NewAmsterdam Pharma Doses First Patient in Phase 3 TANDEM Clinical Trial Evaluating Fixed-Dose Combination of Obicetrapib and Ezetimibe in Patients with HeFH and/or ASCVD

March 12, 2024 at 8:00 AM EDT

-- TANDEM is designed to evaluate obicetrapib and ezetimibe fixed-dose combination ("FDC") as an adjunct to diet and maximally tolerated lipid lowering therapy in patients with HeFH, ASCVD or ASCVD risk equivalents requiring additional lowering of low-density lipoprotein cholesterol ("LDL-C") --

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

-- TANDEM is being conducted in parallel with BROOKLYN, BROADWAY and PREVAIL pivotal Phase 3 studies; data from BROOKLYN and BROADWAY expected in 3Q and 4Q 2024, respectively --

NAARDEN, The Netherlands and MIAMI, March 12, 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 dosing of the first patient and initiation of TANDEM, a pivotal Phase 3 clinical trial to evaluate obicetrapib and ezetimibe FDC 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.

"Ezetimibe has become an established therapy for patients with elevated cholesterol at high risk of CVD; however, a significant proportion of these patients remain unable to achieve target LDL-C levels, highlighting a major unmet need. The ACC Expert Consensus set LDL-C goals of below the 70mg/dl for patients with ASCVD and below the 55mg/dl goal for ASCVD patients with very high risk. By combining obicetrapib, if approved, with ezetimibe in a once-daily pill, this FDC therapy could meaningfully improve the tools available to physicians for addressing elevated LDL-C, and lead to improved health outcomes for millions of people living with increased risk for CVD globally," said Ashish Sarraju, M.D., Cardiovascular Medicine, Cleveland Clinic.

The primary objective of the placebo-controlled, double-blind, four-arm, randomized TANDEM trial is to evaluate the effect of 10mg obicetrapib and 10mg ezetimibe FDC on LDL-C levels, compared to both ezetimibe 10mg and obicetrapib 10mg monotherapy and to placebo. Secondary objectives include evaluating the effect of the FDC on 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.

NewAmsterdam anticipates enrolling approximately 400 patients on maximally tolerated lipid-modifying therapies with HeFH, ASCVD or ASCVD risk equivalents and who have a baseline LDL-C of at least 70 mg/Dl. Patients will be randomized to one of the following groups: placebo, 10 mg obicetrapib, 10mg ezetimibe, or obicetrapib 10mg and ezetimibe 10mg FDC tablet, all groups dosed as a once-daily oral treatment for an 84-day treatment period. HeFH is an inherited genetic disorder that causes dangerously high cholesterol levels. Patients with ASCVD have established cardiovascular diseases characterized by the buildup of plaque in the arteries, including coronary artery stenosis, myocardial infarction or stroke. Patients who have multiple risk factors for ASCVD are at high risk of experiencing a cardiovascular event in the near future.

"The initiation of the Phase 3 TANDEM trial represents a significant milestone for NewAmsterdam, as we are now progressing four pivotal Phase 3 trials – BROADWAY, BROOKLYN, PREVAIL, and TANDEM," said Michael Davidson, M.D., Chief Executive Officer at NewAmsterdam Pharma. "Supported by compelling data from our Phase 2 ROSE2 trial, which demonstrated meaningful reductions in LDL-C, non-HDL, and ApoB in patients already using high-intensity statin therapy, we believe the combination of obicetrapib, if approved, and ezetimibe, in a simple and convenient once-daily tablet, is highly synergistic, with the potential to significantly improve cardiovascular disease treatment for millions of people living with dyslipidemia. TANDEM is a critical component of NewAmsterdam's multi-pronged clinical strategy, and we are optimistic that favorable results from this trial, together with our other ongoing Phase 3 studies, can position us to advance our novel CETP inhibitor franchise as a much-needed therapeutic solution."

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. The Company began enrolling patients in BROADWAY in January 2022 and in BROOKLYN in July 2022 and completed 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.

Company Contact
Matthew Philippe
P: 1-917-882-7512
matthew.philippe@newamsterdampharma.com

Media Contact
Spectrum Science on behalf of NewAmsterdam
Jen Gordon
P: 1-202-957-7795
jgordon@spectrumscience.com

Investor Contact
Stern Investor Relations on behalf of NewAmsterdam
Hannah Deresiewicz
P: 1-212-362-1200
hannah.deresiewicz@sternir.com