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

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**FORM 6-K**

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

For the month of June 2023

Commission File Number: 001-41562

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

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

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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):

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On June 3, 2023, NewAmsterdam Pharma Company N.V. (the “Company”) issued a press release announcing data from its Phase 2 ROSE2 trial evaluating obicetrapib in combination with ezetimibe as an adjunct to high-intensity statin therapy. A copy of the press release is furnished as 99.1 to this Report on Form 6-K.

On June 5, 2023, the Company issued a press release announcing topline results from its Phase 2b dose-finding trial evaluating obicetrapib in Japanese patients. A copy of the press release is furnished as Exhibit 99.2 hereto.

A copy of the Company’s most recent corporate presentation is furnished as Exhibit 99.3 to this Report on Form 6-K.

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EXHIBIT INDEX

Exhibit No.	Description
99.1	<a href="#">Press Release, dated June 3, 2023.</a>
99.2	<a href="#">Press Release, dated June 5, 2023.</a>
99.3	<a href="#">NewAmsterdam Pharma Company N.V. Corporate Presentation.</a>

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**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.

June 5, 2023

**NewAmsterdam Pharma Company N.V.**

By: /s/ Michael Davidson

Name: Michael Davidson

Title: Chief Executive Officer

**NewAmsterdam Pharma Presents Full Data from Phase 2 ROSE2 Trial Evaluating Obicetrapib in Combination with Ezetimibe as an Adjunct to High-Intensity Statin Therapy at NLA Scientific Sessions 2023**

— Met Primary Endpoint with 63.4% Median Reduction in LDL-C ( $p < 0.0001$ ) —

— 87.1% of Patients Treated with Combination of Obicetrapib and Ezetimibe Met Guideline-Recommended LDL-C Goal of  $< 55$  mg/dL compared to 0% of Patients Treated with Placebo ( $p < 0.05$ ) —

— New Data Demonstrate Statistically Significant and Clinically Meaningful Improvements in Additional Lipid and Lipoprotein Parameters Predictive of Cardiovascular Disease Risk, Such as LDL Particles and Lipoprotein(a) —

— Favorable Safety and Tolerability Observed —

— Selected Fixed-Dose Combination Tablet Formula; Phase 3 Trial Expected to Initiate 1Q 2024 —

— Management to Host Conference Call at 8:00 a.m. ET on Monday, June 5, 2023 —

NAARDEN, the Netherlands and MIAMI, June 3, 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 (“CVD”) with residual elevation of low-density lipoprotein cholesterol (“LDL-C” or “LDL”), for whom existing therapies are not sufficiently effective or well-tolerated, today announced the full results of ROSE2, a Phase 2 clinical trial evaluating obicetrapib, the Company’s oral, low-dose and once-daily cholesteryl ester transfer protein (“CETP”) inhibitor, in combination with ezetimibe as an adjunct to high-intensity statin therapy. The data are being presented in an oral late-breaker presentation today at the National Lipid Association (“NLA”) Scientific Sessions 2023 and will be published concurrently in the *Journal of Clinical Lipidology*.

ROSE2 met its primary and secondary endpoints, with statistically significant and clinically meaningful reductions in LDL-C and apolipoprotein B (“ApoB”) observed. Statistically significant improvements in lipoprotein(a) (“Lp(a)”), non-HDL cholesterol (“non-HDL-C”) and total and small LDL particles were also observed. In addition, the combination of obicetrapib and ezetimibe was observed to be well-tolerated, with a safety profile observed to be comparable to placebo. With these data in hand, the Company has selected a formulation for a fixed-dose combination tablet and intends to advance the compound into a Phase 3 trial in the first quarter of 2024.

“The 2022 ACC Expert Consensus Decision Pathway has recommended that very high risk patients with LDL-C above 55mg/dl need additional therapy to maximize proven risk reduction. With these new recommendations, many more patients will fail to achieve guideline-mandated LDL-C goals, demonstrating the limitations of existing therapeutics and the critical need for new options,” said Christie M. Ballantyne, M.D., Chief of Cardiovascular Research and Professor at Baylor College of Medicine and principal investigator on the clinical trial. “The data presented today are highly encouraging, showing that the combination of obicetrapib and ezetimibe delivers robust impacts on multiple atherogenic lipid parameters. I believe the observed reductions in LDL-C, ApoB, Lp(a) and total and small LDL particles are potentially predictive of profound reductions in the risk of cardiovascular events and look forward to further characterizing the combination obicetrapib and ezetimibe regimen in a Phase 3 trial.”

“The ROSE2 data build on our prior clinical experience, supporting the potential for obicetrapib to become a new standard-of-care combined safely with existing options to deliver improved outcomes to the millions of very high-risk patients in need. We are particularly encouraged by the new goal attainment data announced today, through which we observed that 87 percent of patients treated with the combination regimen of obicetrapib and ezetimibe met the most aggressive guideline-mandated LDL-C target of  $< 55$  mg/dL,” said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam, “We have selected a fixed-dose combination tablet formula and look forward

to advancing it into a Phase 3 trial, targeted to commence in the first quarter of 2024. In addition, we continue to progress our ongoing BROADWAY, BROOKLYN and PREVAIL trials according to plan. We believe that clinicians and patients are seeking oral options in addition to maximally tolerated statin therapy to reduce the risk of cardiovascular disease. Obicetrapib 10mg as monotherapy and in a fixed dose combination with ezetimibe, if successful in our Phase 3 trials, could well be the therapeutic solution that is so sorely needed.”

**Full Data from the Phase 2 ROSE2 Clinical Trial of Obicetrapib and Ezetimibe**

ROSE2 (NCT05266586) was designed as a placebo-controlled, double-blind, randomized Phase 2 clinical trial to evaluate the efficacy, safety and tolerability of obicetrapib 10 mg in combination with ezetimibe 10 mg as an adjunct to high-intensity statin therapy. Patients were randomized to receive combination therapy, obicetrapib 10 mg or placebo for a 12 week treatment period. A total of 119 patients enrolled in ROSE2, of which 97 were included in the on-treatment analysis. Patients presented at baseline with a fasting LDL-C greater than 70 mg/dL and triglycerides (“TG”) less than 400 mg/dL and all were receiving a stable dose of high-intensity statin therapy.

The primary endpoint was the percent change from baseline to week 12 in Friedewald-calculated LDL-C for the obicetrapib plus ezetimibe combination treatment group compared with placebo. Secondary efficacy endpoints included the percent changes from baseline to week 12 in LDL-C for obicetrapib monotherapy compared with placebo and in ApoB for the obicetrapib plus ezetimibe combination compared with placebo and the obicetrapib monotherapy compared with placebo. Exploratory endpoints included the percent changes from baseline to week 12 in Lp(a), non-HDL-C, HDL-C, total and small LDL particles assessed by NMR, and the proportion of patients at the end of treatment who achieved LDL-C levels below 100 mg/dL, 70 mg/dL and 55 mg/dL for the obicetrapib plus ezetimibe combination and obicetrapib monotherapy groups compared with placebo.

The p-value for the LS mean for each endpoint compared to placebo was <0.0001. The table below shows the median percent change from baseline in patients receiving the combination of obicetrapib and ezetimibe, obicetrapib monotherapy and placebo.

Median percent change from baseline	Placebo (n=40)	Obicetrapib 10mg (n=26)	Obicetrapib 10 mg + Ezetimibe 10 mg (n=31)
<b>Friedewald-calculated LDL-C</b>	-6.4	-43.5	-63.4
<b>ApoB</b>	-2.1	-24.2	-34.4
<b>Non-HDL-C</b>	-5.6	-37.5	-55.6
<b>Total LDL particles</b>	-5.7	-54.8	-72.1
<b>Small LDL particles</b>	-8.3	-92.7	-95.4
<b>LDL particle size</b>	-0.5	1.5	1.8

The combination of obicetrapib plus ezetimibe resulted in significantly more patients achieving LDL-C levels of less than 100, less than 70 and less than 55 mg/dL than the placebo group (100%, 93.5% and 87.1% vs. 66.7%, 16.7% and 0.0%, respectively) (p<0.05 vs. placebo for all). In addition, we observed a median reduction in Lp(a) of 47.2% and 40.2% in the monotherapy and combination arms, respectively.

Treatment with the combination of obicetrapib and ezetimibe was observed to be generally well-tolerated, with a safety profile comparable to placebo. Adverse events were generally mild to moderate, with the most prevalent adverse events being nausea, urinary tract infection and headache, and no drug-related, treatment-emergent serious adverse events were observed.

“We are particularly encouraged by the new lipid particle analysis, in which we observed reductions in Lp(a) and both total and small LDL particles in patients who received the combination of obicetrapib and ezetimibe,” said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. “An observed reduction of almost 50% in Lp (a) levels and associated reduction in the highly atherogenic small LDL particles of this magnitude are potentially clinically relevant, as LPL particles are believed to be one of the most robust predictors of cardiovascular disease risk. Together, these data further reinforce the potential for obicetrapib to transform the treatment landscape.”

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Under the terms of NewAmsterdam's licensing agreement with the Menarini Group, data from the ROSE2 trial triggered a clinical success milestone payment to NewAmsterdam, which was received in April 2023.

#### **Conference Call Information**

NewAmsterdam will host a live conference call on Monday, June 5, 2023 beginning at 8:00 a.m. ET to review the full data from the Phase 2 ROSE2 clinical trial. Participants may register for the conference call [here](#). While not required, it is recommended that participants join the call ten minutes prior to the scheduled start.

A live webcast of the call will also be available under "Events & Presentations" in the Investors & News section of the Company's website at <https://ir.newamsterdampharma.com>.

#### **About Obicetrapib**

Obicetrapib is a next-generation, oral, low-dose CETP inhibitor that NewAmsterdam is developing to potentially 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 three of the Company's Phase 2 trials, TULIP, ROSE and OCEAN, evaluating obicetrapib as a monotherapy or a combination therapy, the Company observed statistically significant LDL-lowering activity combined with generally moderate side effects and no drug-related, treatment-emergent serious adverse events. Obicetrapib has demonstrated strong tolerability in more than 600 patients with low or 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 potentially enhance LDL-lowering for high-risk CVD patients. The Company began enrolling patients in BROADWAY in January 2022 and in BROOKLYN in July 2022 and completed enrollment of BROOKLYN ahead of schedule in April 2023. The Company also commenced the Phase 3 PREVAIL CVOT in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of MACE, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization.

#### **About NewAmsterdam**

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 successful or well tolerated. 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 ("CVD") patients. Results from NewAmsterdam's ROSE Phase 2b trial (presented at AHA Scientific Sessions in 2021) included observations that patients receiving obicetrapib 10 mg experienced a median reduction in LDL-C of 51% versus baseline in patients on high-intensity statin therapy (vs. a 7% reduction in the placebo arm). In addition, results from NewAmsterdam's ROSE2 trial evaluating the combination of 10 mg obicetrapib and 10 mg ezetimibe demonstrated a median reduction in LDL-C levels of 63% versus baseline in patients on high-intensity statin therapy (vs. a 6% reduction in the placebo arm). Based in the Netherlands, NewAmsterdam recently completed a business combination with Frazier Lifesciences Acquisition Corporation ("FLAC"), a special purpose acquisition company sponsored by an affiliate of Frazier Healthcare Partners. Proceeds from this transaction were approximately \$328 million, prior to deducting transaction expenses. In June 2022, NewAmsterdam entered into an exclusive licensing agreement with the Menarini Group for the commercialization of obicetrapib in Europe, while retaining all rights to commercialize obicetrapib, if approved, in the rest of the world, as well as rights to develop certain forms of obicetrapib for other diseases such as Alzheimer's disease. For more information, please visit: [www.newamsterdampharma.com](http://www.newamsterdampharma.com).

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### **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,” “will,” “continue,” “anticipate,” “intend,” “expect,” “predict,” “potential,” “seek,” “target” 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 clinical trials and the timing for enrolling patients (including commencement of its Phase 3 trial), the timing and forums for announcing data and the achievement and timing of regulatory approvals. 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 related to the approval of the Company’s product candidate and the timing of expected regulatory and business milestones; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive product candidates; ability to obtain sufficient supply of materials; the impact of COVID-19; 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 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.

### **Company Contact**

Matthew Philippe  
P: 917-882-7512  
[matthew.philippe@newamsterdampharma.com](mailto:matthew.philippe@newamsterdampharma.com)

### **Media Contact**

Spectrum Science on behalf of NewAmsterdam  
Jenn Gordon  
P: 202-957-7795



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[jgordon@spectrumsience.com](mailto:jgordon@spectrumsience.com)

**Investor Contact**

Stern Investor Relations on behalf of NewAmsterdam

Hannah Deresiewicz

P: 1 212-362-1200

[hannah.deresiewicz@sternjr.com](mailto:hannah.deresiewicz@sternjr.com)

**NewAmsterdam Pharma Announces Positive Topline Results from Phase 2b Dose-Finding Trial Evaluating Obicetrapib in Japanese Patients**

— Achieved Primary Endpoint with Statistically Significant 45.8% Median Reduction in LDL-C ( $p < 0.0001$ ) in patients treated with 10mg obicetrapib—

— 29.7% Median Reduction in Apo B and 37.0% Median Reduction in non-HDL-C from Baseline ( $p < 0.0001$ ) in patients treated with 10mg obicetrapib —

— Favorable Safety and Tolerability Observed —

— Data Enable PMDA Regulatory Path Aligned with Rest of World; Plan to Leverage Data from Ongoing Phase 3 BROOKLYN, BROADWAY and PREVAIL Trials to Support Potential Approval in Japan —

— Management to Host Conference Call Today at 8:00 a.m. E.T. —

**Naarden, the Netherlands and Miami, USA; June 5, 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 (“CVD”) with residual elevation of low-density lipoprotein cholesterol (“LDL-C” or “LDL”), for whom existing therapies are not sufficiently effective or well-tolerated, today announced statistically significant and clinically meaningful topline results from the Phase 2b dose-finding trial of obicetrapib, the company’s oral, low-dose and once-daily cholesteryl ester transfer protein (“CETP”) inhibitor, as an adjunct to stable statin therapy in Japanese patients with dyslipidemia. Based on the results observed, NewAmsterdam plans to leverage data from the ongoing Phase 3 BROOKLYN, BROADWAY and PREVAIL clinical trials, if supportive, to pursue regulatory approval in Japan.

“Despite the availability of statins, elevated levels of LDL-C continue to pose a significant public health burden. A considerable number of patients fail to achieve sufficient LDL-C lowering on existing treatment options or are unable to access these therapies due to high costs,” said Mariko Harada-Shiba, M.D., Ph.D., Director at the Department of Molecular Innovation in Lipidology at Osaka Medical and Pharmaceutical University. “There are currently millions of people living with atherosclerotic cardiovascular disease (“ASCVD”) or heterozygous familial hypercholesterolemia (“HeFH”) in Japan. Like in other geographies, there is a significant unmet need for an oral therapy that can help many more patients achieve target LDL-C goals. Based on the data reported today, I believe incorporating obicetrapib, if approved, alongside statin therapy may emerge as a promising treatment approach, and I look forward to partnering with the NewAmsterdam team to advance obicetrapib’s development globally.”

**Topline Data from the Phase 2b Japan Trial**

“After announcing positive data from our ROSE2 trial at the National Lipid Association (“NLA”) Scientific Sessions this weekend, we are excited to report strong clinical results from the Phase 2b trial assessing obicetrapib in Japanese patients,” said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. “We are particularly encouraged by the consistency of these results with data observed across our clinical program to-date, which reinforces our belief in obicetrapib as a potentially paradigm-changing medicine. Importantly, we believe these data enable us to pursue a regulatory strategy in Japan aligned with our efforts in the rest of the world and look forward to seeking global approval for obicetrapib, if the data from our three pivotal Phase 3 trials, BROOKLYN, BROADWAY and PREVAIL, is positive. With our operational expertise and a strong partner to support obicetrapib commercialization in Europe, if approved, we believe we are well positioned to significantly improve patient outcomes and to potentially transform healthcare for millions of people who are living with cardiometabolic diseases.”

The Phase 2b trial was a placebo-controlled, double-blind, randomized, dose-finding trial to evaluate the efficacy, safety and tolerability of obicetrapib as an adjunct to stable statin therapy in Japanese patients. The trial enrolled 102 adult participants, who were randomized 1:1:1:1 to receive obicetrapib 2.5mg, 5mg, 10mg or placebo for a 56-day treatment period.

Patients treated with obicetrapib 2.5mg, 5mg, or 10mg, achieved a median reduction in LDL-C of 24.8%, 31.9%, and 45.8%, respectively, as compared to patients treated with placebo, who achieved a median reduction in LDL-C of 0.9%. In addition, patients treated with obicetrapib 10mg achieved a median reduction in apolipoprotein B ("Apo B") of 29.7%, compared to a 1.2% reduction in patients treated with placebo, and a median reduction in non-high-density lipoprotein cholesterol ("non-HDL-C") of 37.0%, as compared to a 0.4% reduction in patients treated with placebo. The p-value for each endpoint compared to placebo was <0.0001. Overall, the different dosages of obicetrapib were observed to be well-tolerated, with a safety profile comparable to placebo.

NewAmsterdam anticipates sharing full data from this Phase 2b clinical trial in a forthcoming publication or in a presentation at an upcoming medical meeting.

#### **Conference Call and Webcast**

NewAmsterdam will host a conference call today at 8:00 a.m. ET to review these data, as well as the full data from the Phase 2 ROSE2 clinical trial, which were presented on Saturday. To access the live conference call, please register [here](#). While not required, it is recommended that participants join the call ten minutes prior to the scheduled start.

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**Company Contact**

Matthew Philippe  
P: 1-917-882-7512  
[matthew.philippe@newamsterdapharma.com](mailto:matthew.philippe@newamsterdapharma.com)

**Media Contact**

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

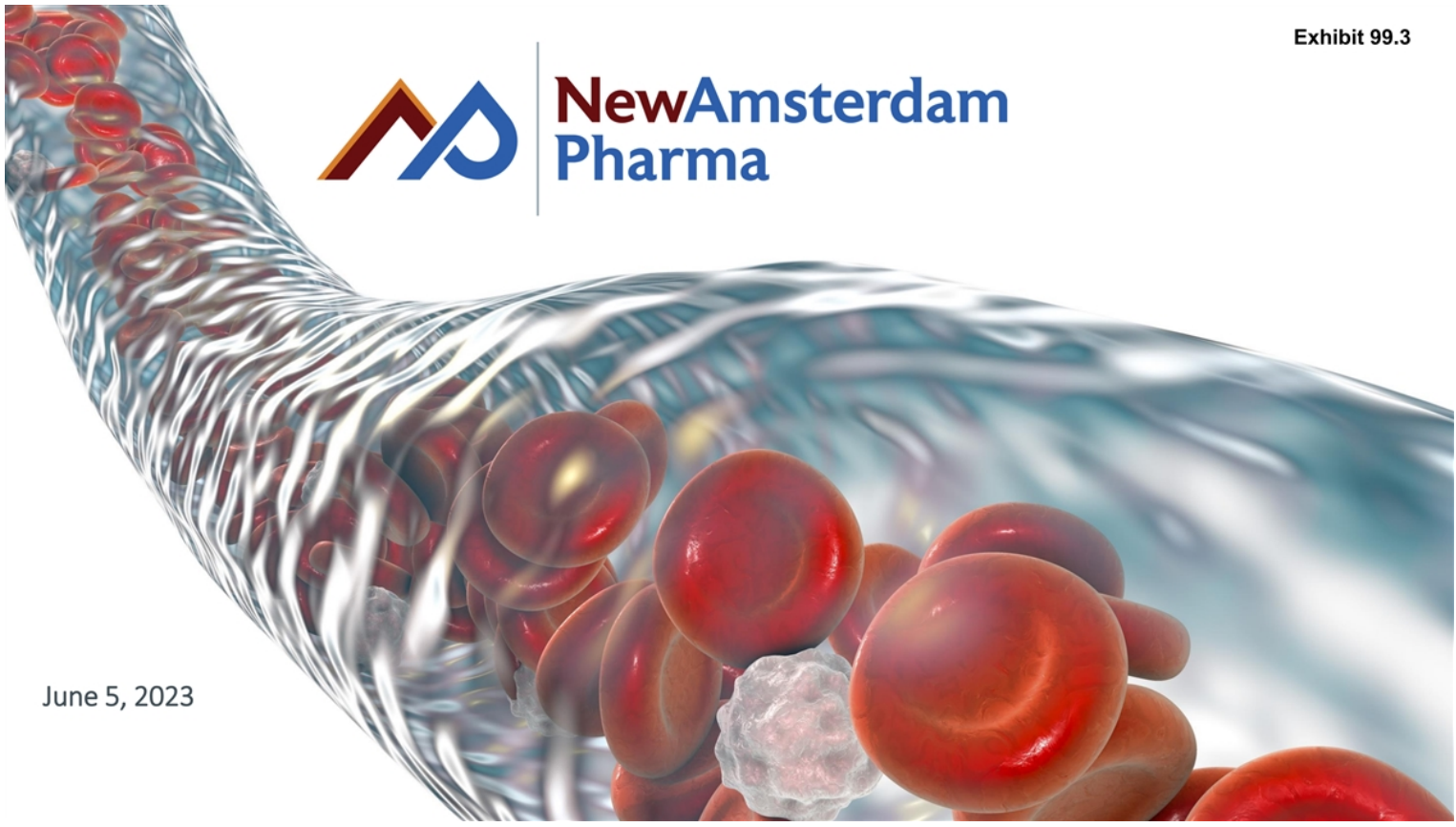
**Investor Contact**

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



**NewAmsterdam  
Pharma**

June 5, 2023





# Disclaimer

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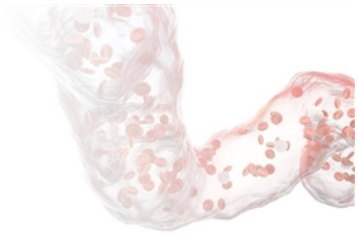


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## Summary of clinical data





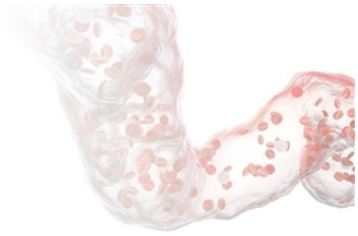


# rose<sup>2</sup>

The combination of Obicetrapib and Ezetimibe observed to lower LDL-C in Patients on High Intensity Statins: Results from the ROSE2 Trial (NCT05266586).

Christie M Ballantyne, Stephen J Nicholls, Marc Ditmarsch, John J Kastelein, Douglas Kling, Danielle L Curcio, Michael H Davidson

# ROSE2 trial: Obicetrapib and high intensity statin 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

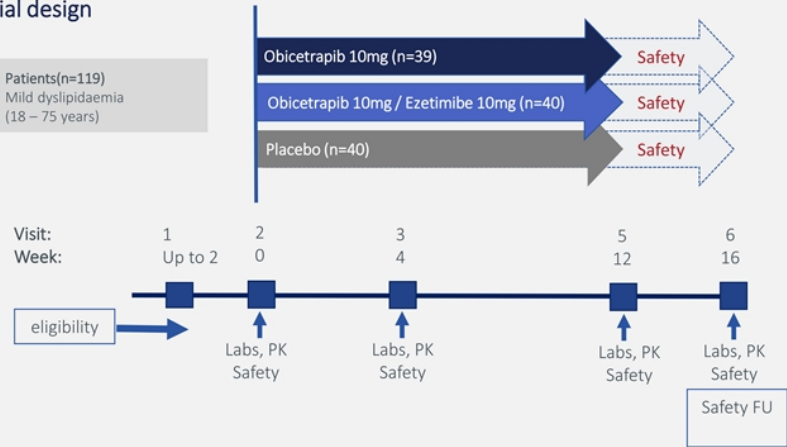
- Current significant CV disease
- HbA1c  $\geq 10\%$
- Uncontrolled hypertension

## Primary efficacy endpoint

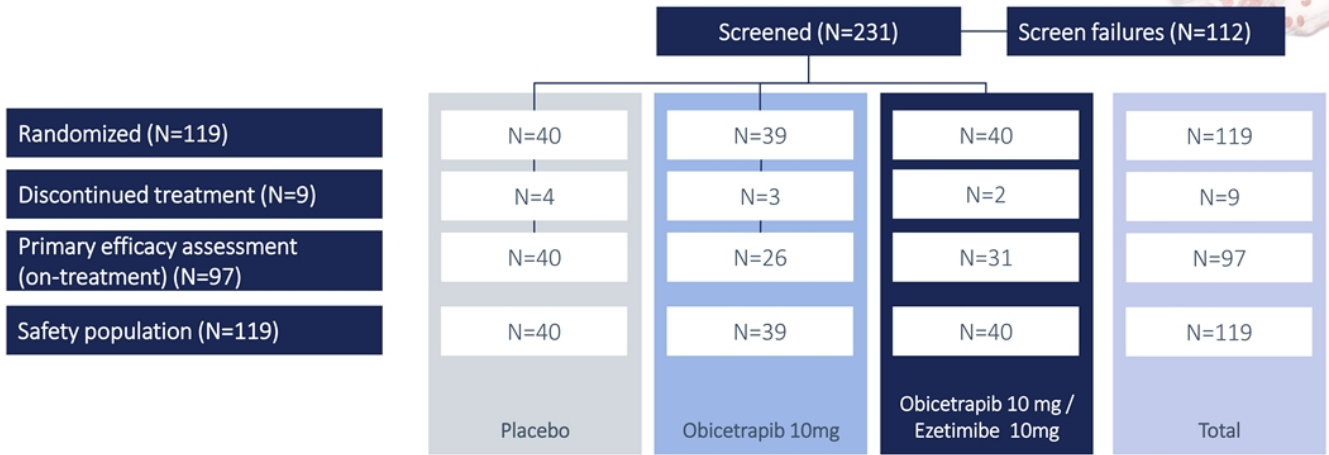
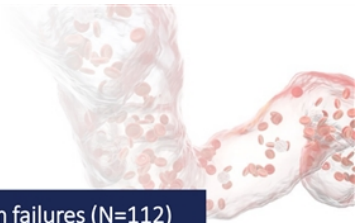
- Percent change from baseline in LDL-C compared to the placebo group

## Trial design

Patients (n=119)  
Mild dyslipidaemia  
(18 – 75 years)

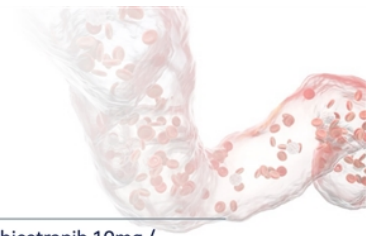


# Patient disposition



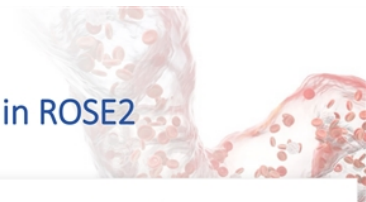


## Baseline characteristics



	Placebo N=40 (%)	Obicetrapib 10 mg N=26 (%)	Obicetrapib 10mg / Ezetimibe 10 mg N=31 (%)
Mean Age (yrs)	60.6	64.8	63.5
Female %	35	34.6	38.7
Mean BMI (kg/m <sup>2</sup> )	30.8	29.9	31.8
Race %			
White	75	88.5	93.5
Black / African American	22.5	11.5	6.5
Statin use (%)			
Atorvastatin 40/80 mg	75	69.2	80.6
Rosuvastatin 20/40 mg	25	30.8	19.4
Baseline level (Median)			
LDL-C (mg/dL)	95.5	100	87
HDL-C (mg/dL)	42.5	47	46

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

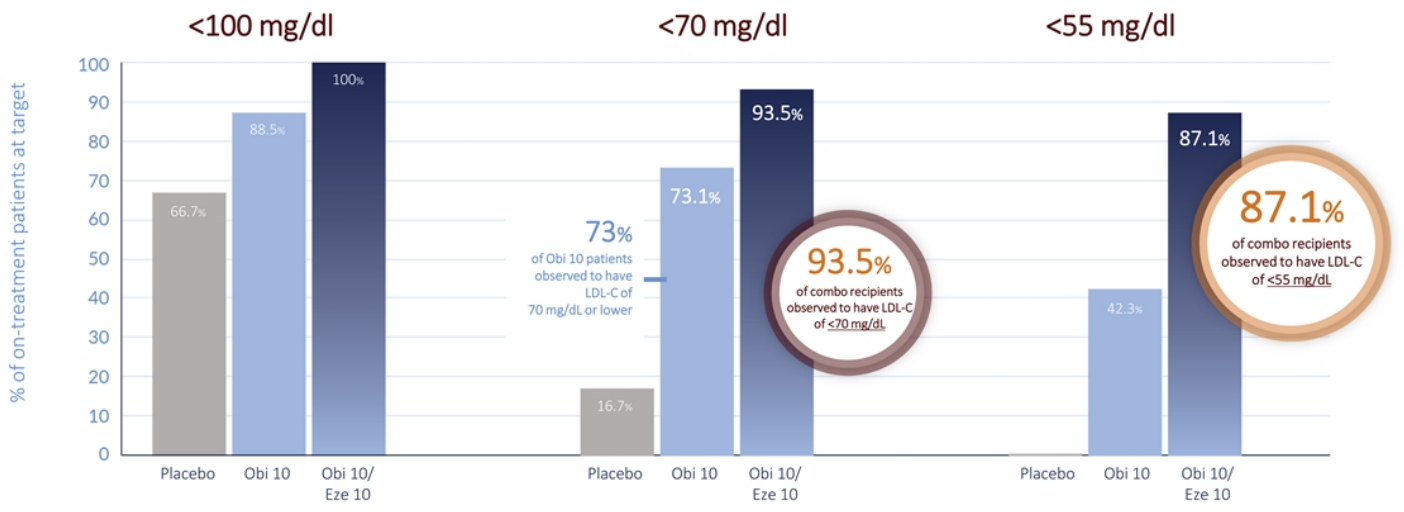
Time	Placebo	Obi 10 mg	Obi 10 / Eze 10
Baseline Median	95.5 (60, 211) (N=40)	100.0 (35, 189) (N=26)	87.0 (62, 152) (N=31)
EoT Median	88.0 (55, 188) (N=36)	55.5 (21, 148) (N=26)	39.0 (15, 96) (N=31)
% Change from Baseline (median)	-6.4 (-36.4, 96.7) (N=36)	-43.5 (-78.4, 22.6) (N=26)	-63.4 (-83.7, -29.7)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



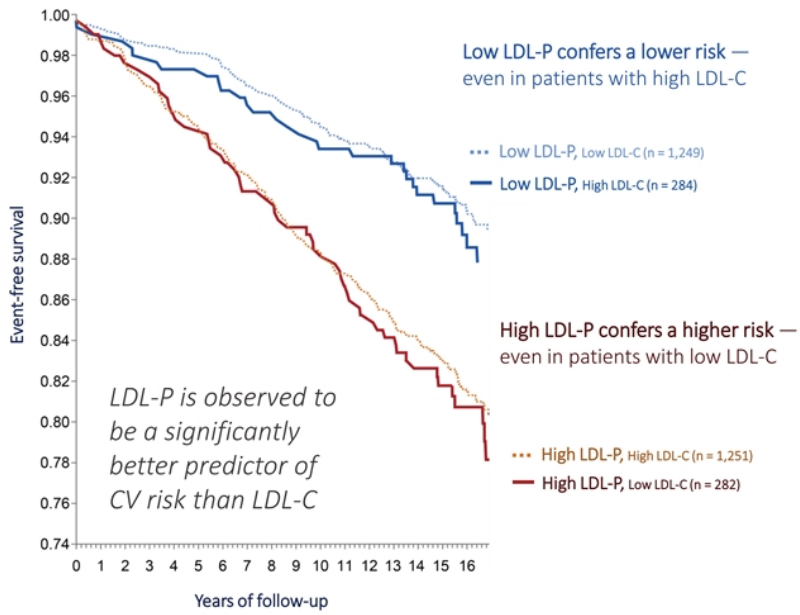
# Positive LDL goal attainment observed with ezetimibe + obicetrapib combination, including >87% of patients observed to attain <55 mg/dl LDL-C levels



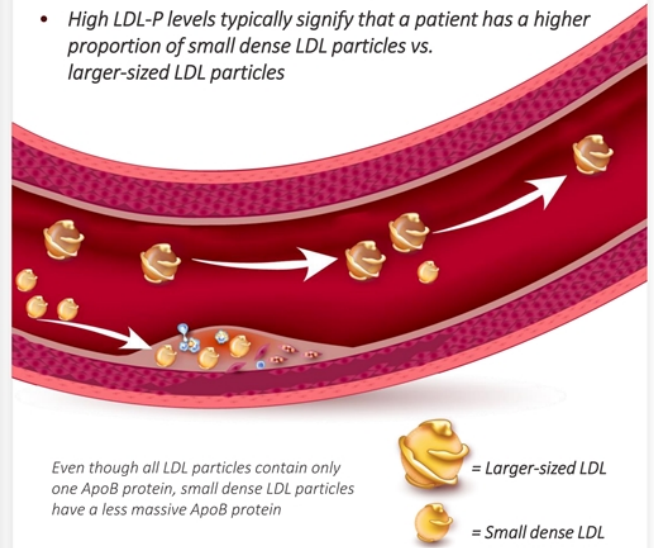
% of patients observed with the following LDL-C levels:



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

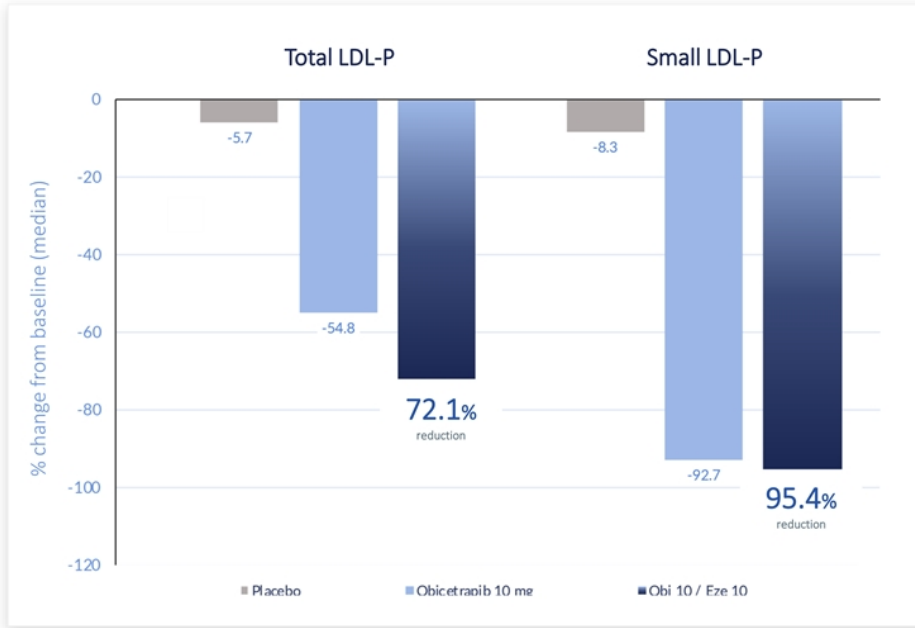


- Small dense LDL particles are more likely to be trapped in arterial wall than larger-sized LDL particles
- High LDL-P levels typically signify that a patient has a higher proportion of small dense LDL particles vs. larger-sized LDL particles





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

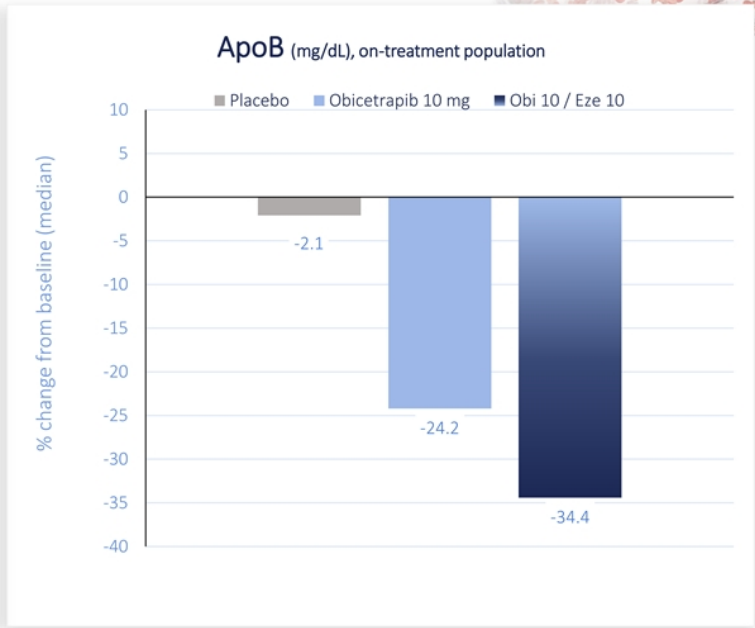
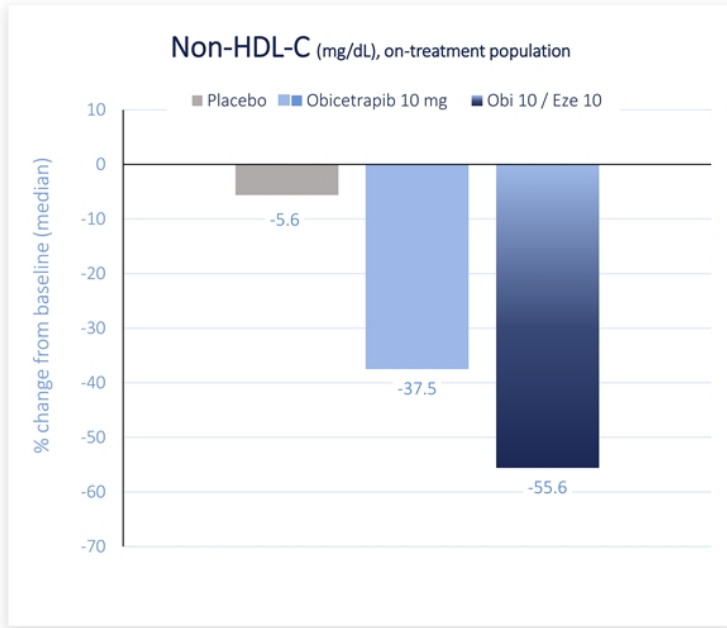
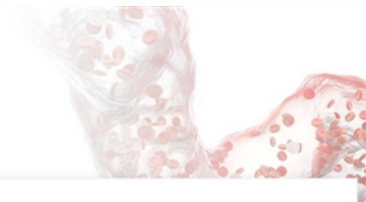
Lipoprotein fractionation 1	ROSE2 placebo	ROSE2 Obi / Obi + Eze
LDL-P (nmol/L)	1012.8	495 / 300
Small LDL-P (nmol/L)	717.5	73.4 / 47.5
LDL size (nm)	20.26	21.0 / 21.0

Key<sup>(2)</sup>

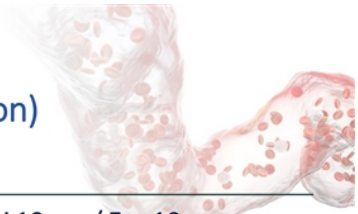
	High	Moderate	Optimal
LDL-P (nmol/L)	>1816	935-1816	<935
Small LDL-P (nmol/L)	>820	467-820	<467
LDL size (nm)	≤20.5	N/A	>20.5



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

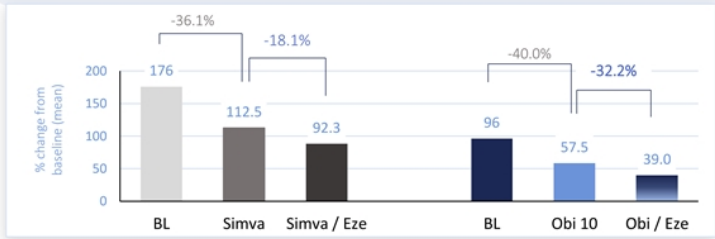
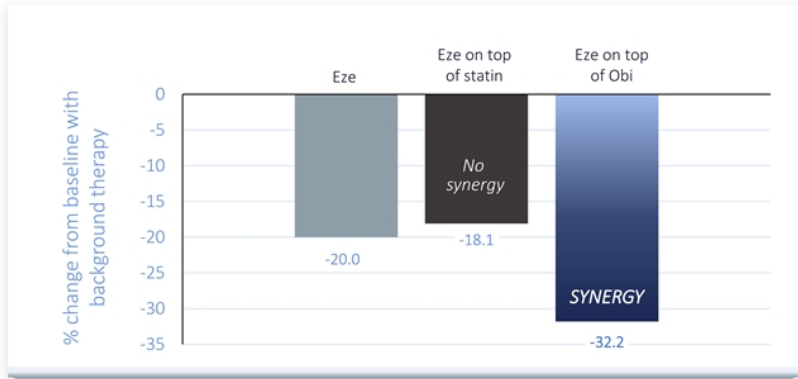


## ROSE2 Safety: TEAEs, TESAEs, and withdrawal overview (safety population)

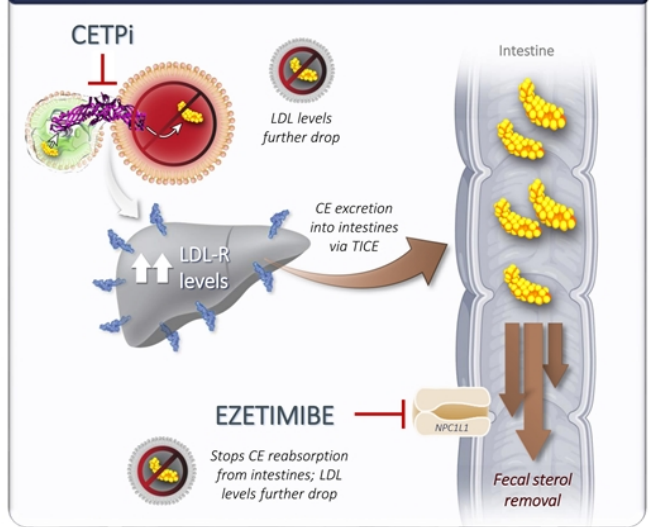


	Placebo N= 40, N (%)	Obicetrapib 10 mg N= 39, N (%)	Obi 10 mg / Eze 10 mg N= 40, N (%)
<b>TEAEs (%)</b>			
TEAEs	16 (40)	8 (20.5)	11 (27.5)
Related TEAEs	2 (5.0)	4 (10.3)	5 (12.5)
Severe TEAEs	2 (5.0)	1 (2.6) <sup>(1)</sup>	0 (0)
<b>TESAEs</b>			
TESAEs, total	1 (2.5)	1 (2.6) <sup>(1)</sup>	0 (0)
Deaths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

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>



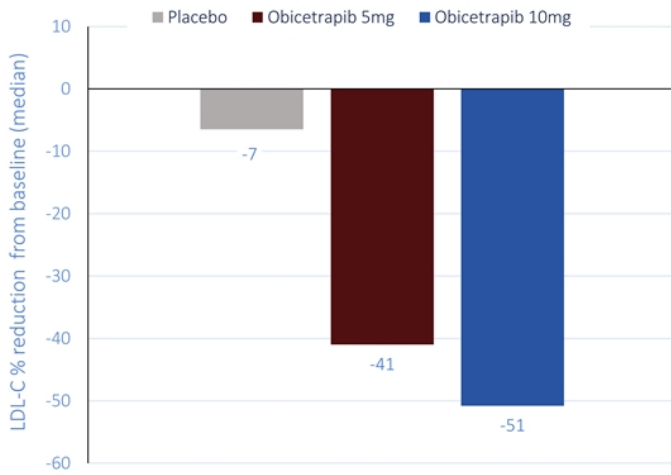
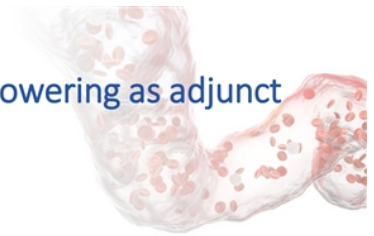
Obicetrapib is designed to promote more cholesterol excretion into the intestines (via TICE) while ezetimibe is designed to block cholesterol reabsorption into the body, synergistically enhancing fecal sterol removal of cholesterol





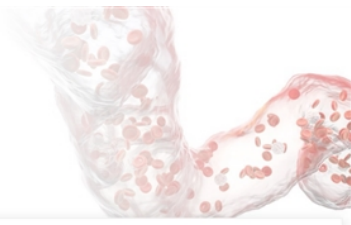
# In ROSE Phase 2b clinical trial, obicetrapib demonstrated robust LDL-C lowering as adjunct to high intensity statins<sup>1</sup>

Preparative ultra-centrifugation (PUC) is "gold-standard" for LDL-C quantification

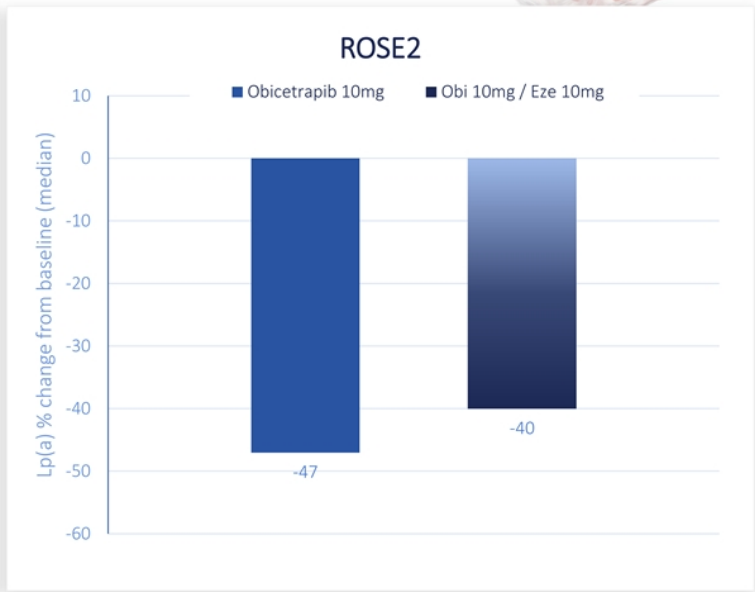
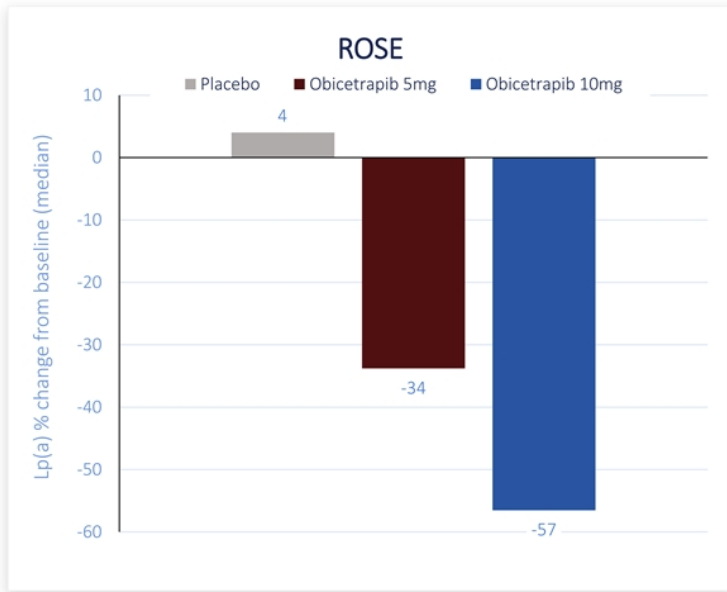


Time	Placebo	Obicetrapib 5mg	Obicetrapib 10mg
Baseline Median	90.0 (63, 204) N=40	95.0 (54, 236) N=39	88.0 (39, 207) N=40
EoT Median	86.0 (43, 137) N=39	53.0 (13, 126) N=39	49.5 (23, 83) N=40
% Change from Baseline (median)	-6.5 (-53.9, 31.6) N=39	-41.45 (-71.2, 62.3) N=38*	-50.75 (-76.9, 15.6) N=40
% Change from Baseline LS mean (95% CI)	-6.7 (-13.17, -0.24)	-35.65 (-42.19, -29.10)	-46.77 (-53.16, -40.38)
p-value compared to placebo	-	<0.0001	<0.0001

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

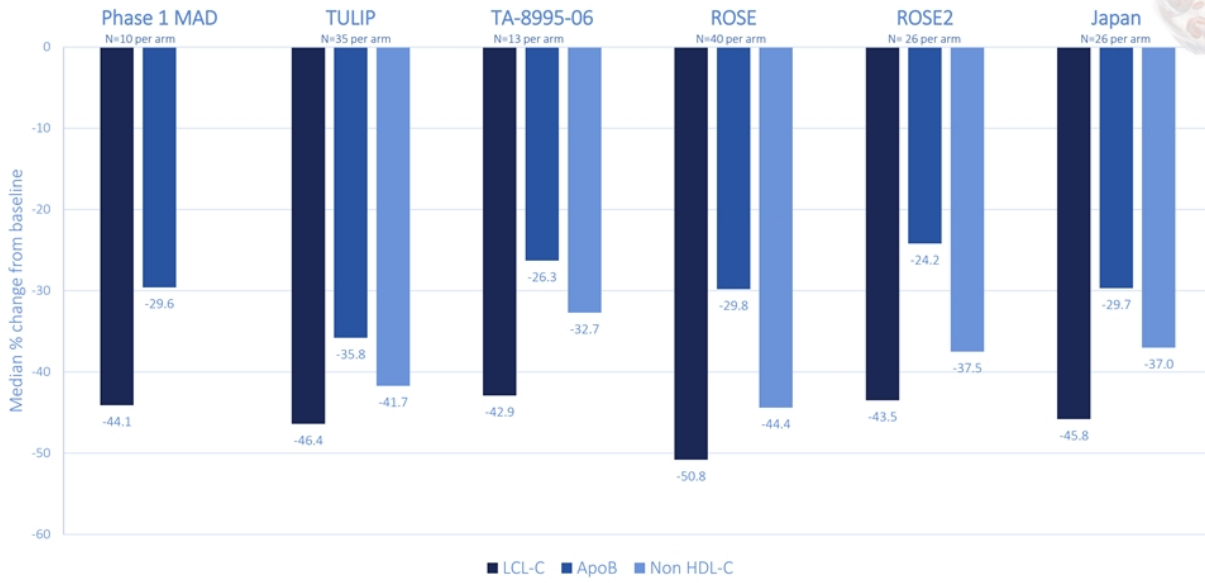
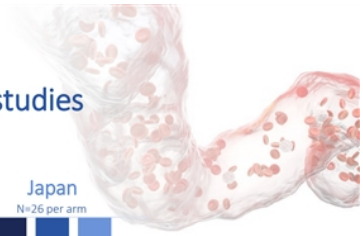


• Lp(a) is emerging as a strong and independent marker of CVD risk and an exciting new CVD drug target





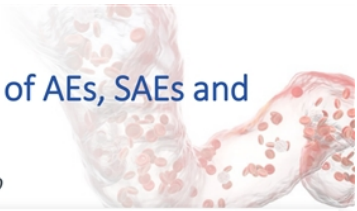
## Changes in lipid biomarkers for obicetrapib 10mg monotherapy across phase 1/2 studies





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

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



## ROSE Safety

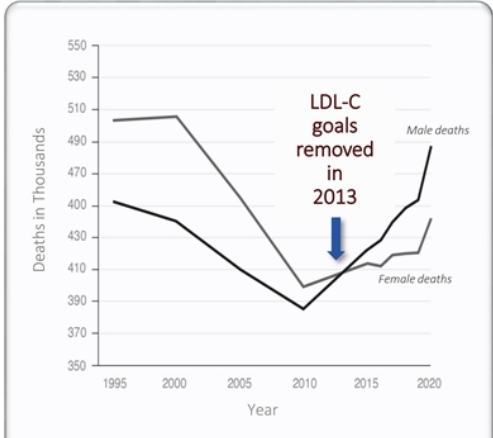
	Placebo (N=40)	Obicetrapib, 5mg (N=40)	Obicetrapib, 10mg (N=40)
<b>TEAEs (%)</b>			
TEAEs, total	19 (47.5)	15 (37.5)	8 (20.0)
TEAEs, related	4 (10.0)	2 (5.0)	1 (2.5)
TEAEs, severe	1 (2.5)	0	0
<b>TESAEs</b>			
TESAEs, total	2 (5.0)	0	0
TESAEs, related	0	0	0
Deaths	0	0	0
<b>Withdrawals study / medication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

## Pooled Safety

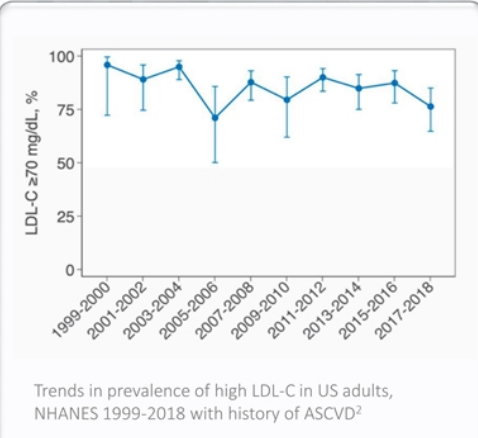
	Comparator <sup>(1)</sup> (N=231)	Obicetrapib Pooled 5mg + 10mg <sup>(2)</sup> (N=309)
<b>TEAEs (%)</b>		
TEAEs, total	136 (58.9)	173 (55.9)
TEAEs, related	45 (19.5)	49 (15.8)
TEAEs, severe	5 (2.2)	7 (2.3)
<b>TESAEs</b>		
*TESAEs, total	6 (2.6)	4 (1.3)
TESAEs, related	0	0
Deaths	0	0
<b>Withdrawals study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



# Despite availability of statins, tremendous unmet need remains – with resurgence of the “lower-is better” paradigm

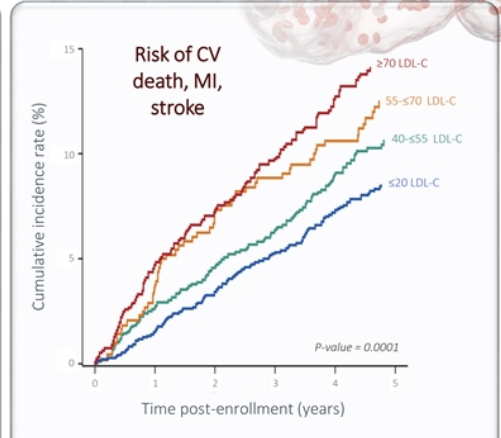


Despite statins, CVD deaths are on the rise



Trends in prevalence of high LDL-C in US adults, NHANES 1999-2018 with history of ASCVD<sup>2</sup>

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



Numerous studies demonstrate resurgence of paradigm “lower is better”

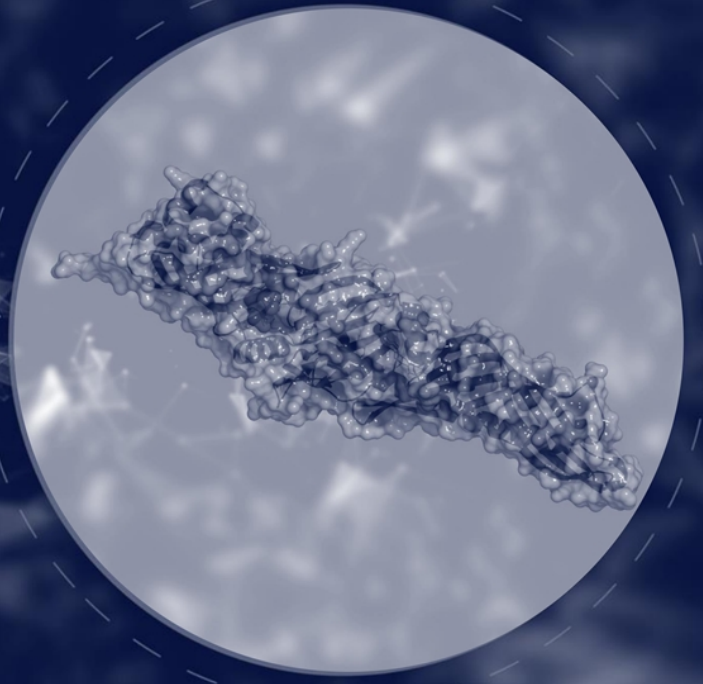
Sources: Trinity NewAmsterdam Market Research Summary, Trinity quantitative market research with N = 100 PCPs and Cardiologists; Bloomberg Prescription Data; IQVIA Rx Tracker. (1) Literature review suggesting hypercholesterolemia prevalence of ~94mm in the US (average of He et al. 2020, Mercado et al. 2015, Muntner et al. 2013) and ~137mm in EUS (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) <3mm 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 EUS. (5) Gaba P, et. al., Association Between Achieved Low-Density Lipoprotein Cholesterol Levels and Long-Term Cardiovascular and Safety Outcomes: An Analysis of FOURIER-OLE. Circulation. 2023 Feb 13. doi: 10.1161/CIRCULATIONAHA.122.063399.



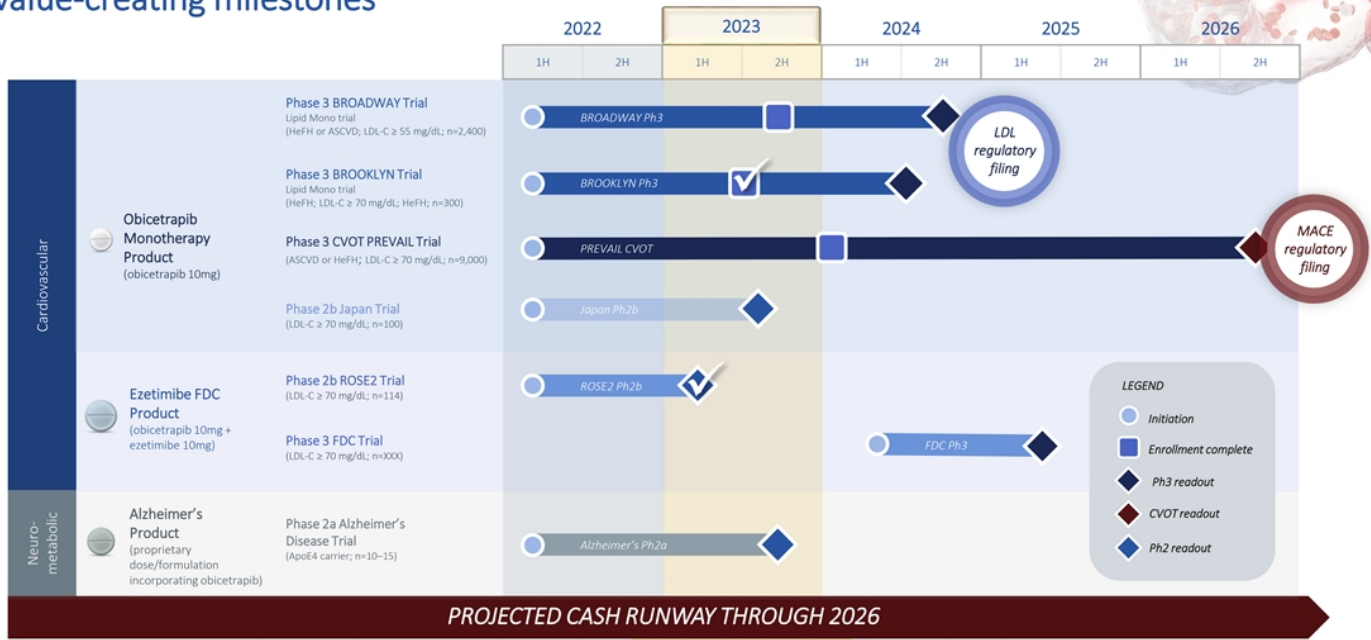


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Clinical development



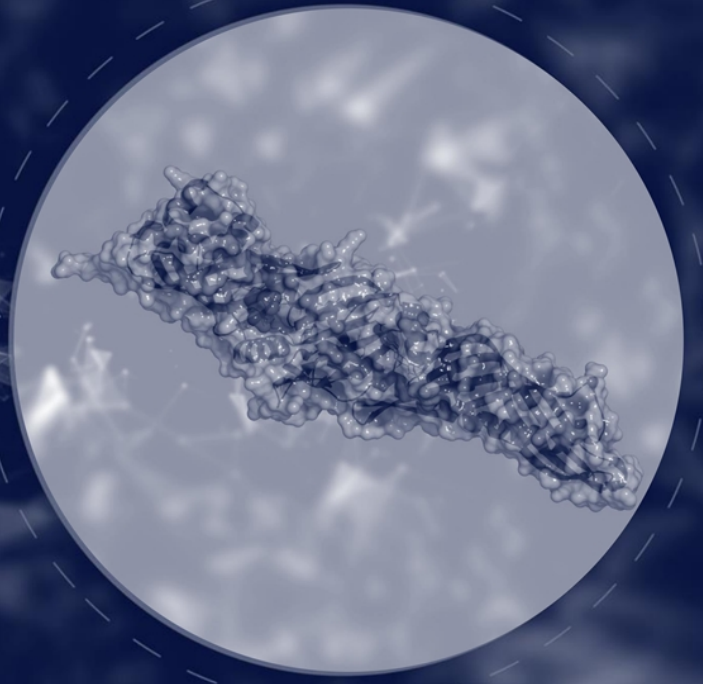
# Current cash expected to fund obicetrapib development through several value-creating milestones



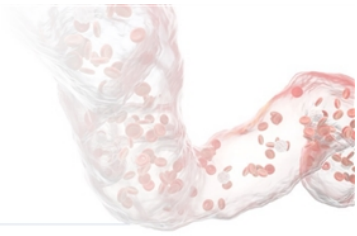


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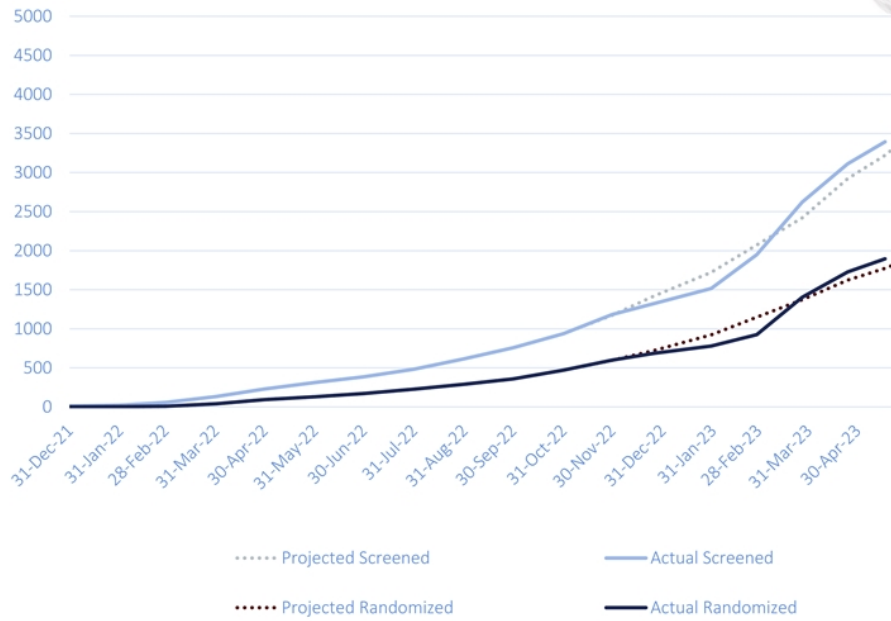
## Clinical Trial Progress Update



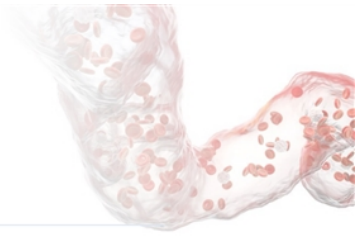
# BROADWAY enrollment on schedule to finish mid-2023



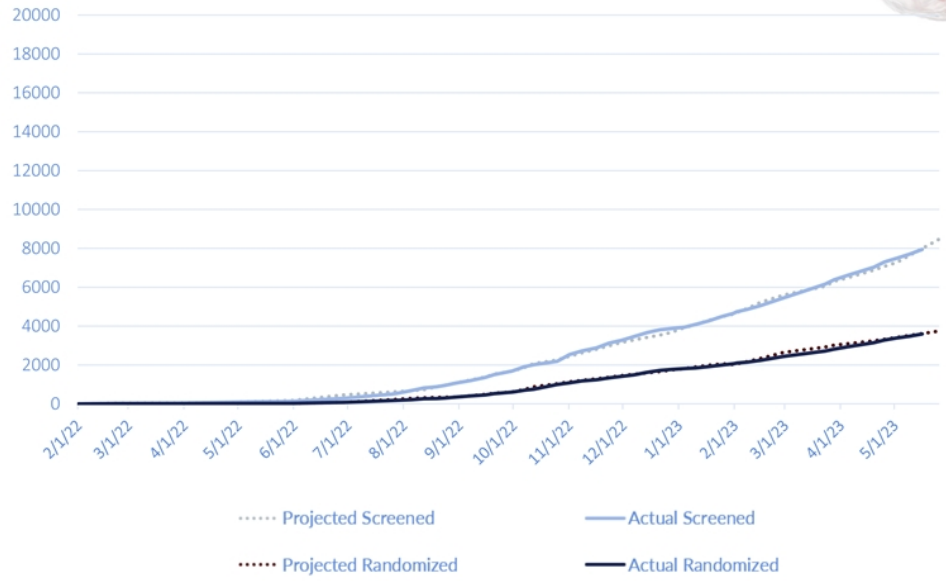
- ASCVD or HeFH with LDL  $\geq$  55 mg/dL; n=2400
- Randomization 2:1; obicetrapib 10 mg:placebo
- Primary endpoint: LDL-C
- Baseline LDL-C = 102 mg/dL; Woman: 35%; Average age: 65 years



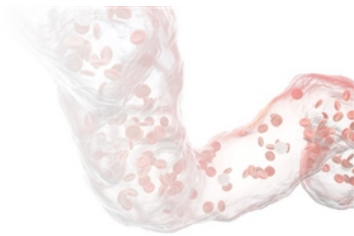
# PREVAIL enrollment currently on schedule to complete 1Q 2024



- ASCVD with LDL  $\geq$  70 mg/dL; n=9000
- Randomization: 1:1; Obi 10 mg vs placebo
- Primary endpoint: MACE-4
- Baseline LDL: 110 mg/dL; Women: 31%; Average age: 65 years



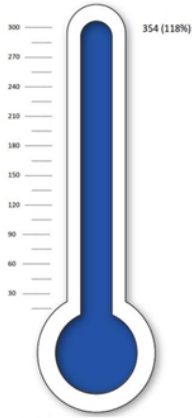
# Update on phase 3 trial enrollment



## BROOKLYN

HeFH with LDL  $\geq$  70 mg/dL  
N=300

Randomization: 2:1  
Obi 10 mg vs placebo  
Primary Endpoint: LDL-C  
Baseline mean LDL: 122 mg/dL  
Women: 53%  
Average Age: 57 years



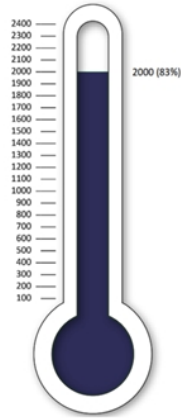
Enrollment completion: ~~July 2023~~

April 2023

## BROADWAY

ASCVD or HeFH with LDL  $\geq$  55 mg/dL  
N=2400

Randomization: 2:1  
Obi 10 mg vs placebo  
Primary Endpoint: LDL-C  
Baseline mean LDL: 102 mg/dL  
Women: 35%  
Average Age: 65 years

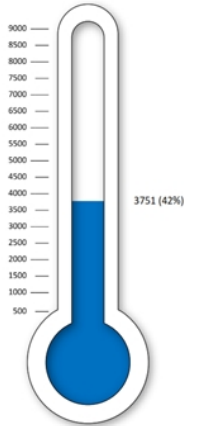


Mid-2023  
*expected*

## PREVAIL

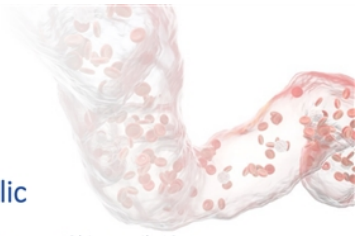
ASCVD with LDL  $\geq$  70 mg/dL  
N=9000

Randomization: 1:1  
Obi 10 mg vs placebo  
Primary Endpoint: MACE-4  
Baseline mean LDL: 110 mg/dL  
Women: 31%  
Average Age: 65 years

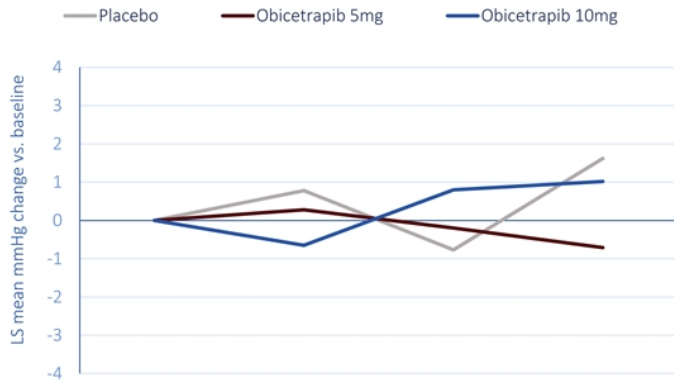


1Q 2024  
*expected*

# Pooled phase 2 trial blood pressure data

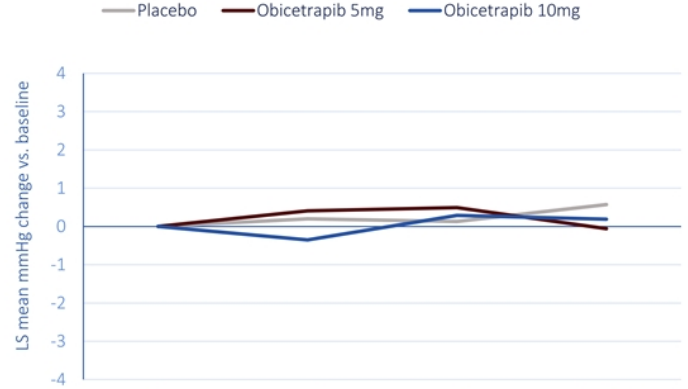


## Systolic



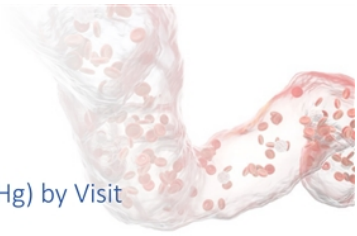
	BL	4	8	Week 12
Placebo (N)	229	222	180	157
Obi 5 mg (N)	135	134	130	63
Obi 10 mg (N)	240	237	155	188

## Diastolic

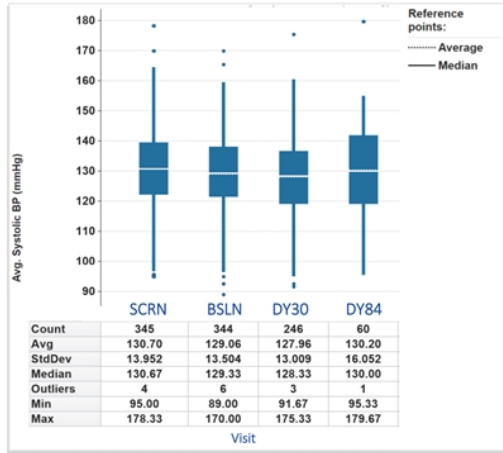


	BL	4	8	Week 12
Placebo (N)	229	222	180	157
Obi 5 mg (N)	135	134	130	63
Obi 10 mg (N)	240	237	155	188

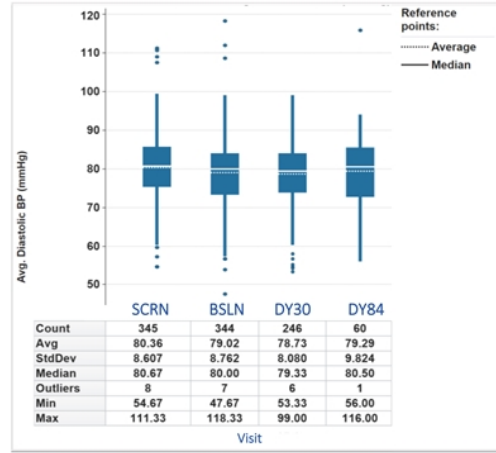
**BROOKLYN: Aggregate blinded average blood pressure is stable over time**



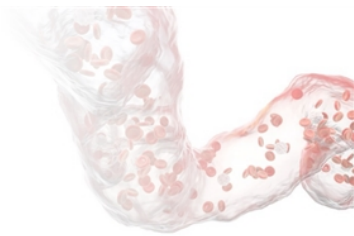
Average Systolic BP (mmHg) by Visit



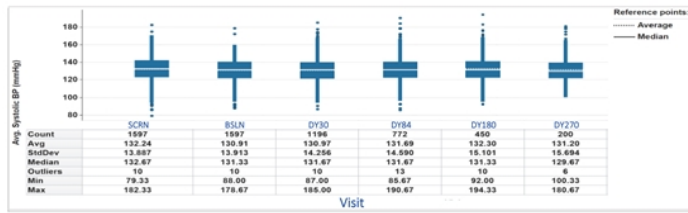
Average Diastolic BP (mmHg) by Visit



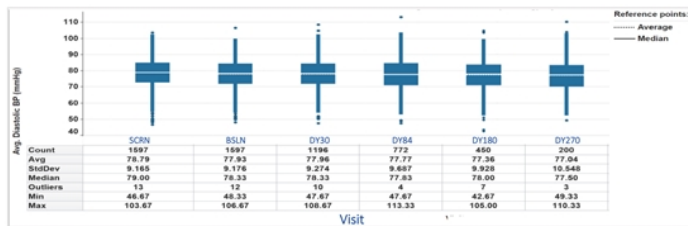




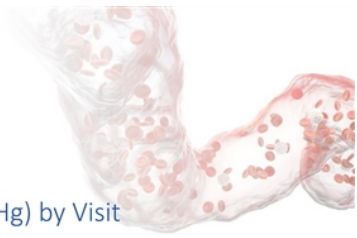
Average Systolic BP (mmHg) by Visit



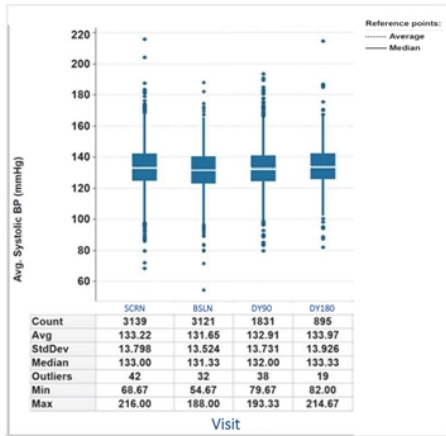
Average Diastolic BP (mmHg) by Visit



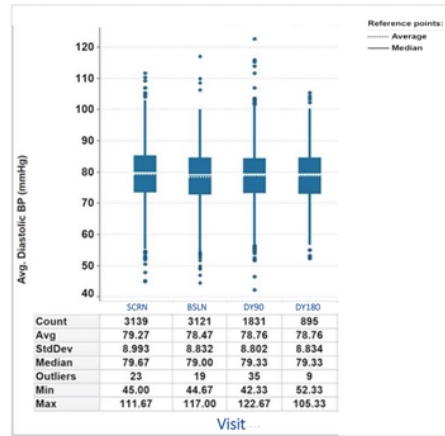
PREVAIL: Aggregate blinded average blood pressure is stable over time



Average Systolic BP (mmHg) by Visit

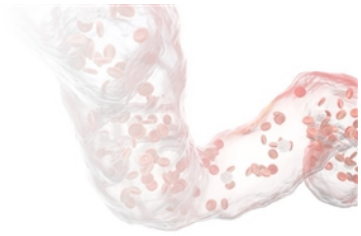


Average Diastolic BP (mmHg) by Visit

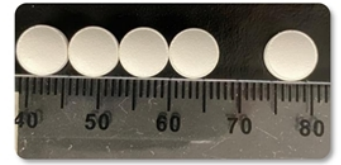


## We have selected a Fixed Dose Combination (FDC) of Obicetrapib + Ezetimibe

- We recently completed a bioavailability study comparing two FDC formulations of obicetrapib + ezetimibe to the component products
- An FDC formulation was selected based on comparable bioavailability and is planned to be advanced into a Phase 3 safety & efficacy trial
- An End-of-Phase 2 meeting has been granted by FDA and scheduled for June 2023 to review the design of our Phase 3 study
- The Phase 3 trial is expected to begin in 1Q 2024
- We currently expect to submit an NDA for the FDC on or around the same time as the obicetrapib monotherapy

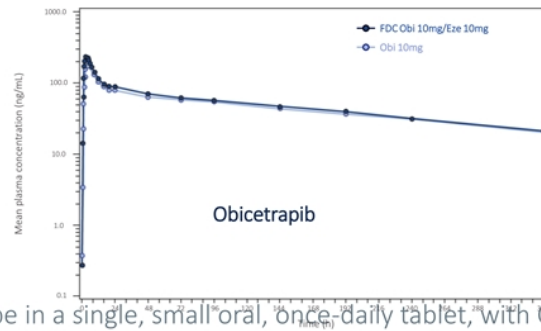
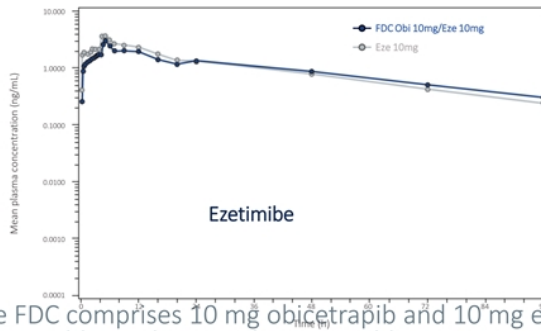


Fixed-Dose Combo Tablet



## Fixed dose combination Obi + Eze: Development update

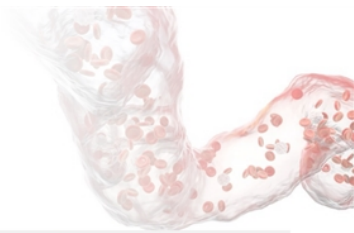
- FDC formulation observed to have comparable pharmacokinetic (PK) profiles to individual products



- The FDC comprises 10 mg obicetrapib and 10 mg ezetimibe in a single, small oral, once-daily tablet, with CoGs comparable to obicetrapib 10 mg tablet
- FDC Phase 3 trial is planned to start in Q1 2024
- The planned manufacturing site for FDC was selected and technology transfer is ongoing for anticipated NDA readiness and commercial supply



# Proposed fixed dose combination phase 3 trial design



## Inclusion criteria

- LDL-C  $\geq$  70 mg/dL
- ASCVD, ASCVD risk equiv, or HeFH
- 18-75 years

## Primary endpoint

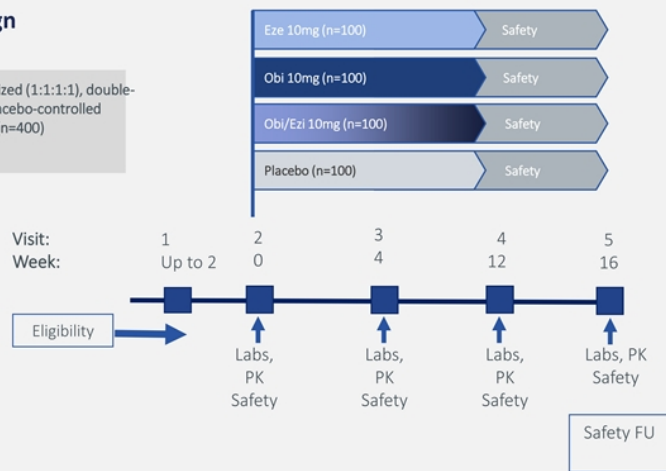
- Percent change from baseline in LDL-C compared to placebo

## Primary efficacy endpoint

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

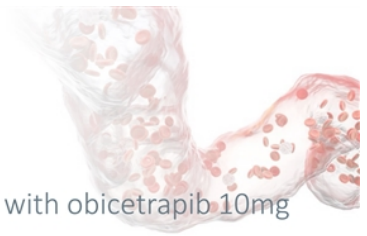
## Trial design

- Randomized (1:1:1:1), double-blind, placebo-controlled
- Patients(n=400)





## Summary of key messages



- ROSE2: 63% median LDL-C reduction observed in patients on high intensity statins with obicetrapib 10mg in combination with ezetimibe
- Japan Phase 2: 46% median LDL-C reduction observed with obicetrapib 10mg; largely consistent with observed results from obicetrapib 10mg across six clinical trials (Range 43-51%) and potentially enabling PMDA regulatory path for approval aligned with the rest of the world
- Well tolerated in Phase 2 trials and Phase 3 blinded safety, including frequent blood pressure assessments, is encouraging
- Robust reductions in Lp(a) and small LDL particles as well as documented diabetes benefits in the CETP inhibitor class are encouraging
- FDC formulation selected with Phase 3 initiation anticipated in Q1 24
- Enrollment in Phase 3 trials is progressing on-track with completion of the two pivotal LDL trials expected in H2 24 and CVOT expected in H2 26



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Concluding Remarks and Q&A

