NewAmsterdam Announces Positive Results from ROSE2, Phase 2 Trial Evaluating Obicetrapib in Combination with Ezetimibe as an Adjunct to High-Intensity Statin Therapy

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-- Achieved primary endpoint with statistically significant reduction in LDL-C ($p < 0.0001$) --
-- Median percent change in LDL-C of -59% in combination arm compared to -6% in placebo arm --
-- Favorable safety and tolerability --
-- Data support advancement of fixed-dose combination into bioequivalence and Phase 3 safety and efficacy trials -

NAARDEN, the Netherlands and MIAMI, Jan. 17, 2023 (GLOBE NEWSWIRE) -- NewAmsterdam Pharma Company N.V. (Nasdaq:NAMS) ("NewAmsterdam" or the "Company"), a clinical-stage company focused on the research and development of transformative oral therapies for major cardiometabolic diseases, today announced topline results from ROSE2, a Phase 2 clinical trial evaluating obicetrapib, the company's oral, low-dose and once-daily cholesteryl ester transfer protein ("CETP") inhibitor, in combination with ezetimibe as an adjunct to high-intensity statin therapy.

Based on the encouraging results observed, NewAmsterdam is now selecting a formulated fixed-dose combination tablet of obicetrapib plus ezetimibe, a non-statin oral LDL-lowering therapy, to be tested in a definitive bioequivalence trial and a Phase 3 safety and efficacy trial.

"Elevated levels of LDL cholesterol (LDL-C) remain a significant public health burden despite the availability of statins. While a range of adjunctive treatments are available, many patients are not able to benefit because these agents either do not sufficiently lower LDL-C or are too expensive," said Christie Ballantyne, M.D., Chief of Cardiovascular Research and Professor at Baylor College of Medicine. "Today, patients – especially those at high-risk – are typically treated with very high-dose statin therapy, which can be associated with intolerable side effects that limit adherence. Combination regimens comprising low-dose statin therapy plus another LDL-C lowering agent, such as a fixed-dose combination of obicetrapib and ezetimibe, may become a powerful strategy to deliver patients better outcomes, while also increasing their willingness and ability to remain on therapy."

Topline Data from the ROSE2 Trial

"We are excited to announce topline data from ROSE2, which provide support for our belief that obicetrapib and ezetimibe have distinct, complementary mechanisms of action that, when synergized, have the potential to deliver positive outcomes for patients needing further LDL-C reduction," said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. "In addition to supporting the development of our fixed-dose combination pill, these results build on prior clinical experience and further characterize obicetrapib as a highly differentiated molecule, with the potential to deliver for the first time the full promise of CETP inhibition."

ROSE2 (NCT05266586) was designed as a placebo-controlled, double-blind, randomized Phase 2 study to evaluate the efficacy, safety and tolerability of obicetrapib 10 mg in combination with ezetimibe 10 mg as an adjunct to high-intensity statin therapy. A total of 119 patients were randomized to receive combination therapy, obicetrapib 10 mg or placebo for an 84-day treatment period. The primary efficacy endpoint was the percent change from Day 1 to Day 84 in LDL-C for the combination treatment group compared to the placebo group and was met. Patients treated with the combination of obicetrapib and ezetimibe achieved a median reduction in LDL-C of 59%, as compared to patients treated with placebo, who achieved a median reduction in LDL-C of 6%. Overall, the combination of obicetrapib and ezetimibe was observed to be well-tolerated, with a safety profile observed to be comparable to placebo.

"Based on the data from ROSE2, we are now focused on selecting a formulated fixed-dose combination tablet of obicetrapib plus ezetimibe to advance into a definitive bioequivalence study and a Phase 3 trial," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "If positive, the results from these trials, coupled with our ongoing BROADWAY, BROOKLYN and PREVAIL studies, if also positive, have the potential to support an application for approval of obicetrapib as an adjunct to maximally tolerated statin therapy and in a fixed-dose combination with ezetimibe. There is a growing consensus that for high-risk patients with atherosclerotic cardiovascular disease ("ASCVD"), the lower the LDL-C, the better. We believe access to a fixed-dose combination of obicetrapib and ezetimibe as an alternative oral therapy for these patients has the potential to support achievement of more aggressive LDL-C targets."

NewAmsterdam anticipates sharing full data from this Phase 2 clinical trial in a forthcoming publication or in a presentation at an upcoming medical meeting.

About Obicetrapib

Obicetrapib is a next-generation, oral, low-dose CETP inhibitor that the Company is developing to potentially 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. In all three of the Company's Phase 2 trials, TULIP, ROSE and OCEAN, evaluating obicetrapib as a monotherapy or a combination therapy, the Company observed statistically significant LDL-lowering activity combined with generally moderate side effects and no drug-related, treatment-emergent serious adverse events. Obicetrapib has demonstrated strong tolerability in more than 600 patients with low or 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 potentially enhance LDL-lowering for high-risk CVD patients. The Company began enrolling patients in BROADWAY in January 2022 and in BROOKLYN in July 2022. The Company also commenced our 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. Based in the Netherlands, NewAmsterdam recently completed a business combination with Frazier Lifesciences Acquisition Corporation ("FLAC"), a special purpose acquisition company sponsored by an affiliate of Frazier Healthcare Partners. Proceeds from this transaction were approximately $328 million, prior to deducting transaction expenses, comprising approximately $93 million in funds from the former FLAC trust account and approximately $235 million from the concurrent, oversubscribed PIPE financing, which was co-led by Frazier Healthcare Partners and Bain Capital Life Sciences and included leading institutional investors. For more information, please visit: www.newamsterdampharma.com.

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 therapeutic and curative potential of the Company's product candidate and the achievement or timing of regulatory approvals. 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 "Risk Factors" section of the Company's registration statement on Form F-1, as amended (File No. 333-268888) and other documents filed from time to time. 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 will 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 undertake any obligation to update these forward-looking statements, except as required by law.

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