



## NewAmsterdam Pharma to Present New Analysis from the Phase 2 ROSE2 Trial Evaluating Obicetrapib in Combination with Ezetimibe at 2024 American College of Cardiology Congress

March 25, 2024 at 8:00 AM EDT

NAARDEN, the Netherlands and MIAMI, March 25, 2024 (GLOBE NEWSWIRE) -- 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 announced that it will present additional data from the Phase 2 ROSE2 clinical trial at the 2024 American College of Cardiology Congress ("ACC") in Atlanta, Georgia, being held April 6-8. ROSE2 evaluated obicetrapib in combination with ezetimibe as an adjunct to high-intensity statin therapy; full results from the trial were previously presented at the National Lipid Association Scientific Sessions in June 2023. At ACC, NewAmsterdam will share new data demonstrating obicetrapib and ezetimibe's impact on small dense LDL-C, a robust predictor of residual risk of future cardiovascular events.

NewAmsterdam recently initiated TANDEM, a pivotal Phase 3 clinical trial to evaluate obicetrapib and ezetimibe FDC ("fixed-dose combination") in adult patients with Heterozygous Familial Hypercholesterolemia ("HeFH") and/or Atherosclerotic Cardiovascular Disease ("ASCVD") or multiple risk factors for ASCVD, whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-modifying therapies.

Details of the presentation are as follows:

### **Presentation at the 2024 American College of Cardiology (ACC) Congress:**

**Session Title:** 1433: Prevention and Health Promotion: Lipids 12

**Session Date/Time:** Sunday, April 7, 2024, 1:15 p.m. EDT

**Session Location:** Hall B4-5, World Congress Center

**Presentation Title:** 211 - Synergistic Effect of Obicetrapib and Ezetimibe on Circulating LDL Particles

**Location:** Atlanta, Georgia, U.S.

### **About Obicetrapib**

Obicetrapib is a novel, oral, low-dose CETP inhibitor that NewAmsterdam is developing to overcome the limitations of current LDL-lowering treatments. The Company believes that obicetrapib has the potential to be a once-daily oral CETP inhibitor for lowering LDL-C, if approved. In the Company's Phase 2b ROSE trial, obicetrapib demonstrated a 51% lowering of LDL-C from baseline at a 10 mg dose level on top of high-intensity statins and, in the Company's Phase 2 ROSE2 trial, the combination of a 10 mg dose of obicetrapib and a 10 mg dose of ezetimibe demonstrated a 63% lowering of LDL-C from baseline. In each of the Company's Phase 2 trials, ROSE2, TULIP, ROSE, and OCEAN, evaluating obicetrapib as monotherapy or combination therapy, the Company observed statistically significant LDL-lowering combined with a side effect profile similar to that of placebo, including no increase in blood pressure or muscle related side effects. Obicetrapib has demonstrated strong tolerability in more than 800 patients with elevated lipid levels ("dyslipidemia") in NewAmsterdam's clinical trials to date. The Company is conducting two Phase 3 pivotal trials, BROADWAY and BROOKLYN, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to provide additional LDL-lowering for CVD patients and TANDEM, to evaluate obicetrapib and ezetimibe as a FDC. The Company began enrolling patients in BROADWAY in January 2022, in BROOKLYN in July 2022, and in TANDEM in March 2024; completing enrollment of BROOKLYN in April 2023 and BROADWAY in July 2023. The Company also commenced the Phase 3 PREVAIL cardiovascular outcomes trial in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of major adverse cardiovascular events, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization.

### **About NewAmsterdam**

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 studies, NewAmsterdam is investigating obicetrapib, an oral, low-dose and once-daily CETP inhibitor, alone or as a fixed-dose combination with ezetimibe, as preferred 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," "could," "plan," "predict," "potential," "position," "seem," "seek," "future," "outlook" and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding the Company's business and strategic plans, the therapeutic and curative potential of the Company's product candidate, the Company's clinical trials and the timing for enrolling patients, the timing and forums for announcing data, the achievement and timing of regulatory approvals and plans for commercialization. These statements are based on various assumptions, whether or not identified in this document, and on the current expectations of the Company's management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; risks relating to the uncertainty of the projected financial information with respect to the Company; risks relating to the uncertainty of the projected regulatory and business milestones, including potential commercialization; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive product candidates; ability to obtain sufficient supply of materials; global economic and political

conditions; the effects of competition on the Company's future business; and those factors described in the Company's public filings with the U.S. Securities and Exchange Commission. Additional risks related to the Company's business include, but are not limited to: uncertainty regarding outcomes of the Company's ongoing clinical trials, particularly as they relate to regulatory review and potential approval for its product candidate; risks associated with the Company's efforts to commercialize a product candidate; the Company's ability to negotiate and enter into definitive agreements on favorable terms, if at all; the impact of competing product candidates on the Company's business; intellectual property related claims; the Company's ability to attract and retain qualified personnel; ability to continue to source the raw materials for its product candidate. If any of these risks materialize or the Company's assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that the Company does not presently know or that the Company currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect the Company's expectations, plans, or forecasts of future events and views as of the date of this document and are qualified in their entirety by reference to the cautionary statements herein. The Company anticipates that subsequent events and developments may cause the Company's assessments to change. These forward-looking statements should not be relied upon as representing the Company's assessment as of any date subsequent to the date of this communication. Accordingly, undue reliance should not be placed upon the forward-looking statements. Neither the Company nor any of its affiliates undertakes any obligation to update these forward-looking statements, except as may be required by law.

**Company Contact**

Matthew Philippe

P: 1 917-882-7512

[matthew.philippe@newamsterdampharma.com](mailto:matthew.philippe@newamsterdampharma.com)

**Media Contact**

Spectrum Science on behalf of NewAmsterdam

Jenn Gordon

P: 1 202-957-7795

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

**Investor Contact**

Stern Investor Relations on behalf of NewAmsterdam

Hannah Deresiewicz

P: 1 212-362-1200

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