



NewAmsterdam Pharma Completes Enrollment in Pivotal Phase 3 BROOKLYN Clinical Trial Evaluating Obicetrapib in Patients with Heterozygous Familial Hypercholesterolemia

April 24, 2023

*-- Enrollment Completed Several Months Ahead of Schedule, Reflecting Significant Unmet Need and Patient Demand for New Options --
-- Topline Results Expected in 2H 2024 --*

NAARDEN, the Netherlands and MIAMI, April 24, 2023 (GLOBE NEWSWIRE) -- NewAmsterdam Pharma Company N.V. (Nasdaq: NAMS or "NewAmsterdam Pharma" or the "Company"), a clinical-stage company focused on the research and development of transformative oral therapies for major cardiometabolic diseases, today announced the completion of patient enrollment in the pivotal Phase 3 BROOKLYN clinical trial evaluating obicetrapib in adult patients with heterozygous familial hypercholesterolemia ("HeFH"), whose low-density lipoprotein cholesterol ("LDL-C") is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam expects to report topline results in the second half of 2024.

"HeFH is a genetic condition resulting in a serious error of metabolism, in which patients present with elevated cholesterol levels from birth and, as a result, are at a very high risk of developing atherosclerotic cardiovascular disease ("ASCVD)," said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. "Effective treatment requires early intervention aimed at lowering patients' LDL-C levels before they suffer the consequences of high cholesterol, which can include damaged blood vessels, myocardial infarction, and premature death. We believe obicetrapib may offer a highly needed treatment for HeFH, with robust LDL-lowering activity and excellent tolerability observed to date, all in a convenient, oral formulation."

The double-blind, placebo-controlled Phase 3 BROOKLYN trial enrolled 354 patients with a history of HeFH across ten countries in North America, Europe, and Africa. The mean baseline LDL-C for enrolled patients is >120 mg/dL despite high intensity statin use reported by approximately 70% of patients during screening. Females comprise approximately 53% of the study population and the median age of participants at baseline is 57 years. Patients were randomized to receive placebo or 10 mg obicetrapib 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. Secondary objectives include evaluating the effect of obicetrapib on non-high-density lipoprotein cholesterol ("non-HDL-C"), apolipoprotein B ("ApoB"), and lipoprotein (a). The trial is also evaluating the safety and tolerability profile of obicetrapib.

"We are delighted to complete enrollment in the Phase 3 BROOKLYN trial several months ahead of schedule," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "We believe the rapid enrollment of this study is a reflection of the deep unmet need in the HeFH community for a potent and well-tolerated oral tablet as an adjunct to maximally tolerated statin therapy, especially for this group of patients who spend most of their lives, some from a young age, taking LDL-lowering therapy. We would like to thank the principal investigators at clinical trial sites worldwide for their significant contributions, and for their trust and belief in obicetrapib as a new medicine with the potential to improve outcomes for patients living with HeFH whose LDL-C levels are not adequately controlled with standard of care. We look forward to continued partnership as we execute the BROOKLYN trial and work to establish obicetrapib as the ideal complement to statin therapy."

About Obicetrapib

Obicetrapib is a next-generation, oral, low-dose CETP inhibitor that NewAmsterdam 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 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 59% lowering of LDL-C from baseline. 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. 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 ("CVD") patients. Results from NewAmsterdam's ROSE Phase 2b trial (presented at AHA Scientific Sessions in 2021) included observations that patients receiving obicetrapib 10 mg experienced a median reduction in LDL-C of 51% versus baseline in patients on high-intensity statin therapy (vs. a 7% reduction in the placebo arm). In addition, topline results from NewAmsterdam's ROSE2 trial evaluating the combination of 10 mg obicetrapib and 10 mg ezetimibe demonstrated a median reduction in LDL-C levels of 59% versus baseline in patients on high-intensity statin therapy (vs. a 6% reduction in the placebo arm). 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. In June 2022, NewAmsterdam entered into an exclusive licensing agreement with the Menarini Group for the commercialization of obicetrapib in Europe, while

retaining all rights to commercialize obicetrapib, if approved, in the rest of the world, as well as rights to develop certain forms of obicetrapib for other diseases such as Alzheimer's disease. 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 most recent Annual Report on Form 20-F (File No. 001-41562) 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.

Media Contact

Spectrum Science on behalf of NewAmsterdam
Bryan Blatstein
P: 917-714-2609
bblatstein@spectrumscience.com

Investor Contact

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