### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 8-K

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

Date of Report (Date of earliest event reported): December 10, 2024

## NewAmsterdam Pharma Company N.V.

(Exact name of registrant as specified in its charter)

The Netherlands (State or other jurisdiction of incorporation) 001-41562 (Commission File Number) N/A (I.R.S. Employe Identification No

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

1411 DC

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

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

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

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

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

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

- $\boxtimes$  Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 ( $\S230.405$  of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 ( $\S240.12b-2$  of this chapter).
- ☐ If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

### Item 7.01 Regulation FD Disclosure.

On December 10, 2024, NewAmsterdam Pharma Company N.V. (the "Company") issued a press release announcing positive topline data from the Company's Phase 3 BROADWAY clinical trial evaluating obicetrapib in adult patients with established atherosclerotic cardiovascular disease and/or heterozygous familial hypercholesterolemia, whose low-density lipoprotein cholesterol is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference

The Company is hosting a live webcast and conference call to discuss the positive topline results of the BROADWAY clinical trial on December 10, 2024 at 8:00 a.m., Eastern Time, and a live webcast of the call will be available through the Company's website. A copy of the slide presentation to be used by the Company during the conference call is furnished as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

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

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
99.1	Press Release, dated December 10, 2024.
99.2	NewAmsterdam Pharma Company N.V., December 10, 2024 BROADWAY Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

NewAmsterdam Pharma Company N.V.

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

Dated: December 10, 2024

# NewAmsterdam Pharma Announces Positive Topline Data from Pivotal Phase 3 BROADWAY Clinical Trial Evaluating Obicetrapib in Patients with Atherosclerotic Cardiovascular Disease and/or Heterozygous Familial Hypercholesterolemia

- Achieved primary endpoint of LS mean reduction vs placebo in LDL-C on top of maximally tolerated lipid modifying therapies at day 84 with statistically significant reduction (p<0.0001) —</p>
  - 21% observed reduction in major adverse cardiovascular events favoring obicetrapib at one year
    - Observed to be well-tolerated with safety results comparable to placebo
      - NewAmsterdam to host conference call at 8:00 a.m. ET today —

Naarden, the Netherlands and Miami, USA; December 10, 2024 – NewAmsterdam Pharma Company N.V. (Nasdaq: NAMS or "NewAmsterdam" or the "Company"), a late-stage, clinical biopharmaceutical company developing oral, non-statin medicines for patients at risk of cardiovascular disease ("CVD") with elevated low-density lipoprotein cholesterol ("LDL-C"), for whom existing therapies are not sufficiently effective or well-tolerated, today anounced positive topline data from the Company's Phase 3 BROADWAY clinical trial (NCT05142722) evaluating obicetrapib in adult patients with established atherosclerotic cardiovascular disease ("ASCVD") and/or heterozygous familial hypercholesterolemia ("HeFH"), whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy.

"We initiated four Phase 3 trials with obicetrapib in December 2021, with the hope that obicetrapib would become the therapeutic option of choice to add to statin therapy to further reduce cardiovascular ("CV") risk," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "Our aspiration was that our Phase 3 trials would not only confirm the efficacy and tolerability observed in Phase 2 but also clearly demonstrate a safety and clinical profile that would differentiate obicetrapib from other LDL-C lowering therapies. We are proud to have observed in our Phase 3 trials to date not only durable LDL-C reduction in both the monotherapy obicetrapib group and the obicetrapib combination with ezetimibe group, but also a safety and tolerability profile that exceeded our expectations. We have observed obicetrapib, an oral, once-a-day, low-dose tablet, to be clinically differentiated from other lipid lowering therapies by lowering Lp(a) and small LDL-particles as well as potentially improving glycemic measures that are linked to high CV risk. Although exploratory at this point, the difference in major adverse cardiovascular events ("MACE") at one year in BROADWAY supports our belief that obicetrapib could provide greater than expected CV risk reductions through mechanisms beyond LDL-C lowering. In 2025, we look forward to presenting additional BROADWAY and TANDEM data at upcoming scientific sessions and meeting with regulatory authorities to discuss filings for this important therapy to address the global unmet need for effective LDL-C lowering therapies."

The primary endpoint was the least-squares mean of the percent change in LDL-C from baseline to day 84 for obicetrapib 10 mg compared to placebo, using imputation for missing data. The primary endpoint was achieved with statistical significance with an LDL-C reduction of 33% (p<0.0001).

### LDL-C percentage change at day 84:

	Placebo (n = 844)	Obicetrapib 10 mg (n = 1686)	Difference
Mean	-2%	-35%	-33%
Median	-4%	-40%	-36%
LS mean (with imputation)	+3%	-30%	-33%

As part of the safety analysis, the trial adjudicated MACE, including death, non-fatal myocardial infarction, non-fatal stroke and coronary revascularization. In addition, a 21% reduction in MACE favoring obicetrapib was observed.

### Major adverse cardiovascular events table:

	Placebo	Obicetrapib 10 mg		
	(n = 844)	(n = 1686)	Hazard Ratio	95% CI
All-cause mortality - no. (%)	12 (1.4)	19 (1.1)	0.83	(0.40-1.71)
Coronary heart death - no. (%)	5 (0.6)	8 (0.5)	0.80	(0.26-2.44)
First 4-point MACE - no. (%)	44 (5.2)	70 (4.2)	0.79	(0.54-1.15)

4-point MACE: CHD death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization. MACE was not a primary or secondary endpoint of the BROADWAY trial.

"I have provided leadership to cardiovascular drug development since the early statin days and was thrilled to see a safety profile as clean as obicetrapib, which has been comparable to placebo. Having lived and witnessed the accumulation of efficacy and safety data for obicetrapib from early Phase 1 through Phase 3, this moment is an exciting milestone," said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. "The unexpected magnitude of difference in MACE and early separation in the Kaplan-Meier curves that we observed may indicate obicetrapib's potential benefit above LDL-C lowering alone. MACE risk is multifaceted and obicetrapib has shown consistent benefit in our clinical trials across a variety of drivers but ultimately, getting patients' LDL-C to target is what I care about. I am optimistic that obicetrapib monotherapy and in combination with ezetimibe each could help most patients reach these goals, if approved."

The observed changes in other biomarkers, including high-density lipoprotein cholesterol ("HDL-C"), non-HDL-C, lipoprotein(a) ("Lp(a)"), apolipoprotein B ("ApoB"), and Apolipoprotein A1 (ApoA1) were consistent with data reported in the Company's prior clinical trials.

As part of the safety analysis, key adverse events ("AE") of special interests were monitored. Among these AEs, glycemic control and renal function were monitored and each of the events favored obicetrapib. Overall, obicetrapib was also observed to be well-tolerated, with safety results, including blood pressure, comparable to placebo. The treatment discontinuation rate for the obicetrapib arm was 11.1% versus 12.4% for placebo. The incidence of treatment-emergent adverse events ("TEAEs"), trial-drug related TEAEs, and treatment-emergent serious adverse events ("TESAEs") are summarized in the table below.

	N=843	N=1,685
	n (%)	n (%)
Any TEAEs	513 (60.9)	1007 (59.8)
Any trial drug related TEAEs	39 (4.6)	76 (4.5)
Any TEAEs leading to discontinuation of trial drug	43 (5.1)	68 (4.0)
Any TESAEs	117 (13.9)	211 (12.5)

"Despite the widespread availability of lipid-lowering therapies, patients are still struggling to achieve target LDL-C levels and CVD-related death rates continue to rise," said Stephen Nicholls, M.B.B.S., Ph.D., Director, Monash Victorian Heart Institute and Professor of Cardiology, Monash University. "The BROADWAY clinical trial highlights the transformative potential of obicetrapib — a powerful, well-tolerated, and convenient treatment option for millions with dyslipidemia, if approved, could help them reach their LDL-C goals and significantly reduce the risk of life-threatening cardiovascular events."

NewAmsterdam plans to present additional results from BROADWAY at an upcoming medical conference and to publish the data in a major medical journal.

### Design of the Pivotal Phase 3 BROADWAY Clinical Trial

The 52-week, global, pivotal, Phase 3, randomized, double-blind, placebo-controlled multicenter trial evaluated the efficacy and safety of 10 mg obicetrapib compared to placebo as an adjunct to maximally tolerated lipid-lowering therapies in patients with ASCVD and/or HeFH whose LDL-C is not adequately controlled. The trial was conducted at sites in North America, Europe, Asia and Australia. A total of 2,530 patients were randomized 2:1 to receive 10 mg obicetrapib or placebo dosed as a once-daily oral treatment, with or without food for 52 weeks. The mean baseline LDL-C for enrolled patients in the obicetrapib arm was approximately 100 mg/dL despite high intensity statin use reported by nearly 70% of patients during screening. Females comprised approximately 34% of the trial population and the median age of participants at baseline was 65 years.

The primary endpoint was LS mean percent change from baseline in LDL-C of obicetrapib 10 mg compared to placebo after 84 days which showed a reduction of 33% with imputation. Secondary endpoints also included percent changes from baseline of obicetrapib 10 mg compared to placebo in ApoB, Lp(a), ApoA1, HDL-C, non-HDL-C, total cholesterol, and triglycerides at day 84, and on LDL-C levels at days 180 and 365 (mean -34% and imputed LS mean of -24%, respectively with p<0.0001). Other exploratory outcome measures included time from randomization until the first confirmed occurrence of MACE in the obicetrapib arm compared to placebo. The trial also evaluated the safety and tolerability profile of obicetrapib.

### Conference Call and Webcast Information

NewAmsterdam will host a live webcast and conference call to review the topline results from BROADWAY at 8:00 a.m. ET today. To access the live webcast, participants may register here. The live webcast will be available under the "Events" section of the Investor Relations page of the NewAmsterdam website at ir.newamsterdampharma.com.

To participate via telephone, please register in advance here. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. While not required, it is recommended that participants join the call ten minutes prior to the scheduled start. An archived replay of the webcast will be available on NewAmsterdam's website.

### About NewAmsterdam's Global Pivotal Phase 3 Program

NewAmsterdam's global, pivotal Phase 3 clinical development program consists of four trials in over 12,250 patients, three for obicetrapib monotherapy and one for a fixed-dose combination ("FDC") of obicetrapib and ezetimibe:

- BROOKLYN evaluated obicetrapib in patients with HeFH, whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam reported topline data in the third quarter of 2024 and presented additional data at the American Heart Association Scientific Sessions 2024 in November.
- TANDEM evaluated obicetrapib as part of a FDC tablet with ezetimibe, a non-statin oral LDL-lowering therapy, in patients with established
  atherosclerotic cardiovascular disease ("ASCVD") or multiple risk factors for ASCVD and/or HeFH, whose LDL-C is not adequately controlled
  despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam reported topline data in November 2024.
- BROADWAY evaluated obicetrapib in adult patients with established ASCVD and/or HeFH, whose LDL-C is not adequately controlled despite
  being on maximally tolerated lipid-lowering therapy. NewAmsterdam completed enrollment of over 2,500 patients in July 2023 and reported
  topline data in the fourth quarter of 2024.
- PREVAIL is a cardiovascular outcomes trial evaluating obicetrapib in patients with a history of ASCVD, whose LDL-C is not adequately
  controlled despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam completed enrollment of over 9,500 patients in April
  2024

### **About Obicetrapib**

Obicetrapib is a novel, oral, low-dose CETP inhibitor that NewAmsterdam is developing to overcome the limitations of current LDL-lowering treatments. In each of the Company's Phase 2 trials, ROSE2, TULIP, ROSE, and OCEAN, as well as the Company's Phase 3 BROOKLYN, BROADWAY and TANDEM trials, evaluating obicetrapib as monotherapy or combination therapy, the Company observed statistically significant LDL-lowering combined with a side effect profile similar to that of placebo. The Company is currently conducting the Phase 3 PREVAIL cardiovascular outcomes trial in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of major adverse cardiovascular events, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization. NewAmsterdam completed enrollment of PREVAIL in April 2024 and randomized over 9,500 patients. Commercialization rights of obicetrapib in Europe, either as a monotherapy or as part of a fixed dose combination with ezetimibe, for cardiovascular diseases have been exclusively granted to the Menarini Group, an Italy-based, leading international pharmaceutical and diagnostics company.

### About Cardiovascular Disease

Cardiovascular disease (CVD) remains the leading cause of death globally, despite the availability of lipid-lowering therapies (LLTs). By 2050 more than 184 million US adults are expected to be affected by CVD and hypertension, including 27 million with coronary heart disease and 19 million with stroke. In the US from 2019 through 2022, CVD age-adjusted mortality rates increased 9%, eversing the trend observed since 2010 and undoing nearly a decade of progress. Despite the availability of high-intensity statins and non-statin LLTs, low-density lipoprotein cholesterol (LDL-C)

target level attainment remains low, contributing to residual cardiovascular risk, and underscoring a significant clinical need for improved therapeutic regimens. Even with 269 million LLT prescriptions written over the last 12 months, 30 million under-treated US adults are not at their risk-based LDL-C goal, of which 13 million have ASCVD. Less than 1 in 4 patients with ASCVD achieve an LDL-C goal of less than 70mg/dL and only 10% of very high risk ASCVD patients achieve the goal below 55 mg/dL. In addition to the 30 million under-treated US adults, there are 10 million patients diagnosed with elevated LDL-C who are not taking any LLTs including statins. Beyond LDL-C additional factors are at play, such as lifestyle choices, tobacco use, and obesity, as well as inflammation, thrombosis, triglyceride levels, elevated Lp(a) levels, and type 2 diabetes.

### About NewAmsterdam

NewAmsterdam Pharma (Nasdaq: NAMS) is a late-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where currently approved therapies have not been adequate or well tolerated. We seek to fill a significant unmet need for a safe, well-tolerated and convenient LDL-lowering therapy. In multiple phase 3 trials, NewAmsterdam is investigating obicetrapib, an oral, low-dose and once-daily CETP inhibitor, alone or as a fixed-dose combination with ezetimibe, as LDL-C lowering therapies to be used as an adjunct to statin therapy for patients at risk of CVD with elevated LDL-C, for whom existing therapies are not sufficiently effective or well tolerated.

### 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 forwardlooking 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; whether topline, initial or preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, or whether projections regarding clinical outcomes will reflect actual results in future clinical trials or clinical use of our product candidate, if approved; 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 and Israel-Hamas 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, forwardlooking statements reflect the Company's expectations, plans, or forecasts of future events and views as of the date of this document and are qualified in their entirety by reference to

the cautionary statements herein. The Company anticipates that subsequent events and developments may cause the Company's assessments to change. These forward-looking statements should not be relied upon as representing the Company's assessment as of any date subsequent to the date of this communication. Accordingly, undue reliance should not be placed upon the forward-looking statements. Neither the Company nor any of its affiliates undertakes any obligation to update these forward-looking statements, except as may be required by law.

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### Forward Looking Statements

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

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.

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## **SPROADWAY**

# Pursuing a New Treatment Paradigm for Cardiometabolic Disease

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

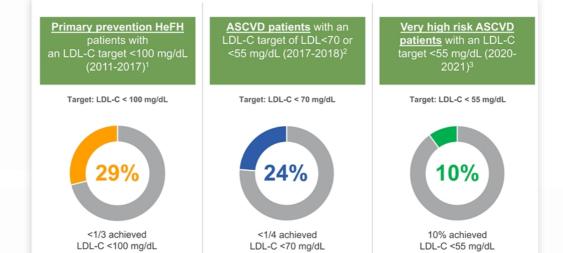
	BROADWAY	BROOKLYN	TANDEM
Day 84 – from placebo	Obicetrapib 10mg	Obicetrapib 10mg	Obicetrapib 10mg + ezetimibe 10mg
Mean	-33%	-36%	-52%
Median	-36%	-39%	-54%
LS mean (with imputation)	-33%	-36%	-49%

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



Note: MACE was evaluated in BROADWAY as an exploratory endpoint

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



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## **Trial Design and Baseline Characteristics**

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

### **Trial Design** 1º endpoint at week 12 N = 2530 Obicetrapib 10 mg (2:1 randomization) Placebo 13-months

### Key Inclusion Criteria

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

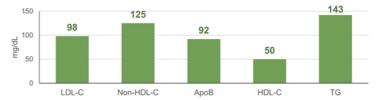
### **Key Exclusion Criteria**

- HoFH
- · Uncontrolled hypertension

### **Endpoints**

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

### Baseline Lipids (total population mean)



### **Demographics**

- 34% Female
- 65 years of age
- BMI: 30 kg/m<sup>2</sup>

### **Baseline Lipid Modifying Therapy** Any statin 91%

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

### Regions

- N. America
- EuropeAsia/Australia

### **Medical History**

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



# **Disposition of All Randomized Participants**

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

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# BROADWAY Demographics

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

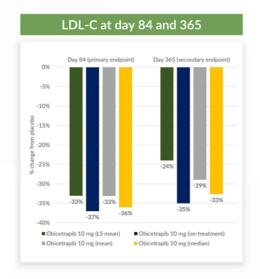
7

# **⇔** BROADWAY Demographics

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

# **♦ BROADWAY**

# Consistent LDL-C reduction observed over one year trial duration



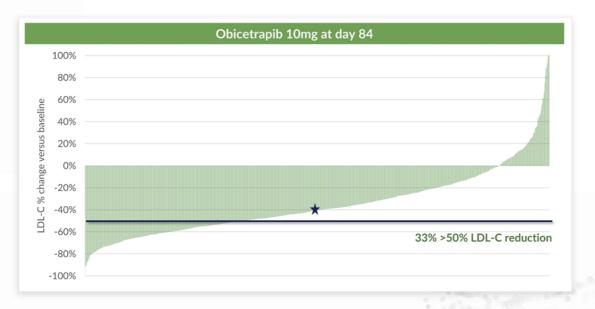




Note: LDL-C at day 84 and 365 chart via PUC. Mean reduction over time chart via Martin/Hopkins.

# **♦ BROADWAY**

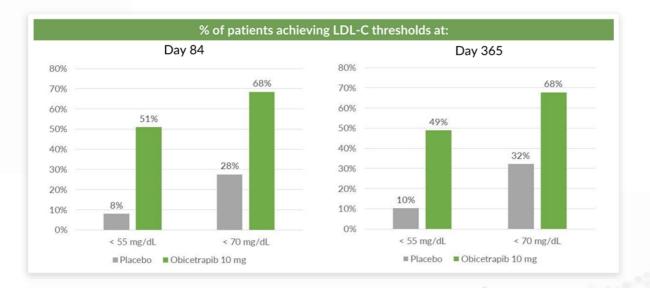
# Median change from baseline of 40%





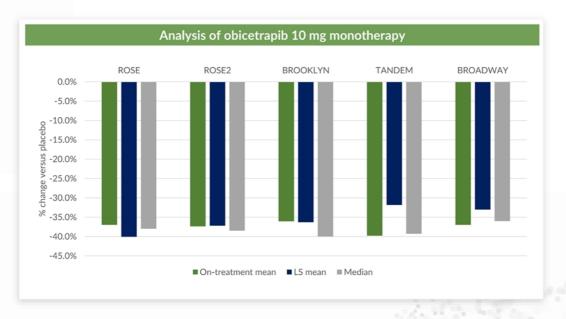
 $10\,$  Note: each line represents a single patient in the obicetrapib 10 mg arm, five patients increase more than 100%

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





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



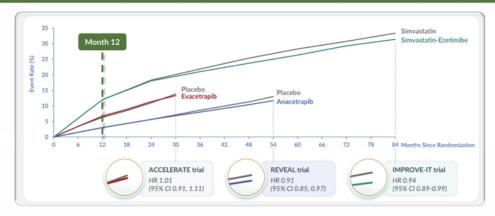


12 Note: ROSE at week 8, ROSE2, BROOKLYN, BROADWAY, and TANDEM as of week 12.

# **SPROADWAY**

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

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



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

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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.

# **Exploratory endpoint: Major adverse cardiovascular events (MACE)**

### BROADWAY MACE Data(1)

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

### BROADWAY + BROOKLYN Pooled MACE Data (1)

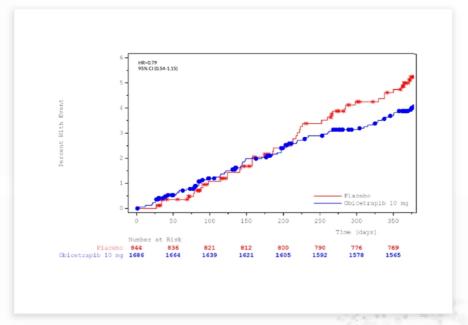
	Placebo N = 962	Obicetrapib N= 1920	Hazard Ratio	95% CI
All-cause mortality – no. (%)	14 (1.5)	20 (1.0)	0.78	(0.39-1.58)
Coronary heart death – no. (%)	7 (0.7)	9 (0.5)	0.63	(0.24-1.70)
First 4-point MACE – no. (%)	49 (5.1)	75 (3.9)	0.75	(0.53-1.08)





# **⇔** BROADWAY

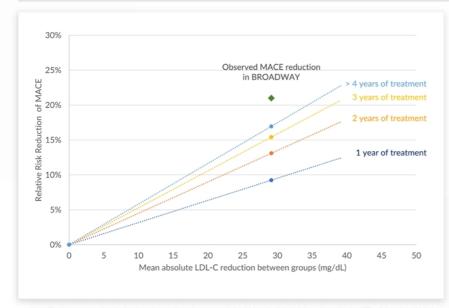
# Kaplan-Meier curve separates at day 200







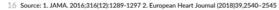
# Observed MACE reduction in BROADWAY suggests potential benefit beyond LDL-C



### CTT regression Line

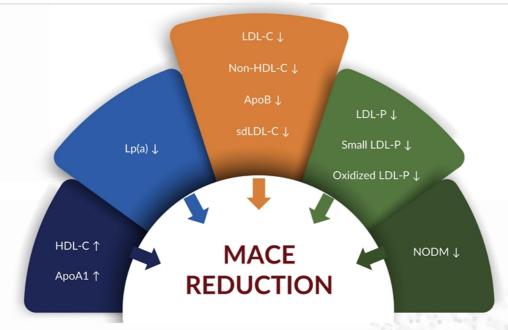
- The CTT regression line (dotted lines) represents the expected relationship between a mean absolute reduction in LDL-C versus placebo and the predicted MACE benefit at different time points based on historical trials
- In BROADWAY, we observed a 21% difference in MACE from placebo, after one year of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

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





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





17 Note: NODM = New onset diabetes mellitus

# **⇔** BROADWAY

# Safety population: Adverse event comparable to placebo

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

# Overview of Events of Special Interest

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

# Key observations from overall phase 3 program

### **Efficacy**

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

### **Tolerability**

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

### **Outcomes**

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

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