NewAmsterdam Pharma Highlights 2024 Achievements and Outlines 2025 Strategic Priorities

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-- Additional data from BROADWAY, BROOKLYN, and TANDEM to be presented throughout 2025; expected to support global regulatory filings for obicetrapib, including EMA submission in 2H25 by our partner Menarini –

-- Data from Phase 2 VINCENT trial expected by 2H25, which explores effect of obicetrapib alone and in combination with a PCSK9i on Lp(a) –

-- Focus on commercial readiness with manufacturing capacity establishment and inventory build-out --

-- Year end, unaudited, cash balance of $835 million following oversubscribed public offering in December 2024 --

NAARDEN, The Netherlands and MIAMI, Jan. 10, 2025 (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 provided an update on the obicetrapib clinical development program and outlined its strategic priorities for 2025.

NewAmsterdam is developing obicetrapib, an oral, low-dose, once-daily, and highly selective cholesteryl ester transfer protein ("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 cardiovascular disease with elevated LDL-C, for whom existing therapies are not sufficiently effective or well tolerated. The Company's global, pivotal Phase 3 clinical development program consists of four trials in over 12,250 patients.

"2024 was a landmark year for NewAmsterdam, underscored by exceptional clinical and operational execution. We announced positive topline results from three pivotal Phase 3 trials, BROOKLYN, TANDEM, and BROADWAY, which will form the foundation for our planned global regulatory filings for obicetrapib," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "We were particularly excited to announce results from BROADWAY, which demonstrated greater than expected reduction in the exploratory outcome measure of major adverse cardiovascular events ("MACE") after only one year of treatment with obicetrapib, with a safety profile that was comparable to placebo. These data not only reinforce obicetrapib's potential to both lower LDL-C and address critical cardiovascular risks, but also support the approach we have taken for our ongoing PREVAIL Phase 3 cardiovascular outcomes trial ("CVOT"), which is designed to assess MACE benefit as its primary endpoint."

"As we move into 2025, we are focused on sharing additional scientific findings on obicetrapib's therapeutic potential through presentations at leading medical meetings and publications in high-impact journals, and on advancing PREVAIL toward a successful data readout. Importantly, following our recent financing, we are operating from a position of financial strength, with capital to support operations through the anticipated PREVAIL CVOT readout and, pending regulatory approval, the commercial launch of obicetrapib. We believe we are at the precipice of a major transformation for CVD care globally and remain steadfast in our mission to unlock the full potential of obicetrapib for the millions of people living with dyslipidemia and at heightened risk for CVD," continued Dr. Davidson.

Key 2024 Achievements:

NewAmsterdam announced positive topline results for three Phase 3 clinical studies, each with safety comparable to placebo:

- BROADWAY evaluated obicetrapib in 2,530 adult patients with established atherosclerotic cardiovascular disease ("ASCVD") and/or heterozygous familial hypercholesterolemia ("HeFH"), whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-lowering therapy. In December, NewAmsterdam reported positive topline data from the BROADWAY study. The primary endpoint was the least-squares mean of the percent change in LDL-C from baseline to day 84 for obicetrapib 10 mg compared to placebo. The primary endpoint was achieved with statistical significance with an LDL-C reduction of 33% ($p<0.0001$). Mean and median reductions in LDL-C at day 84 were 33% and 36%, respectively. As part of the safety analysis, the trial adjudicated MACE, including death, non-fatal myocardial infarction, non-fatal stroke and coronary revascularization, and in an exploratory analysis, a 21% reduction in MACE favoring obicetrapib was observed. NewAmsterdam expects to report additional data at an upcoming medical conference and to publish the data in a major medical journal.

- TANDEM evaluated obicetrapib as part of a fixed-dose combination tablet with ezetimibe, a non-statin oral LDL-lowering therapy, in 407 patients with established ASCVD or multiple risk factors for ASCVD and/or HeFH, whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-lowering therapy. In November, NewAmsterdam reported that the TANDEM trial met all co-primary endpoints, including the obicetrapib-ezetimibe fixed dose combination achieving an LS mean reduction of 49% ($p < 0.0001$) compared to placebo at day 84. Mean and median reductions in LDL-C at day 84 were 52% and 54%, respectively. NewAmsterdam expects to report additional data at an upcoming medical conference and to publish the data in a major medical journal.

- BROOKLYN evaluated obicetrapib in 354 patients with HeFH, whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-lowering therapy. In July, NewAmsterdam reported that the BROOKLYN trial met its primary endpoint, achieving an LS mean reduction of 36% ($p < 0.0001$) compared to placebo at day 84, with additional data

presented at the American Heart Association Scientific Sessions 2024 in November. Mean and median reductions in LDL-C at day 84 were 36% and 39%, respectively.

- PREVAIL is a cardiovascular outcomes trial evaluating obicetrapib in patients with a history of ASCVD, whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam completed enrollment of over 9,500 patients in April 2024 and the trial continues in line with expectations.

In addition, NewAmsterdam announced that the United States Patent and Trademark Office ("USPTO") issued a new patent covering the solid form that will be used in the Company's products. The issuance of this composition of matter patent provides intellectual property protection for obicetrapib until July 2043 in the United States. The USPTO has now issued or allowed a total of nine patents covering obicetrapib and its uses.

Key 2025 Milestones and Ongoing Trials:

Over the course of 2025, NewAmsterdam plans to announce additional data from its Phase 3 studies, including BROADWAY, TANDEM, and BROOKLYN. NewAmsterdam also plans to publish data on a significant number of topics that support the overall benefit and differentiation of obicetrapib and the fixed dose combination of obicetrapib plus ezetimibe, compared to other lipid lowering therapies.

In addition to PREVAIL, NewAmsterdam continues to enroll two studies of obicetrapib, including:

- VINCENT, a Phase 2 clinical study to evaluate the effects of obicetrapib alone and in combination with evolocumab on lipoprotein (a) ("Lp(a)") in patients with mild dyslipidemia. The single arm study will treat patients with obicetrapib 10mg daily for 8 weeks followed by obicetrapib 10mg daily plus evolocumab 140 mg/dL every other week for 8 weeks. The study is expected to complete in the second half of 2025 and to enroll 30 patients with baseline Lp(a) levels above 50 mg/dL.
- REMBRANDT, a Phase 3 cardiovascular computed tomography angiography imaging trial to evaluate the effect of obicetrapib plus ezetimibe FDC on coronary plaque. The placebo-controlled, double-blind, randomized, Phase 3 study is being conducted in adult participants with high-risk atherosclerotic cardiovascular disease (ASCVD) who are not adequately controlled by their maximally tolerated lipid-modifying therapy, to assess the impact of the obicetrapib 10 mg + ezetimibe 10 mg FDC daily on coronary plaque and inflammation characteristics. The study is expected to complete in 2027 and to enroll 300 patients.

An additional focus for the Company throughout 2025 will be on commercial manufacturing and readiness. The Company plans to scale up and build inventory sufficient for both the U.S. and European launches, if approved, which will be supported by the approximately $835 million of unaudited cash on hand at year-end 2024.

About Obicetrapib

Obicetrapib is a novel, oral, low-dose, and highly selective 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, as well as the Company's Phase 3 BROOKLYN, BROADWAY and TANDEM trials, 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 currently conducting the Phase 3 PREVAIL cardiovascular outcomes trial, 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. Commercialization rights of obicetrapib in Europe, either as a monotherapy or as part of a fixed dose combination with ezetimibe, for cardiovascular diseases have been exclusively granted to the Menarini Group, an Italy-based, leading international pharmaceutical and diagnostics company.

About Cardiovascular Disease

Cardiovascular disease remains the leading cause of death globally, despite the availability of lipid-lowering therapies (LLTs). By 2050 more than 184 million US adults are expected to be affected by CVD and hypertension, including 27 million with coronary heart disease and 19 million with stroke. In the United States from 2019 through 2022, CVD age-adjusted mortality rates increased 9%, reversing the trend observed since 2010 and undoing nearly a decade of progress. Despite the availability of high-intensity statins and non-statin LLTs, LDL-C target level attainment remains low, contributing to residual cardiovascular risk, and underscoring a significant clinical need for improved therapeutic regimens. Even with 269 million LLT prescriptions written over the last 12 months, 30 million under-treated US adults are not at their risk-based LDL-C goal, of which 13 million have ASCVD. Less than 1 in 4 patients with ASCVD achieve an LDL-C goal of less than 70mg/dL and only 10% of very high risk ASCVD patients achieve the goal below 55 mg/dL. In addition to the 30 million under-treated US adults, there are 10 million patients diagnosed with elevated LDL-C who are not taking any LLTs including statins. Beyond LDL-C, additional factors are at play, such as lifestyle choices, tobacco use, and obesity, as well as inflammation, thrombosis, triglyceride levels, elevated Lp(a) levels, and type 2 diabetes.

About NewAmsterdam

NewAmsterdam Pharma (Nasdaq: NAMS) is a late-stage, clinical 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 trials, 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; whether topline, initial or preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, or whether projections regarding clinical outcomes will reflect actual results in future clinical trials or clinical use of our product candidate, if approved; 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; and ability to continue to source the raw materials for the Company’s 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
Jaryd Leady
P: 1-856-803-7855
jleady@spectrumscience.com

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