NewAmsterdam Pharma Enrolls Over 9,000 Patients in Pivotal Phase 3 PREVAIL Global Cardiovascular Outcome Trial Evaluating the Effect of Obicetrapib in Patients with Established Atherosclerotic Cardiovascular Disease

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-- Enrollment to continue to the end of April to accommodate strong patient and site interest --

NAARDEN, the Netherlands and MIAMI, April 09, 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 has met the enrollment target of 9,000 patients for the pivotal Phase 3 PREVAIL cardiovascular outcomes trial ("CVOT") evaluating obicetrapib in adult patients with a history of atherosclerotic cardiovascular disease ("ASCVD"), whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. Driven by strong patient and physician interest globally, NewAmsterdam will extend enrollment to the end of April where we expect to randomize over 9,000 patients.

"We are pleased to announce that our enrollment target has been met for our pivotal Phase 3 PREVAIL trial, marking a crucial milestone in NewAmsterdam's mission to advance cardiovascular treatment for the millions of people who are failing to meet their risk-based LDL-C goals despite taking maximally tolerated lipid-lowering therapy," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "PREVAIL, our pivotal CVOT, will potentially demonstrate that obicetrapib's lowering of LDL-C will reduce major adverse cardiac events ("MACE"). We expect data from PREVAIL will complement results from our ongoing pivotal Phase 3 trials, BROADWAY, BROOKLYN and TANDEM, and further support obicetrapib's clinical profile as a well-tolerated and potentially highly effective option for treating hypercholesterolemia and preventing serious cardiovascular disease, if approved."

The double-blind, placebo-controlled Phase 3 PREVAIL trial is now expected to randomize over 9,000 patients with ASCVD in over 500 sites across 23 countries including the United States, Canada, United Kingdom, Netherlands, Germany, Japan, China, Italy, and Australia. Patients enrolling in the study were required to have established ASCVD with LDL-C levels greater than 55 mg/dl, and an additional risk enhancer in participants with an LDL-C level below 100 mg/dl, despite taking maximally tolerated lipid-lowering therapy. Patients were randomized to receive placebo or 10 mg obicetrapib over a 30-month period. The primary objective of the study is to evaluate the effect of obicetrapib compared to placebo on MACE, including cardiovascular death, myocardial infarction, stroke and non-elective coronary revascularization. Secondary objectives include evaluating the effect of obicetrapib on all-cause mortality, total CV events, new-onset diabetes mellitus, and change in LDL-C, non-high-density lipoprotein cholesterol, and apolipoprotein B levels.

"Cardiovascular disease is one of the most common causes of death and disability globally," said Stephen Nicholls, M.B.B.S., Ph.D., Director, Monash Victorian Heart Institute and Professor of Cardiology, Monash University, and primary investigator on the Phase 3 PREVAIL trial. "Despite widespread availability of statin therapies, CVD-related deaths are on the rise, and many patients are not at their risk-based LDL-C goals. Based on clinical data to-date, we believe obicetrapib can meaningfully improve a range of lipid and lipoprotein measurements associated with CVD risk, which could translate into improved long-term outcomes for those patients. I am delighted to partner with the NewAmsterdam team to execute PREVAIL, a well-designed CVOT, and look forward to topline data on obicetrapib's MACE benefit."

"With obicetrapib, we aim to transform the care and treatment of cardiovascular disease, by designing a convenient, once-daily, low dose medicine that has the potential to help patients control their LDL-C levels and, ultimately, avoid catastrophic outcomes, if approved" added John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. "With the PREVAIL CVOT enrollment target met and topline data from BROOKLYN and BROADWAY expected in the third and fourth quarter of 2024, respectively, and TANDEM in the first quarter of 2025, we look forward to executing our ongoing programs and to sharing our first pivotal datasets in the months ahead."

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 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 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 financial information with respect to the Company; risks related to the approval of the Company's product candidate and the timing of expected regulatory and business milestones, 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.

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