



NewAmsterdam Pharma Completes Enrollment in Pivotal Phase 3 BROADWAY Clinical Trial Evaluating Obicetrapib in Patients with Heterozygous Familial Hypercholesterolemia and/or Established Atherosclerotic Cardiovascular Disease

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-- Exceeded Target Enrollment; Expect to Randomize More Than 2,500 Patients --

-- Topline Results Expected in 2H 2024 --

NAARDEN, The Netherlands and MIAMI, July 25, 2023 (GLOBE NEWSWIRE) -- NewAmsterdam Pharma Company N.V. (Nasdaq: NAMS or "NewAmsterdam" or the "Company"), a clinical-stage biopharmaceutical company developing oral, non-statin medicines for patients at high risk of cardiovascular disease ("CVD") with residual elevation of low-density lipoprotein cholesterol ("LDL-C" or "LDL"), for whom existing therapies are not sufficiently effective or well-tolerated, today announced the completion of patient enrollment in the pivotal Phase 3 BROADWAY clinical trial evaluating obicetrapib in adult patients with heterozygous familial hypercholesterolemia ("HeFH") and/or established atherosclerotic cardiovascular disease ("ASCVD"), whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. The target enrollment of 2,400 subjects was exceeded due to strong interest from patients and physicians globally. NewAmsterdam expects over 2,500 patients to be randomized following the completion of ongoing patient screening and remains on track to report topline data in the second half of 2024.

"We are pleased to announce the over enrollment in the Phase 3 BROADWAY trial, highlighting the robust demand for a convenient oral therapy and marking an important next step toward our goal of delivering obicetrapib to the millions of patients who, despite being treated with maximally tolerated lipid-lowering therapy, still do not reach their risk-based LDL-C goals," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "Emerging clinical data continue to demonstrate the potential for our CETP inhibitor to solve a substantial unmet need in dyslipidemia by reducing LDL-C and impacting a number of other lipid and lipoprotein parameters predictive of cardiovascular disease risk."

The double-blind, placebo-controlled Phase 3 BROADWAY trial is expected to randomize over 2,500 patients with HeFH and/or ASCVD across eight countries including the United States, Netherlands, Japan and China. The mean baseline LDL-C for enrolled patients is approximately 100 mg/dL despite high intensity statin use reported by greater than 60% of patients during screening. Females comprise approximately 30% of the study population and the median age of participants is approximately 66 years. Patients were randomized to receive placebo or 10 mg obicetrapib, on top of maximally tolerated lipid-lowering therapy, dosed as a once-daily oral treatment with or without food for 52 weeks. The primary objective is to evaluate the effect of obicetrapib on LDL-C levels at day 84. Secondary objectives include evaluating the effect of obicetrapib on apolipoprotein B, lipoprotein(a), high density lipoprotein cholesterol ("HDL-C"), non-HDL-C, total cholesterol and triglycerides at day 84, and on LDL-C levels at days 180 and 365. The trial is also evaluating the safety and tolerability of obicetrapib.

"HeFH and ASCVD can be devastating diseases which, if inadequately addressed, can result in myocardial infarction, cerebral infarction, or cardiovascular death," said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. "It has become increasingly clear that lower levels of LDL-C are directly correlated with a reduced risk for major adverse cardiovascular events. With obicetrapib, we aim to deliver LDL-C reductions that are substantially better than currently available non-statin oral therapies, in a convenient, tolerable formulation. We are pleased to have both BROADWAY and BROOKLYN, the two pivotal Phase 3 trials necessary to support a potential LDL regulatory filing, fully enrolled and look forward to reporting data from both studies in the second half of 2024."

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 all five of the Company's Phase 2 trials, ROSE2, TULIP, ROSE, OCEAN, and TA-8995-203, 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 high-risk 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 CVOT in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of MACE, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization.

About NewAmsterdam

NewAmsterdam (Nasdaq: NAMS) is a clinical-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where currently approved therapies have not been sufficiently successful or well tolerated. NewAmsterdam is investigating obicetrapib, an oral, low-dose and once-daily CETP inhibitor, as the preferred LDL-C lowering therapy to be used as an adjunct to maximally tolerated statin therapy for high-risk cardiovascular disease patients. Based in the Netherlands, NewAmsterdam recently completed a business combination with Frazier Lifesciences Acquisition Corporation, a special purpose acquisition company sponsored by an affiliate of Frazier Healthcare Partners.

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 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 related to the approval of the Company’s product candidate and the timing of expected regulatory and business milestones; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive product candidates; ability to obtain sufficient supply of materials; the impact of COVID-19; global economic and political conditions, including the Russia-Ukraine conflict; the effects of competition on the Company’s future business; and those factors described in the Company’s public filings with the SEC. 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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