NewAmsterdam Pharma Completes Enrollment in Pivotal Phase 3 TANDEM Clinical Trial Evaluating Fixed-Dose Combination of Obicetrapib plus Ezetimibe in Patients with HeFH and/or ASCVD or ASCVD Risk Factors

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-- Company expects to report topline data in the first quarter of 2025 --

NAARDEN, The Netherlands and MIAMI, July 08, 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 the completion of patient enrollment in the pivotal Phase 3 TANDEM clinical trial evaluating the fixed-dose combination ("FDC") of obicetrapib plus ezetimibe 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.

"Completing enrollment of the pivotal Phase 3 TANDEM trial marks an important step in our mission of advancing obicetrapib through late-stage clinical development and brings us closer to delivering a simple and convenient once-daily tablet to the millions of people suffering from dyslipidemia," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam Pharma. "With positive enrollment trends observed in four ongoing contemporaneous pivotal Phase 3 studies – BROOKLYN, BROADWAY, PREVAIL and TANDEM – we continue to be encouraged by physician and patient interest in our clinical trials, which we believe reflects growing awareness of our CETP inhibitor and its potential ability to address elevated LDL-C and improve health outcomes for millions of patients globally, if approved. We look forward to sharing topline data from the TANDEM study in the first quarter of 2025."

The double-blind, placebo-controlled Phase 3 TANDEM clinical trial enrolled 407 patients with HeFH and/or ASCVD or ASCVD risk equivalents, who have a baseline LDL-C of at least 70 mg/dL. The primary objective of the placebo-controlled, double-blind, four-arm, randomized TANDEM trial is to evaluate the effect of 10 mg obicetrapib and 10 mg ezetimibe FDC on the change in LDL-C levels from baseline, compared to both ezetimibe 10 mg and obicetrapib 10 mg monotherapy and to placebo. Secondary objectives include evaluating the effect of the FDC on lipoprotein(a) ("Lp(a)"), apolipoprotein B ("ApoB") and non-high-density lipoprotein cholesterol ("non-HDL-C"). The trial will also evaluate the safety and tolerability profile of the FDC.

"Cardiovascular disease is one of the most impactful global health issues, and while statins and ezetimibe have become standard therapies for patients with elevated cholesterol at high cardiovascular risk, a significant proportion of these patients still struggle to achieve target LDL-C levels," said Ashish Sarraju, M.D., Cardiovascular Medicine, Cleveland Clinic. "Based on clinical data generated to date, and a promising synergistic effect observed when combined with ezetimibe, obicetrapib has potential to play a critical role in the lipid-lowering and CVD treatment landscapes, if approved. I'm excited to partner with NewAmsterdam on the TANDEM trial and look forward to results early next year."

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, 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 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 fixed-dose combination. 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, BROADWAY in July 2023 and TANDEM in July 2024. 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. NewAmsterdam completed enrollment of PREVAIL in April 2024 and randomized over 9,500 patients.

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 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 forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; risks related to the approval of the Company's product candidate and the timing of expected regulatory and business milestones, including potential commercialization; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive product candidates; ability to obtain sufficient supply of materials; global economic and political conditions, including the Russia-Ukraine 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, 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

Media Contact
Spectrum Science on behalf of NewAmsterdam
Bryan Blatstein
P: 1-917-714-2609
bblatstein@spectrumscience.com

Investor Contact
Precision AQ on behalf of NewAmsterdam
Austin Murtagh
P: 1-212-698-8696
austin.murtagh@precisionaq.com