NewAmsterdam Pharma Announces Positive Topline Data from Pivotal Phase 3 BROOKLYN Clinical Trial Evaluating Obicetrapib in Patients with Heterozygous Familial Hypercholesterolemia

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-- Achieved primary endpoint of LS mean reduction in LDL-C on top of maximally tolerated lipid modifying therapies at day 84 with statistically significant reduction (p<0.0001), which was sustained at day 365 (p<0.0001) --

-- Obicetrapib lowered LDL-C by 36.3% at day 84 and 41.5% at day 365, compared to placebo --

-- Observed to be generally well-tolerated with safety results comparable to placebo --

-- NewAmsterdam to host conference call at 8:30 a.m. ET, Today --

NAARDEN, the Netherlands and MIAMI, July 29, 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 positive topline data from the Company's Phase 3 BROOKLYN clinical trial (NCT05425745). BROOKLYN, the first of four studies in NewAmsterdam's pivotal clinical development program, was designed to evaluate obicetrapib in adult patients with heterozygous familial hypercholesterolemia ("HeFH"), whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy.

The BROOKLYN trial met its primary endpoint, achieving an LS mean reduction of 36.3% ($p < 0.0001$) compared to placebo at day 84, which was sustained at day 365 with an LS mean LDL-C reduction of 41.5% ($p < 0.0001$). The observed reductions in other biomarkers, including high-density lipoprotein cholesterol ("HDL-C"), non-HDL-C, lipoprotein(a) ("Lp(a)"), and apolipoprotein B ("ApoB"), met statistical significance and were consistent with data reported from the Company's prior clinical trials.

LDL-C LS mean percentage change:

	% Change from Baseline		Obicetrapib % Change	
	Placebo (n=118)	Obicetrapib (n=236)	Compared to Placebo	p-value
Day 84	+0.3%	-36.1%	-36.3%	<0.0001
Day 365	+10.3%	-31.1%	-41.5%	<0.0001

"My career has been dedicated to the treatment of patients with familial hypercholesterolemia," said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. "Many of these patients have exhausted available treatment options and we are delighted by the topline data from BROOKLYN, with 51% of patients achieving an LDL-C level below 70 mg/dl. Our goal is to provide physicians and patients with a novel, once-daily, low dose, oral option that can potentially transform the treatment landscape."

In the trial, obicetrapib was observed to be well-tolerated, with safety results comparable to placebo and no increase in blood pressure. The treatment discontinuation rate for the obicetrapib arm was 7.6% versus 14.4% for placebo. The incidence of treatment-emergent adverse events ("TEAEs"), study-drug related TEAEs, and treatment-emergent serious adverse events ("TESAEs") are summarized in the table below.

	Placebo N=118 n (%)	Obicetrapib 10 mg N=234 n (%)	Total N=352 n (%)
Any TEAEs	83 **(70.3)**	149 **(63.7)**	232 **(65.9)**
Any study drug related TEAEs	8 **(6.8)**	10 **(4.3)**	18 **(5.1)**
Any TEAEs leading to discontinuation of study drug	8 **(6.8)**	10 **(4.3)**	18 **(5.1)**
Any TESAEs	8 **(6.8)**	13 **(5.6)**	21 **(6.0)**

"Today's announcement marks an important milestone for NewAmsterdam, the HeFH community, and CVD more broadly," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "Despite the widespread availability of lipid lowering therapies, CVD-related deaths have risen and patients remain above LDL-C targets. Patients and their doctors need additional options. We are very excited about the results from our BROOKLYN trial and believe they support obicetrapib's potential to significantly reduce LDL-C in a challenging patient population, over a duration of one year. Adverse events and discontinuations due to side effects were similar to placebo, consistent with what was observed in Phase 2 studies. In the safety population, there was also no increase in blood pressure, nor any difference from placebo in liver enzymes, hs-CRP, or renal function. We look forward to building on these results with topline data from BROADWAY expected in the fourth quarter of 2024, and topline data from TANDEM expected in the first quarter of 2025."

"The data announced today are another indication of obicetrapib's potential to significantly reduce LDL-C in HeFH patients, a population already on multiple lipid-lowering therapies. I am incredibly encouraged by these results, which suggest that obicetrapib, if approved, has the potential to be a new oral option for a difficult-to-treat patient population and am excited to be a partner with the NewAmsterdam team on the remainder of the obicetrapib pivotal program," said Stephen Nicholls, M.B.B.S., Ph.D., Director, Monash Victorian Heart Institute and Professor of Cardiology, Monash University.

“HeFH affects 1 in 250 people worldwide and leads to increased risk of major adverse cardiovascular events, including stroke, myocardial infarction, or death, in the prime of life because of life-long burden of high LDL-C. Many individuals living with HeFH are unable to attain guideline-recommended LDL-C levels, despite currently available treatment options,” said Katherine Wilemon, Founder and CEO of the Family Heart Foundation. “Familial hypercholesterolemia often requires multiple therapies to achieve safer levels of LDL cholesterol. We are highly encouraged with these results and the potential to have another efficacious oral option.”

NewAmsterdam plans to present full results from BROOKLYN at an upcoming medical conference and to publish the data in a major medical journal.

Design of the Pivotal Phase 3 BROOKLYN Clinical Trial

The 52-week, global, pivotal, Phase 3, randomized, double-blind, placebo-controlled multicenter study evaluated the efficacy and safety of 10 mg obicetrapib compared to placebo as an adjunct to maximally tolerated lipid-lowering therapies in patients with HeFH whose LDL-C is not adequately controlled. The study was conducted at sites in North America, Europe and Africa. A total of 354 patients were randomized 2:1 to receive 10 mg obicetrapib or placebo dosed as a once-daily oral treatment, with or without food. The mean baseline LDL-C for enrolled patients in the obicetrapib arm was 123 mg/dL despite high intensity statin use reported by approximately 79% of patients during screening. Females comprised approximately 53% of the study population and the median age of participants at baseline was 57 years.

The primary endpoint was percent change from baseline in LDL-C of obicetrapib 10 mg compared to placebo after 84 days. Secondary endpoints also included percent changes from baseline of obicetrapib 10 mg compared to placebo after 84 days in HDL-C, non- HDL-C, ApoB, and Lp(a). The trial also evaluated the safety and tolerability profile of obicetrapib.

Conference Call and Webcast Information

NewAmsterdam will host a live webcast and conference call to review the topline results from BROOKLYN at 8:30 a.m. ET today. To access the live webcast, participants may register here. The live webcast will be available under the "Events” section of the Investor Relations page of the NewAmsterdam website at ir.newamsterdampharma.com.

To participate via telephone, please register in advance here. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. While not required, it is recommended that participants join the call ten minutes prior to the scheduled start. An archived replay of the webcast will be available on NewAmsterdam’s website.

About NewAmsterdam’s Global Pivotal Phase 3 Program

NewAmsterdam’s global, pivotal Phase 3 clinical development program consists of four studies in over 12,250 patients, three for obicetrapib monotherapy and one for a fixed-dose combination (“FDC”) of obicetrapib and ezetimibe:

- BROOKLYN evaluated obicetrapib in patients with HeFH, whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam reported topline data in the third quarter of 2024.
- BROADWAY is evaluating obicetrapib in adult patients with established atherosclerotic cardiovascular disease (“ASCVD”) and/or HeFH, whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam completed enrollment of over 2,500 patients in July 2023 and expects to report topline data in the fourth quarter of 2024.
- TANDEM is evaluating obicetrapib as part of a FDC tablet with ezetimibe, a non-statin oral LDL-lowering therapy, in 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. NewAmsterdam completed enrollment of over 400 patients in July 2024 and expects to report topline data in the first quarter of 2025.
- 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.

About Obicetrapib

Obicetrapib is a novel, oral, low-dose 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 trial, 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 conducting an additional Phase 3 pivotal trial BROADWAY, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to provide additional LDL-lowering for CVD patients, and TANDEM, to evaluate obicetrapib and ezetimibe as a fixed-dose combination. The Company began enrolling patients in BROADWAY in January 2022 and in TANDEM in March 2024; completing enrollment of BROADWAY in July 2023, and TANDEM in July 2024. 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. 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 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 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; 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; 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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