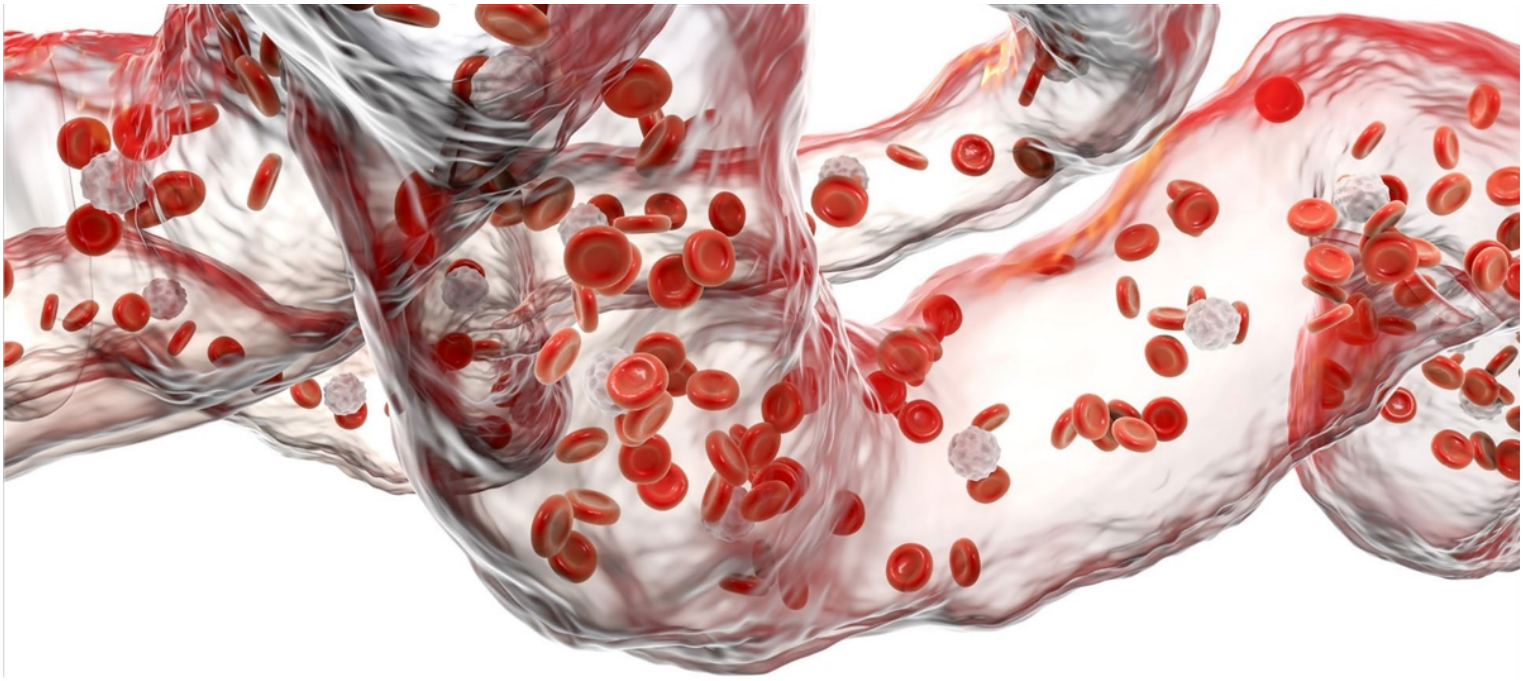

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