# 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 February 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 February 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 99.1 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 | 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.

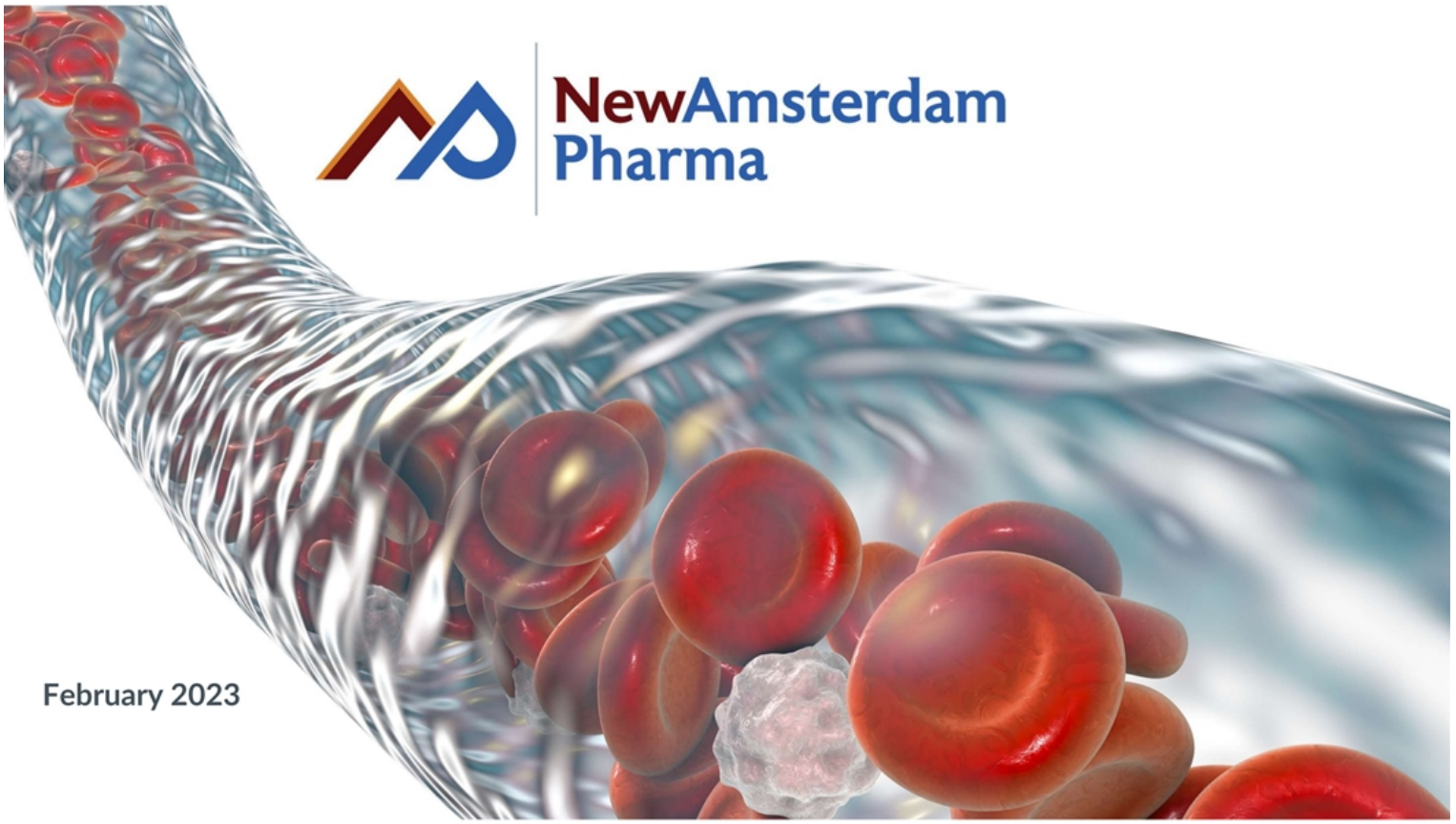
**NewAmsterdam Pharma Company N.V.**

February 14, 2023

By: /s/ David Topper
Name: David Topper
Title: Chief Financial Officer

Exhibit 99.1

NewAmsterdam Pharma



February 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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Certain statements included in this Presentation 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 by NewAmsterdam Pharma Company N.V. ("NewAmsterdam" or the "Company") regarding estimates and forecasts of other financial and performance metrics and projections of market opportunity; expectations and timing related to the success, cost and timing of product development activities, including timing of initiation, completion and data readouts for clinical trials and the potential approval of the Company's product candidate; the size and growth potential of the markets for the Company's product candidate; the therapeutic and curative potential of the Company's product candidate; financing and other business milestones; and the Company's expected cash runway. These statements are based on various assumptions, whether or not identified in this Presentation, 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 NewAmsterdam'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 NewAmsterdam's future business; and those factors discussed in documents filed by the Company with the SEC. Additional risks related to NewAmsterdam'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; and the Company's ability to continue to source the raw materials for its product candidate, together with the risks described in the Company's filings made with the U.S. Securities and Exchange Commission from time to time.

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

**Market Data**

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

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# 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)
- Nov '22: **NASDAQ listing** (*NAMS*) with **$328M total proceeds** ($93M from FLAC trust in deSPAC, plus $235M PIPE co-lead by Frazier and Bain)
- Jan '23: **~$1B market cap** and **$450M 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 efficacy and safety observed through Phase 2b:
  - **~50%** LDL-lowering as monotherapy, **~59%** in combination with ezetimibe, observed on top of high-intensity statins
  - Strong safety and tolerability in **>700 pts**
  - Robust effects on **ApoB, non-HDL-C, HDL-C and Lp(a)**
- **Convenient oral format + low cost of goods sold** (COGS) enables broad market access strategy to address existing unmet need

**>35M** addressable patient population

**~59%** LDL-lowering observed in Phase 2b

**$4B+** global market opportunity

## Achievements and milestones:

- **Fully-funded through 2026** including CVOT readout and potential global launch
- **Significant number** of patients randomized in Phase 3 to-date, first DSMB meeting completed
- **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

# Expert cardiometabolic leadership supported by top investors

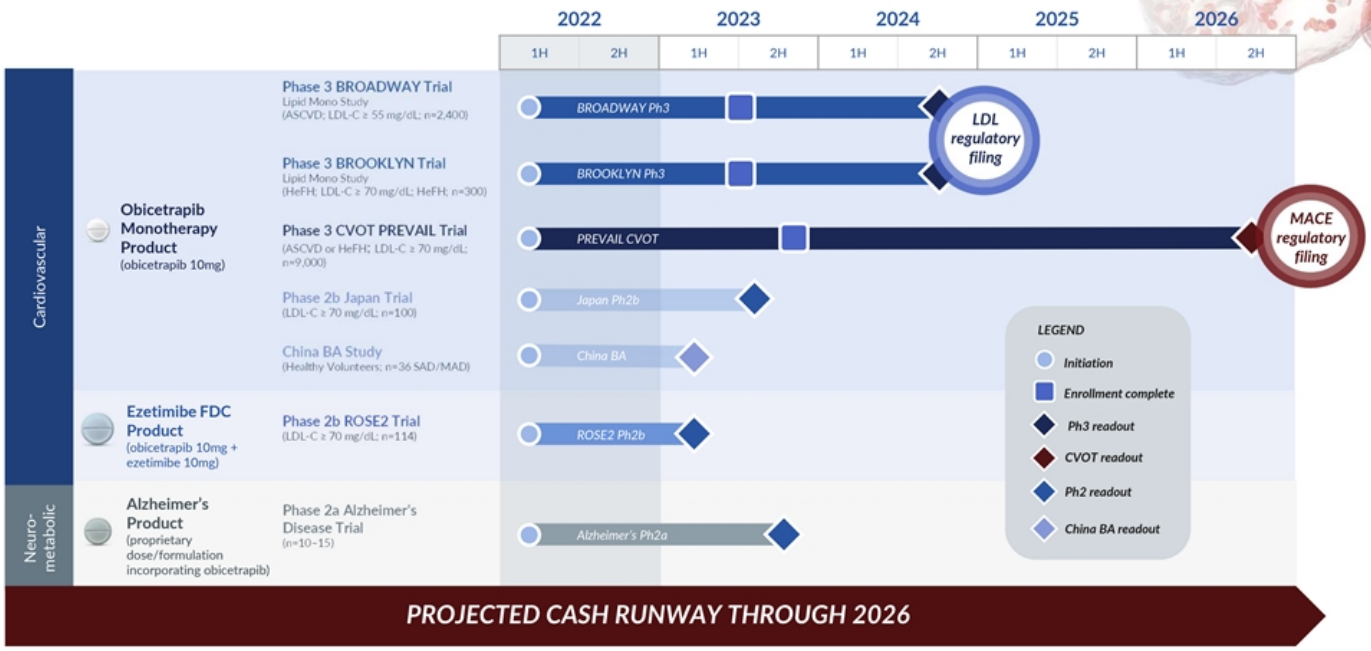
| Michael Davidson, M.D. | John Kastelein, M.D. | Douglas Kling | Lina Gugucheva | David Topper | Marc Ditmarsch, M.D. |
|---|---|---|---|---|---|
| CEO | CSO | COO | CBO | CFO | CDO |
| CORVIDIA, mthera | uniQure | CORVIDIA, mthera | IFM, SCORPION | GENERAL ATLANTIC, J.P.Morgan | AstraZeneca, Roche |

**SEASONED BOARD OF DIRECTORS:**

| Sander Slootweg | Juliet Audet | Jamie Topper | Nicholas Downing | Lou Lange | Michael Davidson | John Kastelein | John W. Smither |
|---|---|---|---|---|---|---|---|
| *Managing Partner, Forbion* | *Partner, Forbion* | *Managing Partner, Frazier Life Sciences* | *Partner, Bain Capital* | *Partner, Asset Management Ventures* | *CEO, NewAmsterdam Pharma* | *CSO, NewAmsterdam Pharma* | *Independent* |

**BACKED BY TOP TIER INVESTORS:** BVF Partners L.P., Forbion, FRAZIER LIFE SCIENCES, BainCapital, RACAPITAL, MORNINGSIDE, LSP, medicxi, DEERFIELD, Janus Henderson INVESTORS, KAISER PERMANENTE VENTURES, GMT CAPITAL, VIKING CAPITAL

# Net proceeds expected to fund obicetrapib development through several value-creating milestones




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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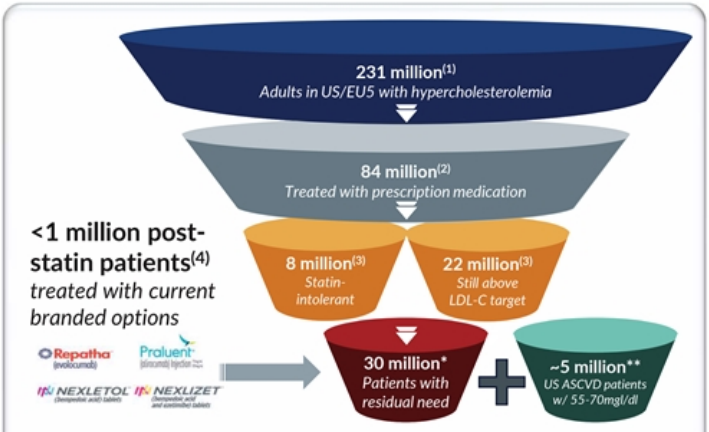
# Obicetrapib to Treat Cardiovascular Disease

# Despite availability of statins, CVD remains the leading cause of death worldwide




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

***Factoring in new U.S. guidance lowering LDL-C goals to 55 mg/dL for very high-risk patients, which will grow addressable patient population*


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

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).
(2) 2020 US prescription data for statins, PCSK9s, and bempedoic acid were pulled from the Bloomberg Prescription Data Portal that Trinity subscribes to; assuming 12 scripts/year per patient and 70% compliance for PCSK9s (based on PCSK9 literature) and 59% compliance for statins & Nex/Nex (based on statin literature) treated patient volume estimates were derived from the prescription data and extrapolated to the EU5.
(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.

# Current post-statin LDL-lowering products all fall short of the profile patients need

| | Ezetimibe | Nexletol | PCSK9 | Patients need a drug that fits the following profile: |
|---|---|---|---|---|
| **Efficacy** | Modest | Modest(1) | Strong | Strong(1) |
| **Administration/ Dose** | Oral, Low Dose 10mg | Oral, **High Dose** 180mg | **Injectable, High Dose** ~140-150mg | **Oral, Low Dose** |
| **Market Access/Price** | Generic, Broad Access | **Branded Price, Limited Access** | **Very High Price, Highly Restricted Access** (High COGS) | **Disruptive Price, Broad Access** (Low COGS) |
| **Safety & Tolerability** | Safe, Well Tolerated | **FDA Label:** Tendon rupture & gout warning | Safe **Painful injection site reactions** | **Safe, Well-Tolerated** |
| **Ancillary Benefit(s)** | None | None | Modest Lp(a) Lowering | **Strong Lp(a) Lowering, HDL Raising has Potential Benefits in Alzheimer's and Diabetes** |

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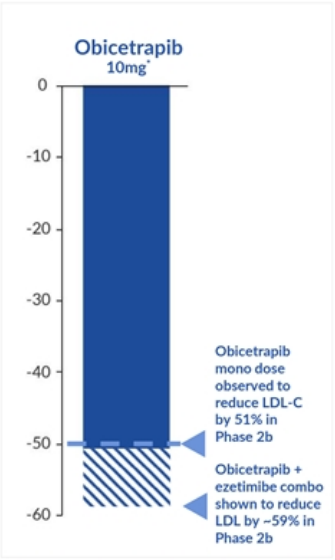
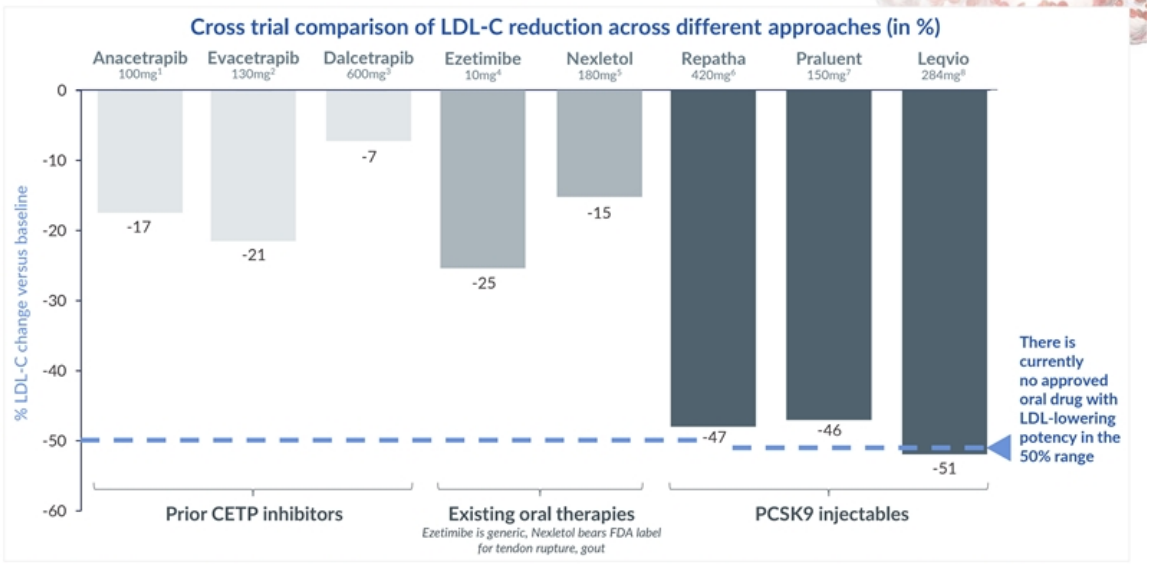
Note: Novartis' stated price of Inclisiran to be approximate to net prices of PCSK9 mAbs.
(1) Lighter shaded region of bar chart represents the additional potential efficacy for fixed dose combinations with ezetimibe.

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



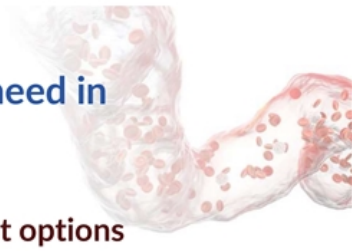




**The trials represented were selected due to their shared features that reflect the Phase 3 obicetrapib studies. Selecting trials with shared features allows for a potentially more accurate comparison of the LDL-C lowering results, with factors being considered such as: a)** presence of intensive LDL-lowering 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.** PI Repatha; study 3. refers to; Blom, D et al. N Engl J Med 2014. Also included hyperlipidaemia patients. **7.** PI Praluent; study 3. refers to; Kereiakes, D et al. Am Heart J 2015. **8.** PI Leqvio; study 1. Refers to; Ray, K. N Engl J Med 2020.

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



**231mm[1]** *Patients with hyperlipidemia* → **>35mm patients not sufficiently addressed by available treatment options**

**Fewer than 1mm** patients treated with current branded options:


PCSK9s | Bempedoic Acid

**THE PROBLEM**

- Payors highly restrict access
- Low prescriber enthusiasm
- Relatively low patient compliance

**THE SOLUTION**

**OBICETRAPIB**  *10mg*

- ✓ ~50% LDL-lowering observed for monotherapy, ~59% in combination with ezetimibe in Phase 2b
- ✓ Potential for attractive pricing to unlock broad access
- ✓ Strong safety and tolerability profile observed
- ✓ Convenient once-daily oral tablet
- ✓ High prescriber and payor enthusiasm

**>$4B[2] global market opportunity**

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(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.

# US market research indicates strong prescriber and payor enthusiasm, wide window of pricing opportunity to enable broad market access strategy

## Strong enthusiasm from prescribers and payors:

PRESCRIBER ENTHUSIAM:

| | Nexletol | PCSK9i | Obicetrapib |
|---|---|---|---|
| Efficacy | Moderate/Low* | High | High |
| Safety/ Tolerability | Moderate | High | High |
| Route of Administration | High | Low | High |

PAYOR ENTHUSIAM:

"Biggest need (is) a product that works like the PCSK9s but with a more convenient ROA and no diabetes risk"

"Fulfills an important unmet need"

## Broad market access opportunity:

### Market access hurdles plague existing brands:

$$$$

Repatha Praluent

**PRICE IS TOO HIGH** for meaningful access (~$6K)

*"There is a lot of documentation involved as we're **really trying to restrict to the highest risk patients** that actually need these costly products"*

*-Payor*

$$$

NEXLETOL NEXLIZET

**MODEST EFFICACY**, comparable to generics, make *any* branded price hard to justify (~$4K)

### Obicetrapib positioned to unlock significantly better access:

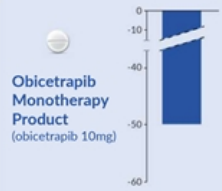
$$

- ✓ Low COGS enables favorable pricing
- ✓ Strong LDL-C lowering, virtually same as injectables
- ✓ Simple, convenient oral pill gives payors confidence around patient compliance
- ✓ Ancillary benefits for diabetes prevention, Lp(a) lowering



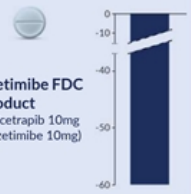
Key: Blue cells denote high ratings (6.5 – 9) / Yellow cells denote moderate ratings (5 – 6.4) / Red cells denote lowest ratings (1 – 4.9); ratings were given on a 9-point scale, thus lower / red ratings actually reflect the ~midpoint of the scale.
*In our survey, obicetrapib mono therapy received a moderate score and obicetrapib FDC therapy received a high score. Source for other scores: Trinity quantitative market research; N = 100 (50 PCPs + 50 cardiologists).

# Developing monotherapy and FDC in parallel builds in optionality for patients and prescribers, optimizes chances of broad market access




**Obicetrapib Monotherapy Product**
(obicetrapib 10mg)

- Expected to be preferred:
  - Initially, by **less aggressive** prescribers and those seeking **more experience** with CETPi class
  - By prescribers with **lingering misperceptions** about ezetimibe
  - Over time, expect that this will be the product that moves into earlier lines of therapy and primary care utilization




**Ezetimibe FDC Product**
(obicetrapib 10mg + ezetimibe 10mg)

- Expected to be preferred:
  - By **more aggressive** prescribers & KOLs
  - For **highest risk** patients
  - By **more physicians over time** as treatment paradigms shift, CETPi experience is gained

*Parity pricing with monotherapy should ensure parity access*
*CVOT data from both obicetrapib and ezetimibe monotherapies + Phase 3 FDC data would be included in FDC label*

**Note:**
Nexletol/Nexlizet scripts are currently generating 1:1 sales, however ESPR has signaled expectations for Nexlizet to become preferred with time

Obicetrapib mono utilization

Ezetimibe FDC utilization

MORE EXPERIENCE WITH CETPi

*plus*

BROADER ADOPTION OF NEW TREATMENT PARADIGMS:

- ✓ "Lower is better"
- ✓ Decreased LDL target goals
- ✓ Earlier-line use of combination therapy

**Expected to drive heavier FDC utilization over time**

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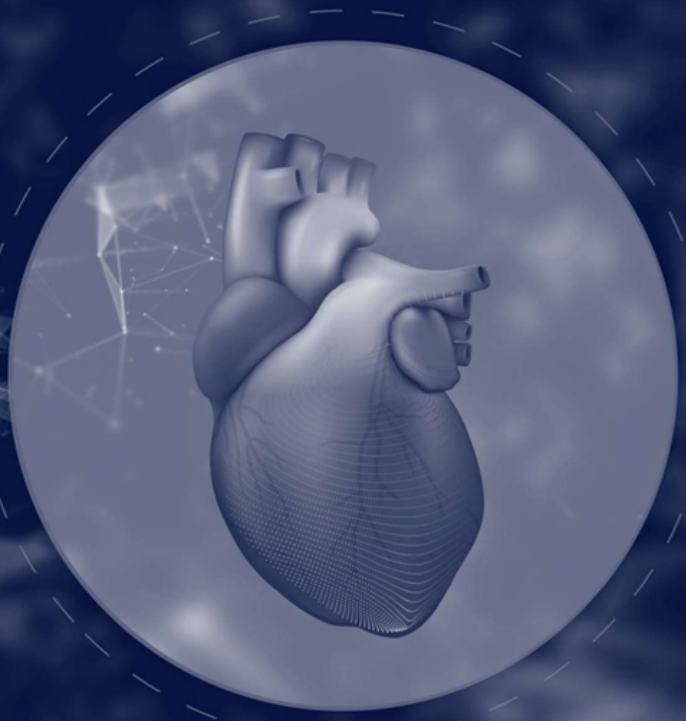
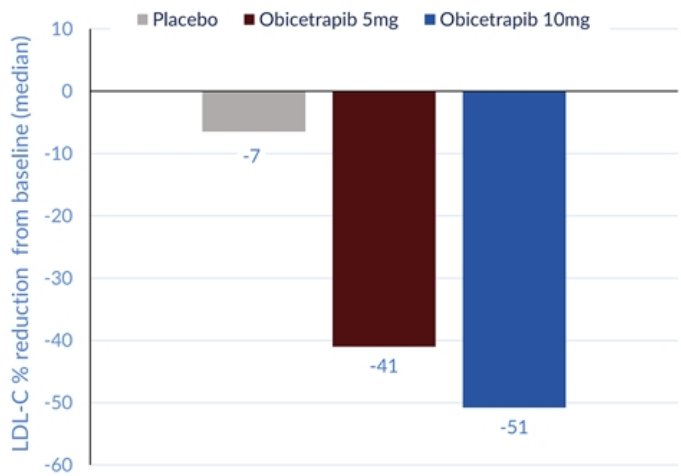
# Disease background and summary of clinical data



# In ROSE Phase 2b clinical trial, obicetrapib demonstrated robust LDL-C lowering as adjunct to high intensity statins[1]

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




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

| Time | Placebo | Obicetrapib 5mg | Obicetrapib 10mg |
|---|---|---|---|
| Baseline Median | 90.0 | 95.0 | 88.0 |
| | (63, 204) | (54, 236) | (39, 207) |
| | N=40 | N=39 | N=40 |
| EoT Median | 86.0 | 53.0 | 49.5 |
| | (43, 137) | (13, 126) | (23, 83) |
| | N=39 | N=39 | N=40 |
| % Change from Baseline (median) | -6.5 | -41.45 | -50.75 |
| | (-53.9, 31.6) | (-71.2, 62.3) | (-76.9, 15.6) |
| | N=39 | N=38* | N=40 |
| % Change from Baseline LS mean (95% CI) | -4.76 | -37.98 | -44.15 |
| | (-11.74, 2.22) | (-44.80, -31.17) | (-50.95, -37.35) |
| P-value | 0.1814 | <0.0001 | <0.0001 |

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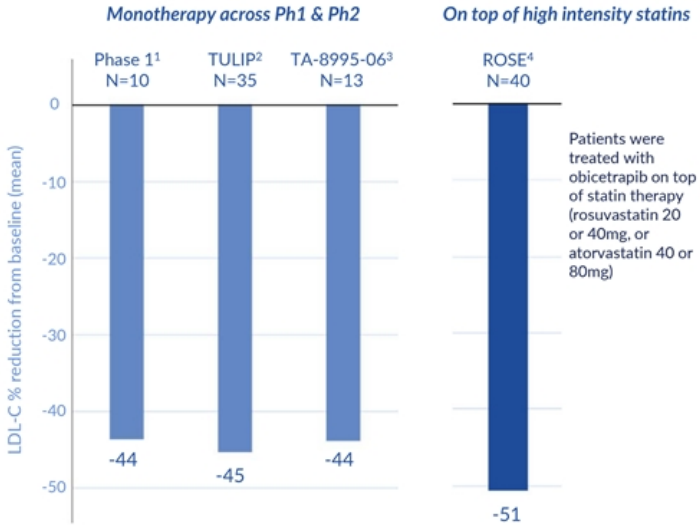
* In obicetrapib 5mg arm, 40 patients were randomized. N-value at end-of-treatment decreased to 38 because one patient was missing an LDL value at baseline and a second patient was missing an LDL value at end-of-treatment reading.

Source: 1. Nicholls SJ, et al. Nat Med 2022;28:1672-1678.

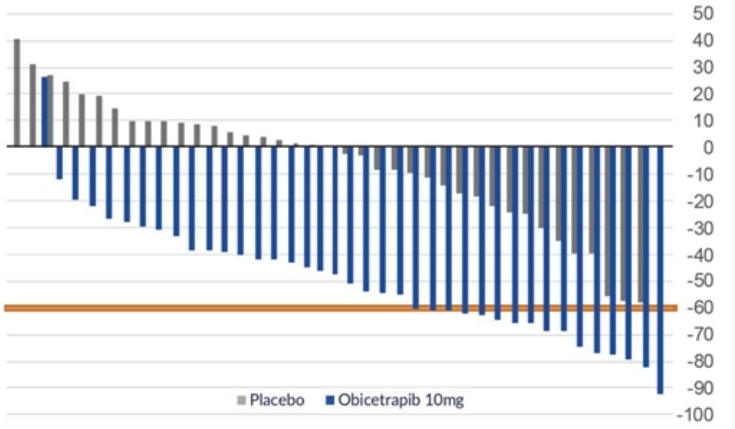
# Robust consistency of efficacy profile across multiple studies and within ROSE

## LDL-C lowering activity of obicetrapib 10mg across all efficacy studies to-date




## ROSE waterfall: 10mg vs. placebo

- *Almost all patients experienced meaningful LDL-C reductions*
- *LDL-C reduction of >60% was observed in 40% of obicetrapib 10mg patients*

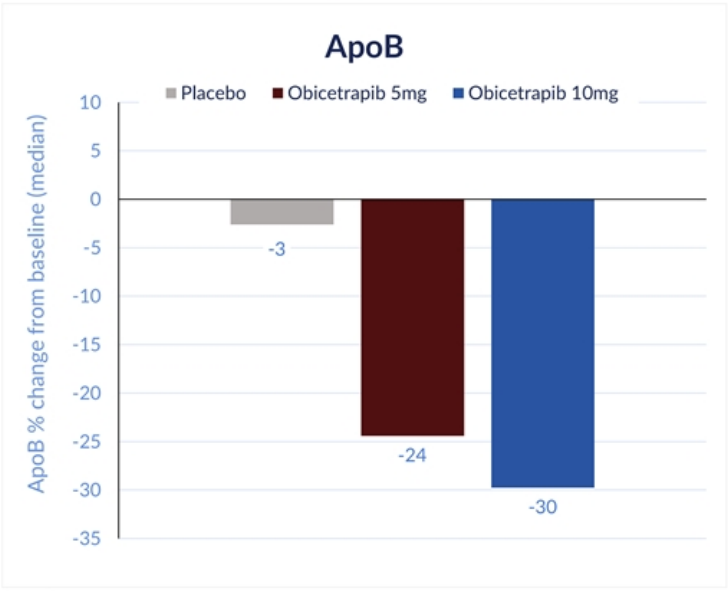


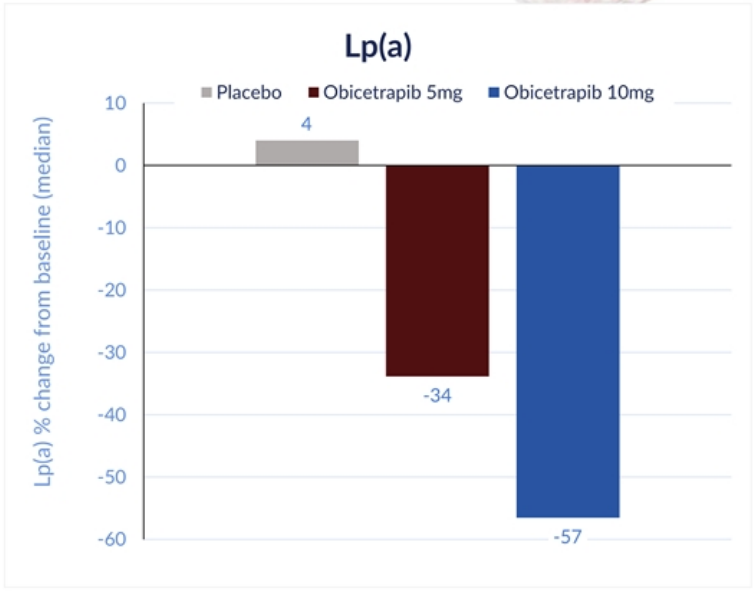

Note: Each bar represents one subject in the trial.

Source: 1. Ford J, et al. Br J Clin Pharmacol 2014;78:498-508; 2. Hovingh GK, et al. Lancet 2015;386:452-460; 3. Data on file; 4. Nicholls SJ, et al. Nat Med 2022;28:1672-1678

# ApoB & Lp(a) percent reduction from baseline in ROSE[1]

- *ApoB is currently considered the most important biomarker for CVD risk reduction (in addition to non-HDL and LDL-C)*
- *Elevated Lp(a) is emerging as a strong and independent marker of cardiovascular risk and an exciting new CVD drug target*

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Source: 1. Nicholls SJ, et al. Nat Med 2022;28:1672-1678.

# 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) |
|---|---|---|---|
| **AEs (%)** | | | |
| AEs, total | 19 (47.5) | 15 (37.5) | 8 (20.0) |
| AEs, related | 4 (10.0) | 2 (5.0) | 1 (2.5) |
| AEs, severe | 1 (2.5) | 0 | 0 |
| **SAEs** | | | |
| SAEs, total | 2 (5.0) | 0 | 0 |
| SAEs, related | 0 | 0 | 0 |
| Deaths | 0 | 0 | 0 |
| **Withdrawals study / medication** | | | |
| TEAEs leading to discontinuation of study drug | 1 (2.5) | 0 | 0 |
| TESAEs leading to discontinuation of study | 0 | 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) |
| TESAEs leading to discontinuation of study | 0 | 0 |

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

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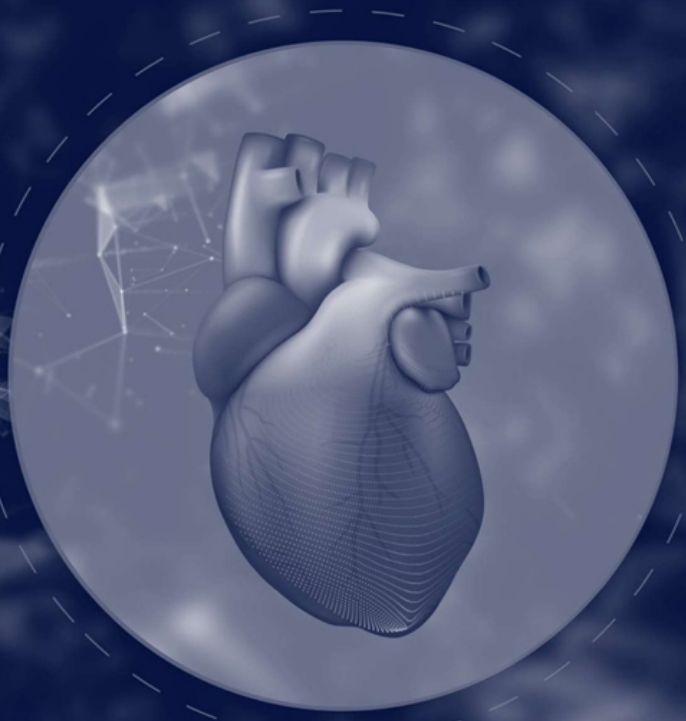
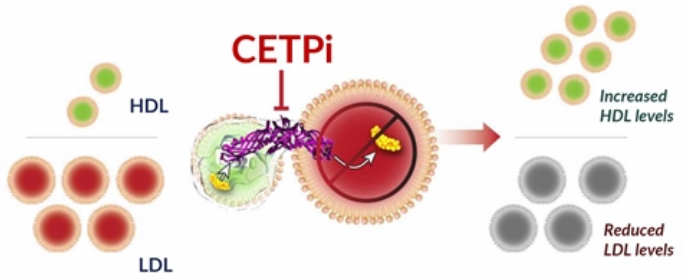
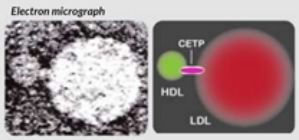
# Target biology and class overview:
*Key lessons learned*

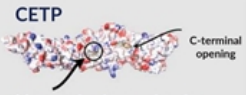


# CETP inhibition works to lower LDL via a two-step mechanism of action

## STEP 1: CETPi stops transfer of cholesterol from LDL to HDL, increasing HDL-C and lowering LDL-C

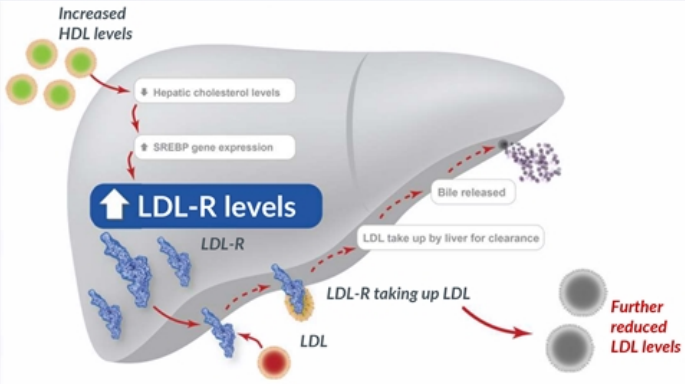


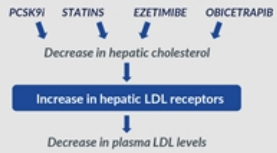




N-terminal opening is where CETPi bind

## STEP 2: Increase in HDL particles leads to increased LDL-R expression in the liver, promoting further clearance of LDL




Most current LDL-lowering therapies, including CETPi, work by promoting LDL receptor upregulation

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Note: Figures adapted from Meng Zhang, at al., Assessing the mechanisms of cholesteryl ester transfer protein inhibitors, Biochimica et Biophysica Acta (BBA) - Molecular and Cell Biology of Lipids, 1862(12), 2017, 1606-1617, and from Lei D, et al., Insights into the Tunnel Mechanism of Cholesteryl Ester Transfer Protein through All-atom Molecular Dynamics Simulations, J Biol Chem., 2291(27), 2016, 14034-14044.

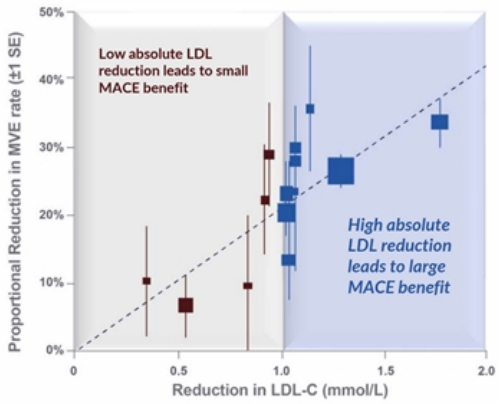
# *Absolute* reduction of LDL-C and ApoB, and *duration* of that reduction are key to reducing cardiovascular risk

MACE benefits impacted by 2 key factors:

- ABSOLUTE REDUCTION
- STUDY DURATION

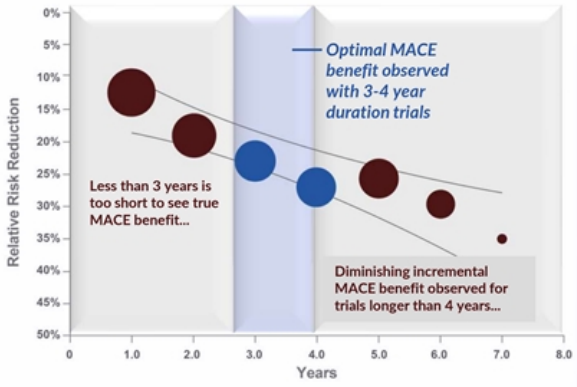
## Key factor 1: Absolute reduction

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*






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.

# 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 | | |
| **DALCETRAPIB**[2] Drug showed no LDL-lowering efficacy (Roche) | Safe & well-tolerated | | | |
| **EVACETRAPIB**[3] CVOT was too short to demonstrate MACE benefit (Lilly) | Safe & well-tolerated | Modest LDL-lowering | INSUFFICIENT TRIAL DURATION *(only 2 years)* | |
| **ANACETRAPIB**[4] *Meaningful MACE benefit observed* - but drug accumulated in fat tissue (Merck) | Safe & well-tolerated | Modest LDL-lowering | Sufficient duration *(4.1 years, with 6.4 year follow up)*<br>Baseline LDL too low *(60 mg/dL)* | COMMERCIALLY UNVIABLE - HIGH LIPOPHILICITY AND FAT TISSUE ACCUMULATION LED TO 4+ YEAR HALF-LIFE |
| | *Strong safety profile across ~59k patients* | | | |
| **OBICETRAPIB**[5] | ✓ Strong safety and tolerability profile observed in >600 patients through Phase 2b<br>✓ No concerns seen in biomarker safety data, including blood pressure-associated biomarkers | ✓ ~50% LDL-LOWERING OBSERVED IN PHASE 2B | ✓ Longer trial duration *(4 yrs)* + ✓ High baseline LDL *(100 mg/dL)*(1)<br>*= PREVAIL CVOT design expected to translate into >20% MACE benefit* | ✓ Favorable PK/PD profile<br>✓ 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.

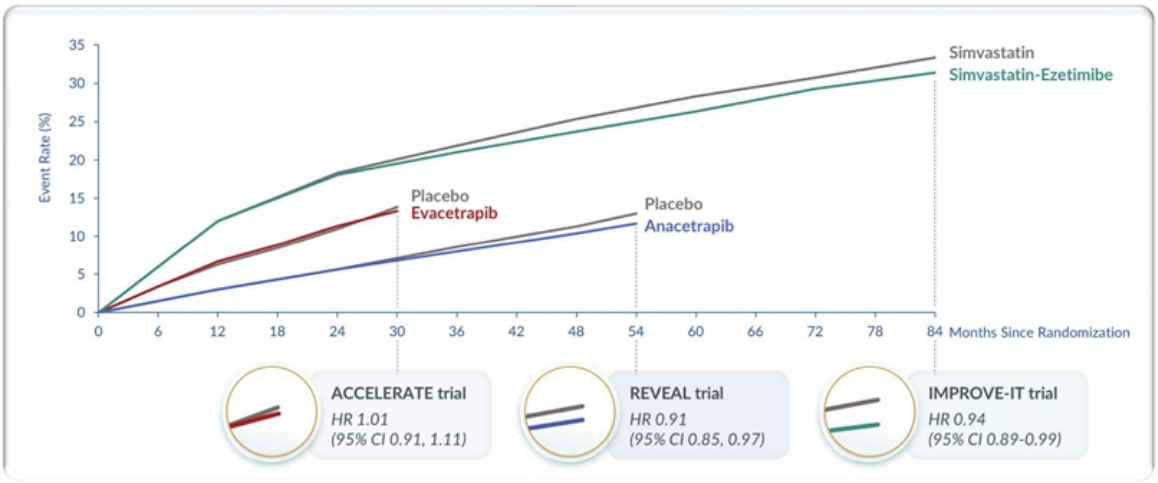
Sources: 1. Barter PJ, et al. N Engl J Med 2007;357:2109-2122; 2. Schwartz GG, et al. N Engl J Med 2012;367:2089-2099; 3. Lincoff AM, et al. N Engl J Med 2017;376:1933-1942; 4. The HPS3/TIMI55–REVEAL Collaborative Group. N Engl J Med 2017; 377:1217-1227; 5. Data on file

# ACCELERATE, REVEAL and IMPROVE-IT demonstrate 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.

# MACE benefits in CVOT of anacetrapib (REVEAL) observed to be exactly as expected, informing NewAmsterdam's CVOT design for obicetrapib

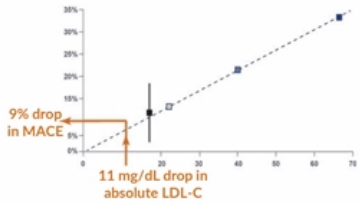
**MACE benefits impacted by 2 key factors:**

- ABSOLUTE REDUCTION
- STUDY DURATION

At 4.1 years, two important learnings:

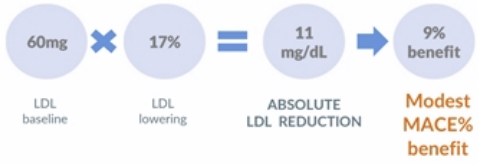
## Learning 1: Predictable MACE benefit

- 9% drop in MACE is exactly predicted by the CTT metaregression line
- Indicates CETPi behaves like statins in reducing MACE




## Learning 2: Baseline levels were too low

- Baseline 60 mg/dL already below U.S. guideline goals
- Modest drug LDL-lowering potency (17%) resulted in very small absolute reduction (only 11 mg/dL)




At 6.4 years: 20% additional MACE risk reduction

Anacetrapib's long half-life causes it to continue to have effects in patients (patients remained randomized)

*At both time readouts, REVEAL showed statistically significant drop across **all composites** of MACE**

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Source: The HPS3/TIMI55-REVEAL Collaborative Group. European Heart Journal (2021) 00, 1–9; The HPS3/TIMI55–REVEAL Collaborative Group. N Engl J Med 2017; 377:1217-1227
*Composites of MACE included in this analysis were coronary death, myocardial infarction or coronary revascularization.

# REVEAL supports translation from absolute LDL reduction to MACE benefit

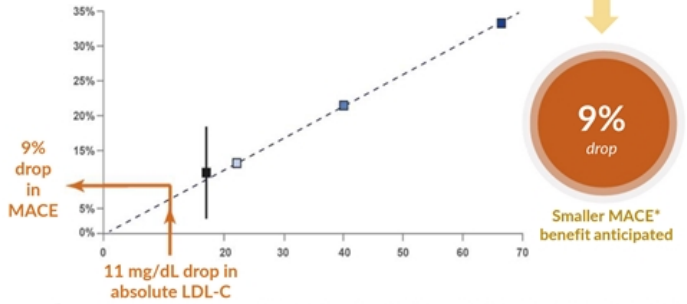
## EXPERIENCE: *REVEAL (anacetrapib)*

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

* 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.

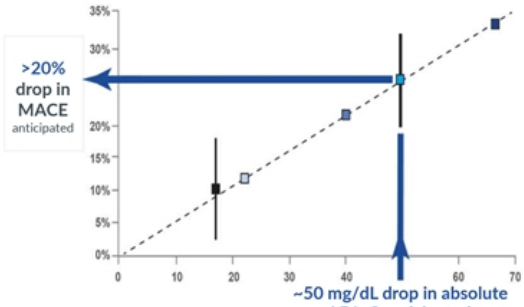
## PREDICTION: *PREVAIL (obicetrapib)*

~100 mg/dL(1) × 51% *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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# PREVAIL trial design & power calculations leverage lessons learned

- **Study design:**
  - n = 9000
  - Inclusion: ASCVD patients on maximally tolerated statins with risk enhancers and LDL-C > 70mg/dl
  - Minimum follow up 2.5 years
- **Primary endpoint:** 4-point MACE
- **First secondary:** 3-point MACE
- **Prespecified endpoints:**
  - Conversion of pre-diabetes to diabetes
  - A1c levels in diabetes patients
- **Power assumptions:**
  - 4.4% annual event rate
  - 45mg/dl reduction in LDL-C
  - 90% power to achieve a 20% relative risk reduction ($p < 0.01$)

## Differentiation over prior CVOTs

**Superior LDL-lowering activity**
*51% observed in Phase 2b*
*plus*
**Targeting higher baseline LDL patients**
*~100mg/dc anticipated*

→ ✓ **Higher *absolute* LDL-c reduction leads to greater MACE benefit**

**Longer duration of follow up**
*Median of 48 months vs. only 2.1 years in ACCELERATE*
*plus*
**Targeting higher-risk patient population**
*ASCVD patients further enriched with with risk enhancers shown in REVEAL long-term follow up to have stronger relative risk reduction (high LDL/ApoB, diabetes, high triglycerides, recent MI)*

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

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

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

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Note: Actual results may differ from expectations.

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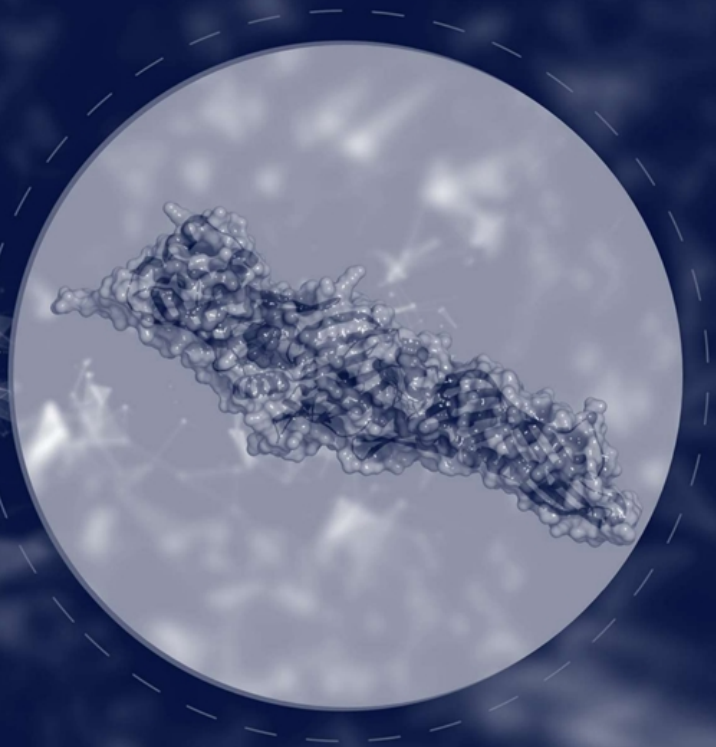
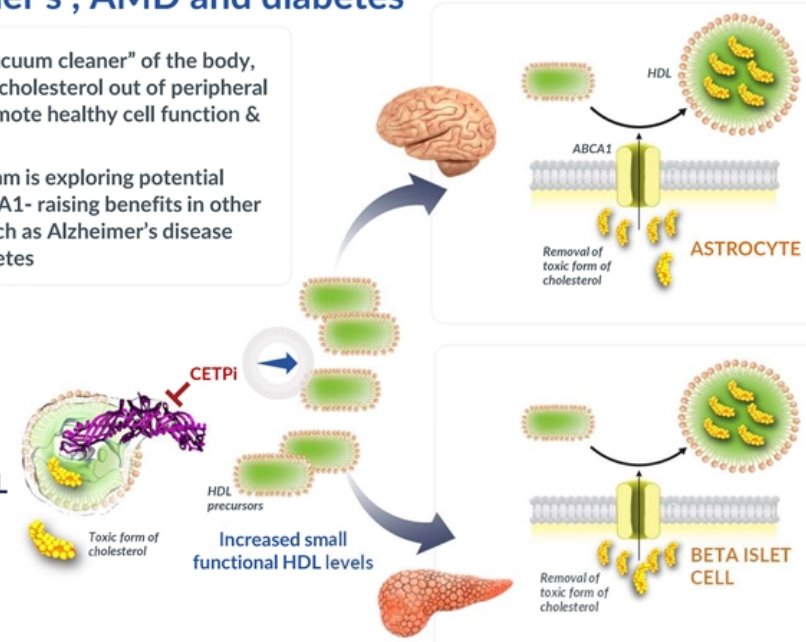
# Therapeutic area expansion opportunities



# HDL and apoA1 effects potentially offer pipeline expansion opportunities in Alzheimer's , AMD and diabetes

- HDL is the "vacuum cleaner" of the body, effluxing free cholesterol out of peripheral tissues to promote healthy cell function & survival[1]
- NewAmsterdam is exploring potential HDL- and apoA1- raising benefits in other indications such as Alzheimer's disease (AD) and diabetes




**Obicetrapib observed to increase HDL by >160%**

**POSITIVE TISSUE EFFECTS IN THE BRAIN**

- Increasing HDL and apoA1 is expected to promote healthy tissue survival in the brain[2]
- Administration of CETPi to APP/CETP knock-in mice observed to promote cholesterol removal from the brain and improve cognition[3]
- We are testing obicetrapib in Alzheimer's patients in a Phase 2a biomarker study

**POSITIVE BETA ISLET CELL EFFECTS IN THE PANCREAS**

- Increasing HDL is expected to promote beta islet cell survival in the pancreas, potentially improving insulin production[4,5]
- All four prior CETPi CVOTs demonstrated statistically significant reduction of diabetes risk or reversal of diabetes progression[6-9]
- We are measuring diabetes progression as an endpoint in PREVAIL and are exploring regulatory paths for a diabetes prevention indication

Sources: 1. Tall AR, et al. Nat Rev Immunol 2015;15:104-116; 2. Hottman DA, et al. Neurobiol Dis 2014 2014;72:22-36; 3. Phenix J, et al. Alzheimer's Dement. 2021;17(Suppl. 3):e051134; 4. Fryirs MA, et al. Arteriosclerosis, Thrombosis, and Vascular Biology. 2010;30:1642–1648; 5. Petremand J, et al. Diabetes 2012;61:1100-1111; 6. Barter PJ, et al. N Engl J Med 2007;357:2109-2122; 7. Schwartz GG, et al. N Engl J Med 2012;367:2089-2099; 8. Lincoff AM, et al. N Engl J Med 2017;376:1933-1942; 9. The HPS3/TIMI55–REVEAL Collaborative Group. N Engl J Med 2017; 377:1217-1227

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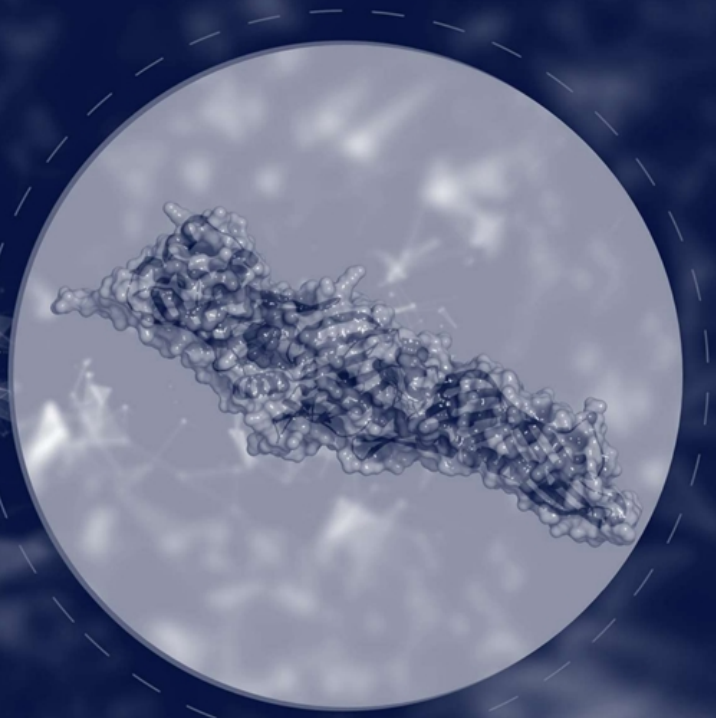
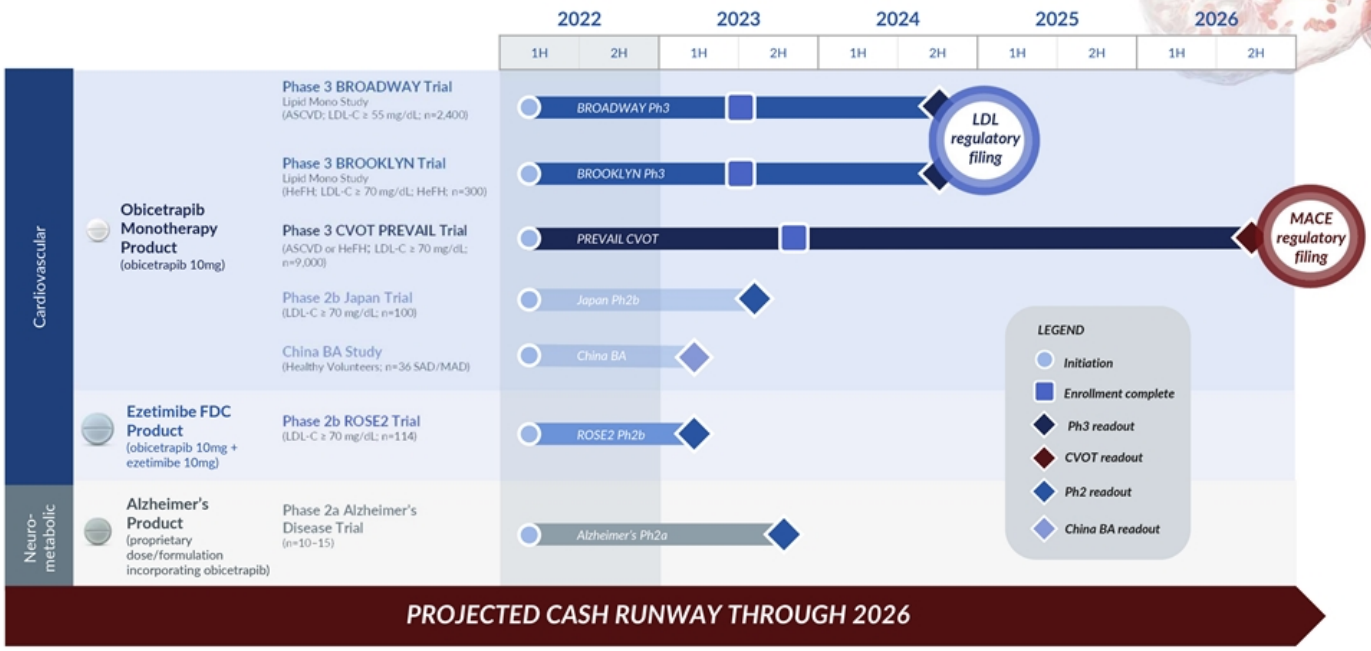
# Clinical development and exclusivity timelines



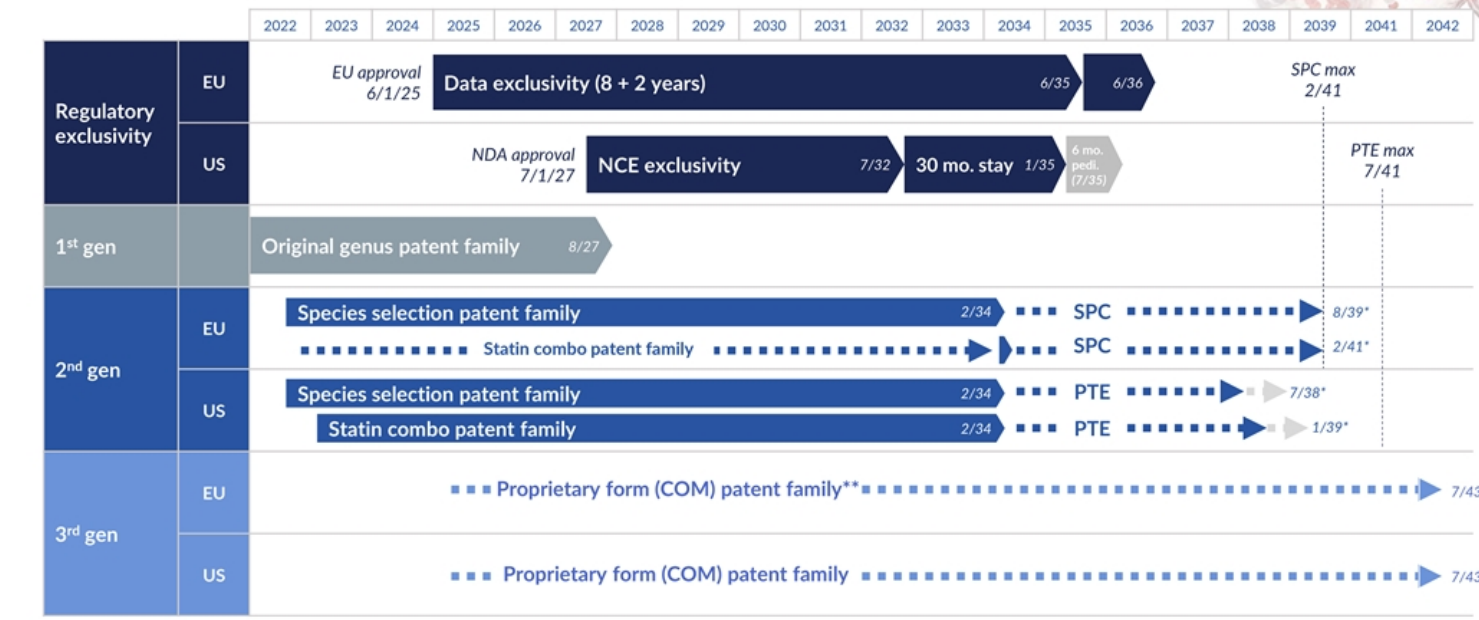
# Net proceeds expected to fund obicetrapib development through several value-creating milestones




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.

# Projected exclusivity timelines in the EU and US

*Assumes EU approval on June 1, 2025 and US approval on July 1, 2027*

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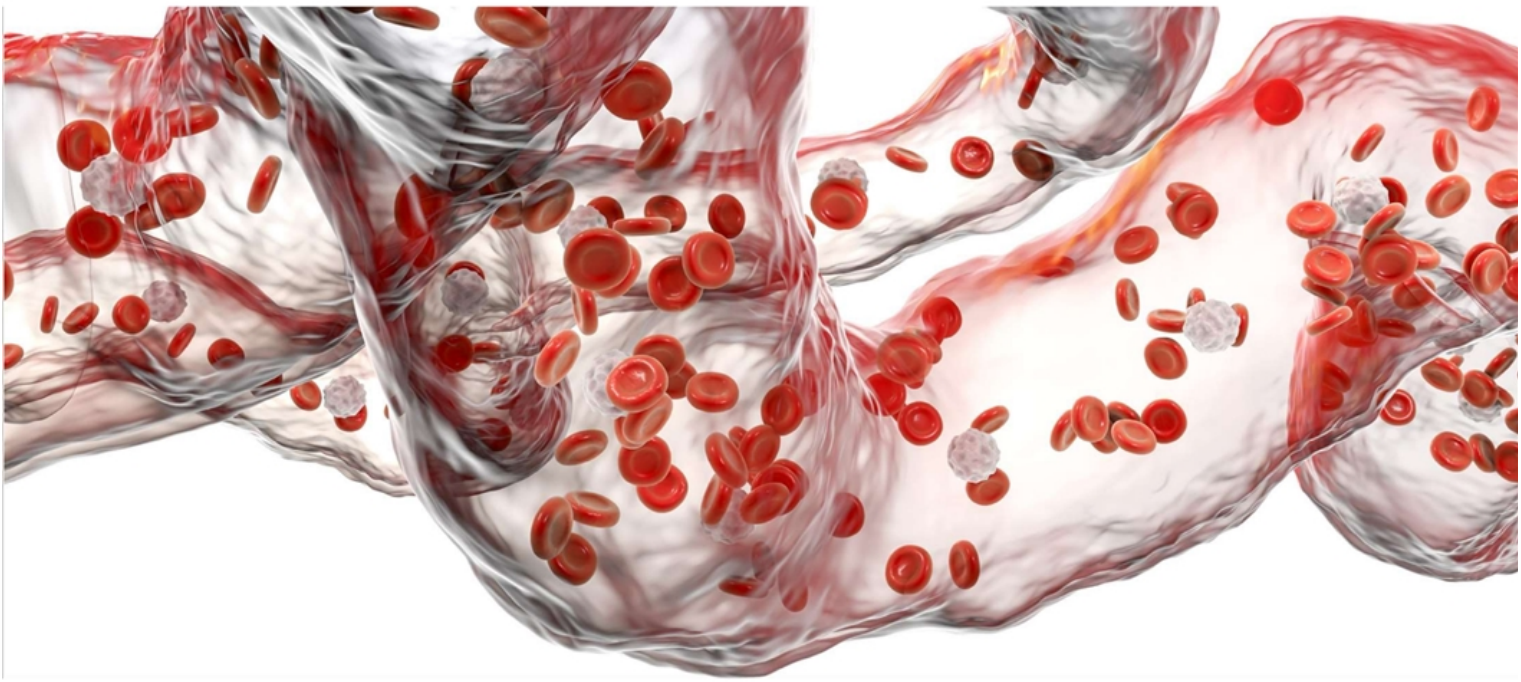
Note: Filled colors = granted patents & dotted lines = pending patents; one patent only to be selected for SPC/PTE; an earlier US approval leads to earlier regulatory expiry & shorter PTE; *including pediatric extension 6m; ** will be pending once a PCT application is filed; actual results may differ from expectations.



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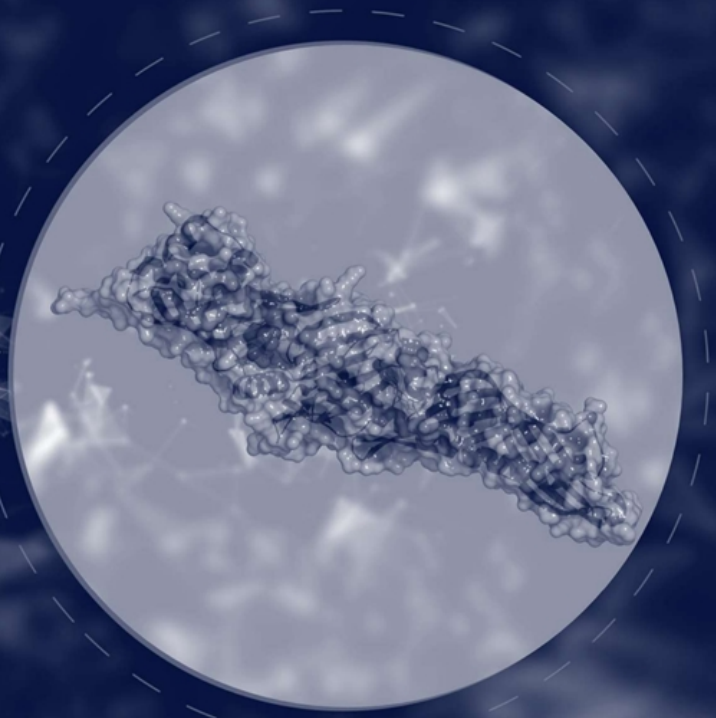
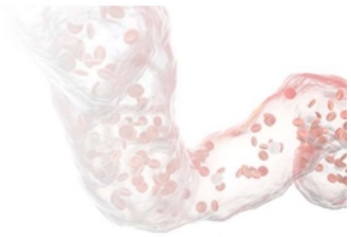
# Appendix



# Obicetrapib development history



***Preclinical—Phase 1b (2008-2012)***

- Mitsubishi Tanabe (MTPC) is a Japanese pharmaceutical company, invented obicetrapib in late 2000's
- MTPC completed development through Phase 1b and thereafter deprioritized any lipid-lowering therapeutics
- Dr. Kastelein was a consultant of MTPC, Phase 1b data compelled him to spin-out program to NewCo (Dezima Pharma) in 2012

Mitsubishi Tanabe Pharma

***Further development through Phase 2a (2012-2015)***

- Completed further early Phase 1/2 studies
- Completed Phase 2a TULIP study on top of **low-dose statins,** demonstrating ~45% LDL-lowering efficacy
- Company was acquired by Amgen in 2015 for **$300M** upfront + **$1.5B** in CVRs

DEZIMA pharma

***Manufacturing scale-up (2015-2016)***

- "Paused" clinical development to scale-up manufacturing to support Phase 3/commercial supply
- Discovered manufacturing process that led to current $3/month projected peak COGS
- In 2015/2016, a "perfect storm" of external factors (incl. Merck and Lilly CETPi CVOT read-outs) led to a re-prioritization within Amgen's CVD portfolio, and obicetrapib was de-prioritized to 4th-in-line for a CVOT

AMGEN

- Dr. Kastelein and Forbion led spin-out of obicetrapib program from Amgen to NAMS in 2020
- Spin-out negotiations also led to full transfer of IP *ownership* to NAMS, including global rights (Asian territories had previously been retained by MTPC)
- Amgen and MTPC are shareholders of NAMS *(hold no other commercial or economic rights; i.e., no milestones/royalties)*

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***Phase 2b through CVOT and commercialization (2020 through present)***

# Menarini partnership overview

*Partnership with Menarini brings in significant non-dilutive capital and could enable NewAmsterdam to simultaneously launch obicetrapib in different markets with the ideal partner to optimize the commercial opportunity in the EU*

## RIGHT PARTNER

**MENARINI IS A LEADING EUROPEAN PHARMACEUTICAL COMPANY**

***Leading presence in cardiovascular disease:***

- 18 marketed products in cardiometabolic diseases
- #1 share of voice among cardiologists, internists and GPs in EU5

***Deep commercial expertise:***

- 540 launches in 50 countries
- >2,500 sales reps and >280 specialist field force members in Europe
- Successfully secured access for >500 products

***Strong partnering track record, with 60+ partnerships spanning small biotech to large pharma***

## RIGHT TIME

**~3 YEARS FROM LAUNCH OPTIMIZES EUROPEAN DEVELOPMENT WITH AN EXCELLENT EUROPEAN PARTNER**

- Pricing and access in Europe is critical for obicetrapib's success
- Local expertise is needed to jumpstart P&MA strategy, including evidence generation and proactive HTA engagement
- Strong relationships with EU KOLs will support obicetrapib market entry while more effectively disseminating the obicetrapib value story

## RIGHT DEAL

**MENARINI TO RECEIVE EXCLUSIVE RIGHTS TO OBICETRAPIB MONOTHERAPY AND EZETIMIBE FDC FOR CVD IN EUROPE**

***NewAmsterdam retains all other global rights and is eligible for significant non-dilutive financial terms:***

- **€142.5mm** committed capital

  *(Consisting of **€115mm** upfront + €27.5mm committed R&D funding)*
- Up to **€863mm** payable upon achievement of certain clinical, regulatory and commercial milestones
- Tiered royalties from teens to **mid-twenties**

**UP TO €1,005.5mm OF TOTAL CASH CONSIDERATION**

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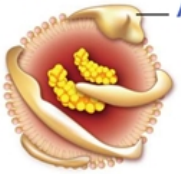
# LDL-C, ApoB and Lp(a) are causal in the development of atherosclerosis and heart disease

*ApoB is a molecule that envelopes LDL in a 1:1 ratio*

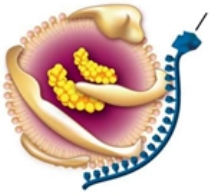
## LDL-C



**ApoB: Each LDL-C particle contains one ApoB molecule**

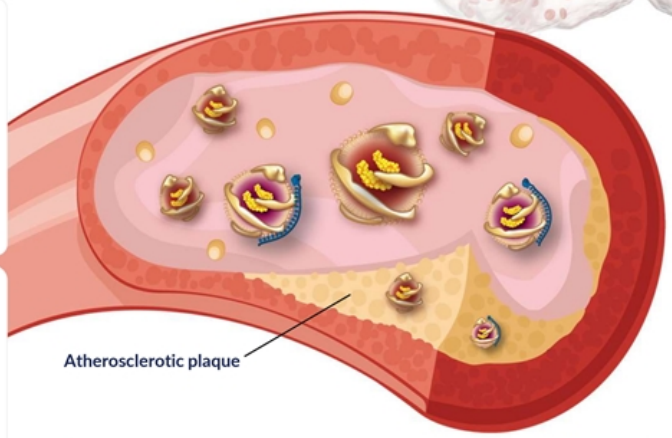
- ApoB-containing particles can become trapped in the arterial wall
- High ApoB levels lead to atherosclerotic plaque formation and buildup over time

## Lp(a)



**Each Lp(a) particle has a LDL particle that contains an ApoB wrapped with an Apo(a) molecule**

- Genetic mutations can lead to higher Lp(a) levels in certain individuals
- These individuals are at a higher risk of developing arterial plaques and experiencing adverse cardiovascular events




**Reducing the number of ApoB and Lp(a) particles in circulation is critical to halting plaque build-up and reducing CV risk**

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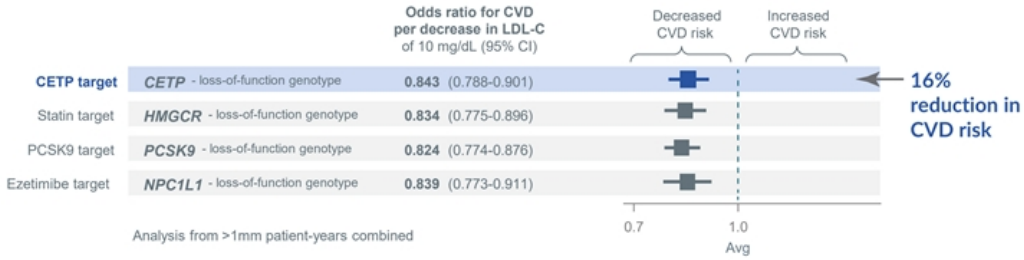
Source: Adapted from Ference BA, Kastelein JPP, Catapano AL. JAMA, 2020.

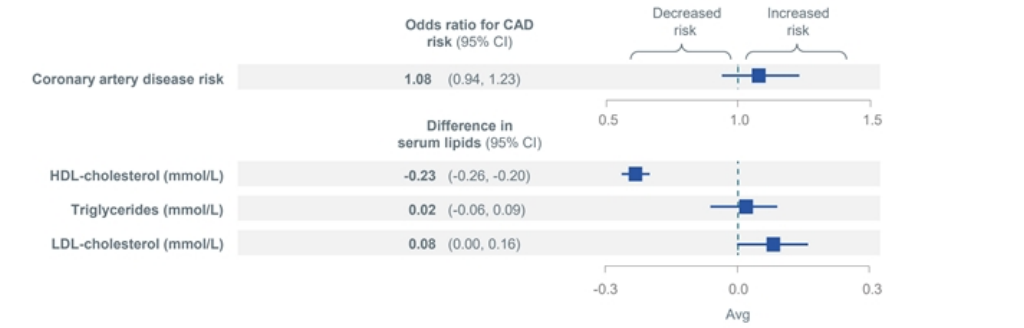
# Genetic support that CETPi drives CVD benefit through LDL reduction

*Analysis of >1mm patient-years' shows loss-of-function equivalent to targets of other LDL-lowering drugs*




**16% reduction in CVD risk**

- A **16% reduction** in CVD risk is observed for every 10 mg/dL decrease in LDL levels
- This is ~equivalent to the effect seen in loss-of-function genotypes for **statins**, **PCSK9 inhibitors** and **ezetimibe**




***More CETP = more CAD risk, less HDL, more LDL and more ApoB***

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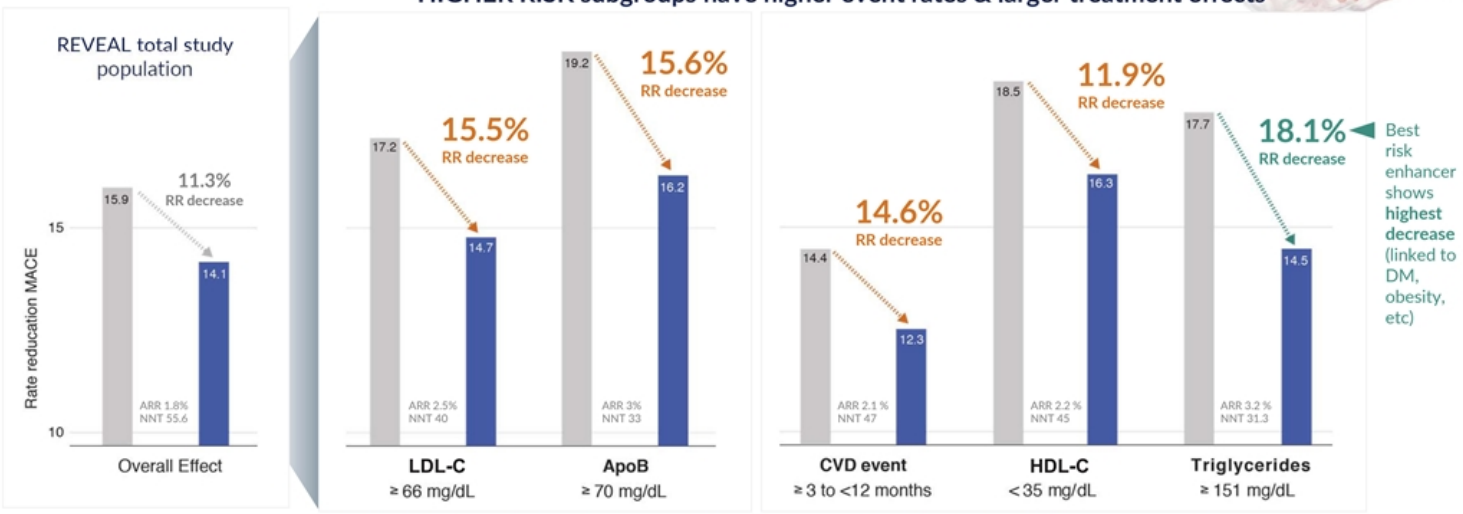
Sources: Ference BA et al. JAMA 2017; Blauw et al; Genome-Wide Association Study on Circulating CETP.
Note: CAD means coronary artery disease.

# REVEAL long-term follow-up identified risk enhancers important for PREVAIL

## HIGHER RISK subgroups have higher event rates & larger treatment effects




RR = relative risk
ARR = absolute risk reduction
NNT = number needed to treat

PREVAIL study **inclusion criteria** requires high baseline LDL-C (also translates to high ApoB)

Inclusion criteria: LDL-C ≥70 mg/dL

PREVAIL study **risk enhancers** will increase high-risk patient populations

Inclusion criteria: Lp(a) >75 mg/dL, HDL-C <40 mg/dL, triglycerides >150 mg/dL

Source: The HPS3/TIMI55-REVEAL Collaborative Group. European Heart Journal (2021) 00, 1–9

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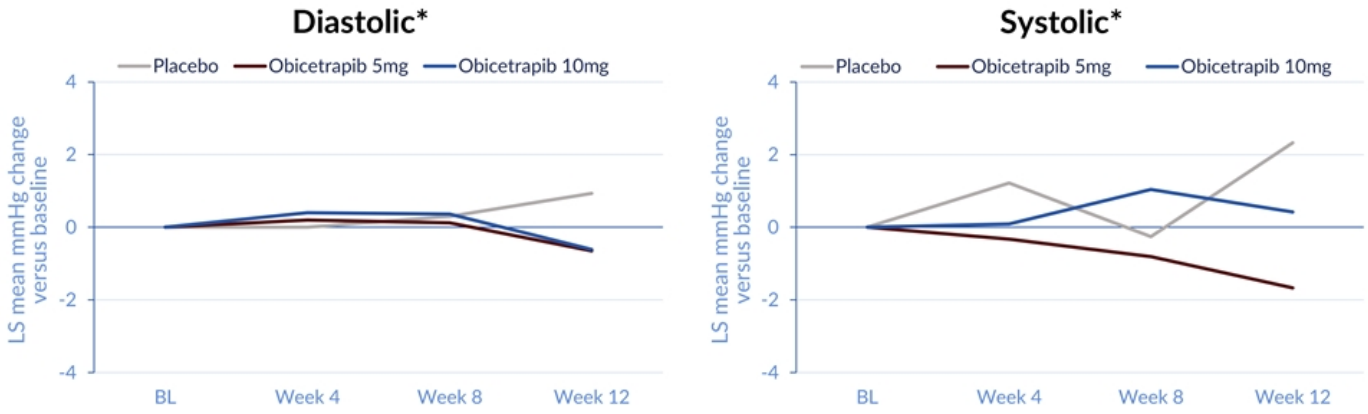
# Obicetrapib does not show an effect on systolic and diastolic blood pressure

- In the TULIP study, obicetrapib did not show any effect on blood pressure, aldosterone and electrolytes
- A dedicated meta-analysis of the obicetrapib ROSE, TULIP and OCEAN 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

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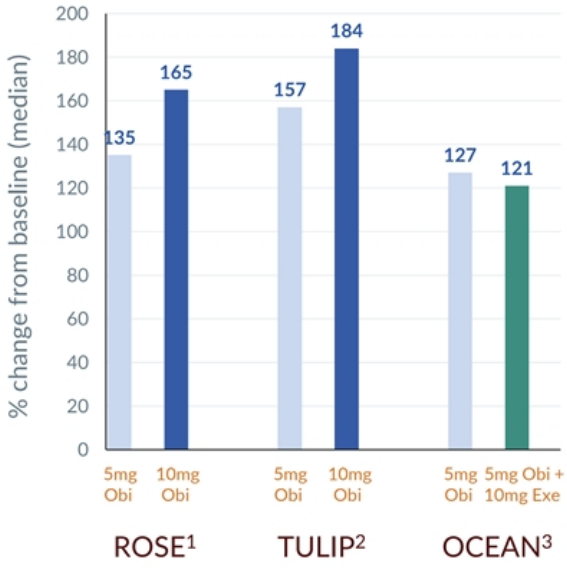
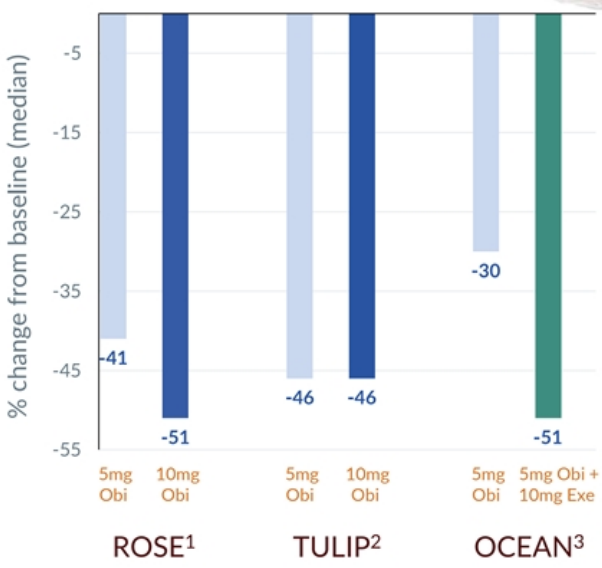
Sources: Circulation 2021;144:e564–e593 17065: Obicetrapib Lowers LDL-C in Patients Taking High Intensity Statins: Results From Rose Clinical Trial.
*Represents pooled data from the ROSE, TULIP and OCEAN clinical trials.

# Consistent LDL-C lowering and HDL-C increase observed across three Phase 2 studies of obicetrapib

## HDL-C levels increase




## LDL-C levels decrease

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Source: 1. Nicholls SJ, et al. Nat Med 2022;28:1672-1678; 2. Hovingh GK, et al. Lancet 2015;386:452-460; 3. Data on File

# OCEAN: Phase 2b evaluating 5mg obicetrapib in combination with 10mg ezetimibe

**Objective** To evaluate the effect of obicetrapib in combination with ezetimibe compared to placebo on LDL-C

## Inclusion criteria

- Mild dyslipidaemia
- Fasting LDL-C levels >2.5 mmol/L and <4.5 mmol/L

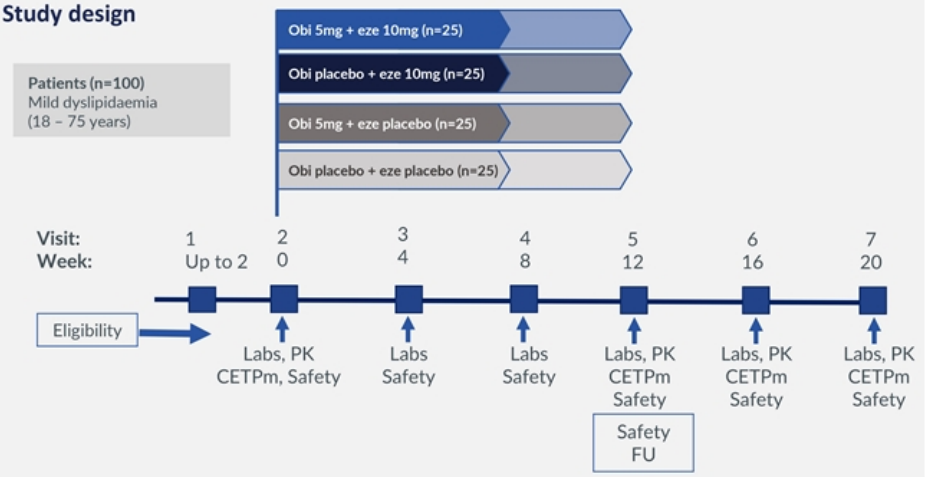
## Exclusion criteria

- Currently taking any lipid-lowering therapy
- Any clinical manifestation of atherosclerotic CVD
- Diagnosis of type 1 or type 2 diabetes mellitus
- Uncontrolled hypertension

## Primary efficacy endpoint

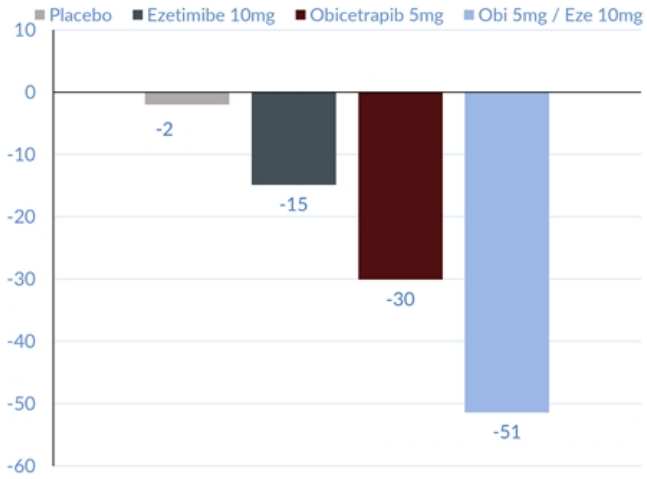
- **Percent change from baseline in LDL-C** for the combination therapy group compared to the placebo group

## Study design



# In OCEAN, obicetrapib was observed to have LDL-lowering efficacy that is additive with ezetimibe

## LDL-C in mg/dL by PUC & Percent change from baseline




Median (min, max) LDL-C levels (mg/dL) at baseline and EOT

| Time | Placebo | Ezetimibe 10mg | Obicetrapib 5mg | Obi 5 + Eze 10mg |
|---|---|---|---|---|
| Baseline Median | 136.0 (101, 177) (N=24) | 127.0 (76, 189) (N=27) | 121.0 (82, 153) (N=27) | 123.0 (89, 186) (N=27) |
| EoT Median | 138.0 (88, 193) (N=25) | 105.0 (66, 142) (N=24) | 86.5 (38, 137) (N=26) | 63.5 (34, 133) (N=24) |
| % change from BL median | -2.0 (-24.5, 35.9) (N=27) | -14.90 (-46.8, 46.9) (N=25) | -30.10 (-56.7, 19.1) (N=25) | -51.40 (-69.6, 8.1) (N=24) |
| % change from BL LS Mean (95% CI) | 1.40 (-6.03, 8.84) | -12.86 (-20.29, -5.42) | -30.70 (-38.21, -23.19) | -40.95 (-48.73, -33.16) |
| p-value | 0.7116 | 0.0007 | <0.0001 | <0.0001 |

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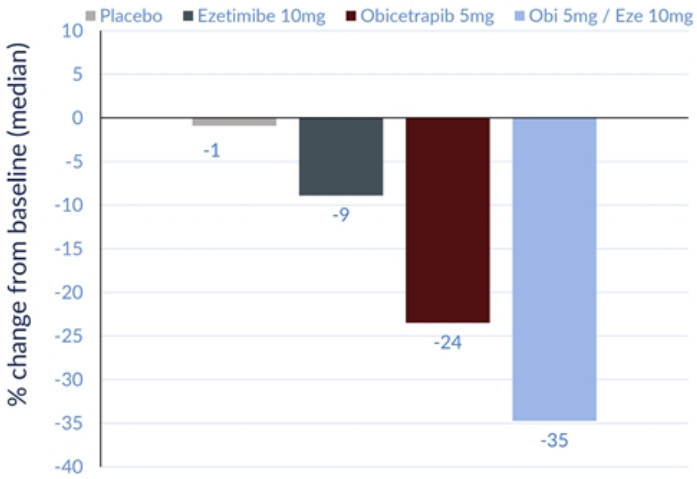
Data on File

# OCEAN: ApoB in mg/dL & percent change from baseline




Median (min, max) ApoB levels (mg/dL) at baseline and EOT

| Time | Placebo | Ezetimibe 10mg | Obicetrapib 5mg | Obi 5mg + Eze 10mg |
|---|---|---|---|---|
| Baseline Median | 105.5 (74, 141) (N=28) | 103.0 (79, 133) (N=28) | 102.0 (74, 124) (N=28) | 105.0 (77, 158) (N=27) |
| EoT Median | 107.0 (69, 153) (N=27) | 94.0 (59, 137) (N=25) | 75.0 (45, 103) (N=26) | 73.0 (49, 105) (N=24) |
| % change from BL Median | -0.9 (-19.8, 25.4) (N=27) | -8.9 (-45.4, 32.3) (N=25) | -23.5 (-39.3, 21.2) (N=26) | -34.8 (-53.0, 8.9) (N=24) |

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# OCEAN safety: TEAEs, TESAEs and withdrawals overview

## Obicetrapib 5mg well tolerated compared to placebo

| | Placebo | Ezetimibe 10mg | Obicetrapib 5mg | Obi 5mg / Eze 10mg |
|---|---|---|---|---|
| **TEAEs (%)** | | | | |
| TEAEs, total | 6 (21.4) | 8 (28.6) | 4 (14.3) | 9 (33.3) |
| TEAEs, related | 4 (14.3) | 3 (10.7) | 1 (3.6) | 3 (11.1) |
| TEAEs, severe | 0 | 1 (3.6) | 0 | 0 |
| **TESAEs** | | | | |
| TESAEs, total | 0 | 2 (7.1) | 0 | 0 |
| TESAEs, related | 0 | 0 | 0 | 0 |
| Deaths | 0 | 0 | 0 | 0 |
| **Withdrawal's study / medication** | | | | |
| TEAEs leading to discon of study drug | 1 (3.6) | 1 (3.6) | 0 | 2 (7.4) |
| TESAEs leading to discon of study | 0 | 1 (3.6) | 0 | 0 |

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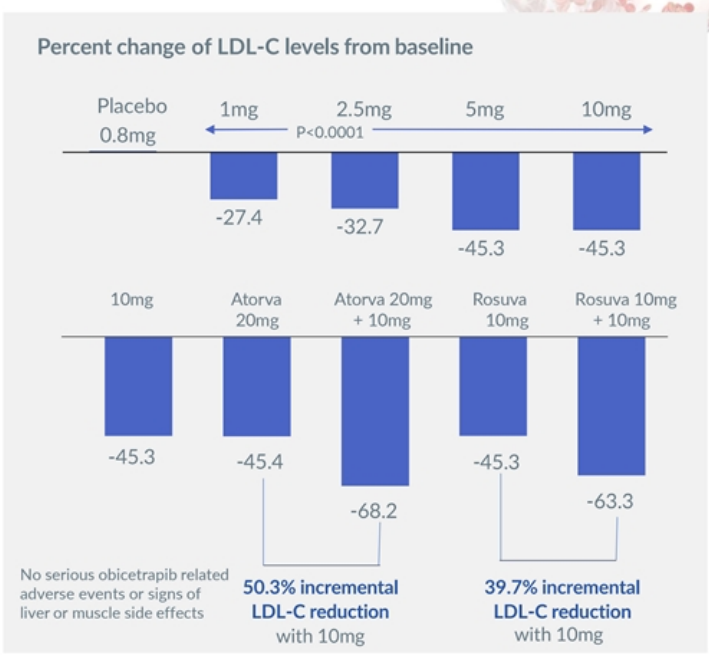
Data on File

# TULIP Phase 2a trial results

## TULIP clinical trial design

- Randomized double-blind placebo-controlled trial, once daily dosing
- Endpoints:
  - Percent change in LDL-C at week 12 compared to baseline
  - Safety
  - Tolerability
- Duration: 12 weeks treatment
- Patients:
  - 364 patients (aged 18–75 years)
  - Fasting LDL-C levels: 2.5 - 4.5 mmol/L

OUTCOMES OF TULIP TRIAL

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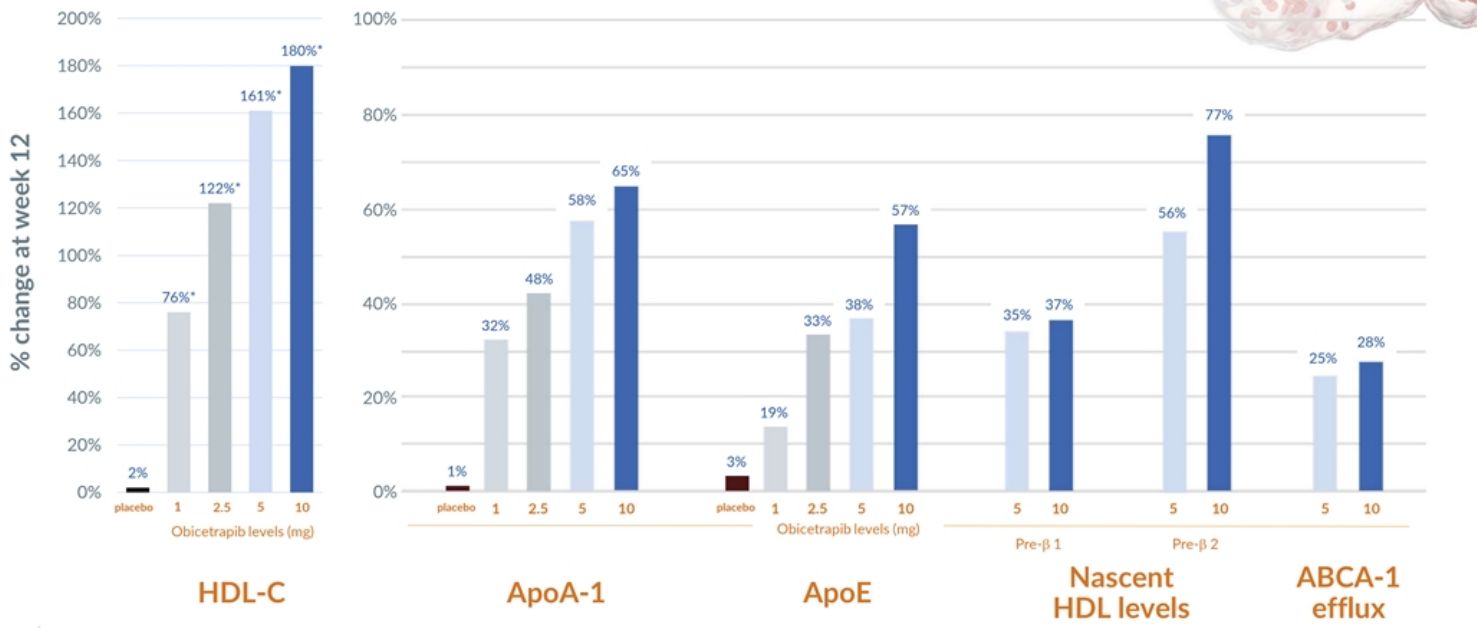
Source: Hovingh GK, et al. Lancet 2015;386:452-460

# TULIP: HDL-C, ApoA-1, ApoE and nascent HDL levels increases observed

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Source: Hovingh GK, et al. Lancet 2015;386:452-460; Van Capelleveen JC, et al. J Clin Lipidol 2016;10:1137-1144