NewAmsterdam Pharma Announces Positive Topline Data from Pivotal Phase 3 TANDEM Clinical Trial Evaluating the Fixed-Dose Combination of Obicetrapib 10 mg and Ezetimibe 10 mg in Patients with ASCVD or ASCVD Risk Factors and/or HeFH

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-- Achieved all co-primary endpoints of LS mean reduction in LDL-C on top of maximally tolerated lipid-modifying therapies versus each of placebo, ezetimibe 10 mg, and obicetrapib 10 mg monotherapy at day 84 with statistical significance (p<0.001) --

-- Obicetrapib and ezetimibe fixed-dose combination observed to lower LDL-C by approximately 50% at day 84, compared to placebo, with over 70% of patients achieving LDL-C levels below 55 mg/dL --

-- Data supports global regulatory filings of the obicetrapib 10 mg and ezetimibe 10 mg fixed-dose combination --

-- Observed to be well tolerated with safety results in line with prior studies --

-- NewAmsterdam to host conference call today at 8:00 a.m. ET --

NAARDEN, The Netherlands and MIAMI, Nov. 20, 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 TANDEM clinical trial (NCT06005597). TANDEM will support global regulatory filings for the 10 mg obicetrapib and 10 mg ezetimibe fixed-dose combination in adult patients with heterozygous familial hypercholesterolemia ("HeFH") and/or atherosclerotic cardiovascular disease ("ASCVD") or multiple ASCVD risk factors, whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy.

The co-primary endpoints were percent change from baseline in LDL-C of the fixed-dose combination compared to each monotherapy arm after 84 days and obicetrapib 10 mg compared to placebo after day 84. Secondary endpoints incorporated percent changes from baseline in other biomarkers, including lipoprotein(a), non-high-density lipoprotein cholesterol and apolipoprotein B.

The TANDEM trial met all co-primary endpoints, including the obicetrapib-ezetimibe fixed dose combination achieving an LS mean reduction of 48.6% (p < 0.0001) compared to placebo at day 84. The observed reductions in all co-primary endpoints are summarized below.

LDL-C percentage change:

	Ezetimibe (n=101)	**Obicetrapib** (n=102)	**Obicetrapib and Ezetimibe FDC** (n=102)
Day 84 – from placebo			
Mean %	-23.3	-35.5	**-52.2**
Median %	-22.6	-37.2	**-54.0**
LS mean %	-20.7	-31.9	**-48.6**
Comparison to pbo	-	(p<0.0001)	**(p<0.0001)**
Comparison to eze 10 mg	-	-	**(p<0.0001)**
Comparison to obi 10 mg	-	-	**(p=0.0007)**

"Millions of people across the world are impacted by cardiovascular disease and, despite lifestyle modifications and current treatment options, a substantial portion of those living with ASCVD and/or HeFH fail to meet their individual LDL-C goals," said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. "We observed clinically meaningful and statistically significant LDL-C lowering, with safety results consistent with our previous clinical studies, in a once daily oral tablet of the fixed-dose combination of obicetrapib and ezetimibe. We believe these data highlight a potential new treatment that, if approved, could expand options for physicians and contribute to improved patient care for those impacted by CVD."

In the trial, the fixed-dose combination of obicetrapib and ezetimibe was observed to be well tolerated, with safety results comparable to placebo. The below table summarizes study drug-related treatment emergent adverse events ("TEAEs") and study drug-related treatment emergent serious adverse events ("TESAEs").

	Placebo (n=102)	**Ezetimibe** (n=101)	**Obicetrapib** (n=102)	**Obicetrapib / Ezetimibe FDC** (n=102)
Any study drug-related TEAEs	4 (3.9%)	3 (3.0%)	7 (6.9%)	3 (2.9%)
Any study drug-related TEAEs leading to discontinuation of study drug	2 (2.0%)	1 (1.0%)	6 (5.9%)	1 (1.0%)
Any study drug related TESAEs	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

“Today’s announcement represents a major achievement in our mission to bring a new and effective therapy to millions of patients struggling with dyslipidemia,” said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam Pharma. “We expect these promising results will support our regulatory filings globally and they reinforce our belief that, if approved, obicetrapib in combination with ezetimibe will potentially offer a simple, once-daily treatment capable of significantly reducing LDL-C and improving cardiovascular outcomes. After the BROOKLYN trial’s successful readout in July and the additional safety and efficacy data released this week, we strongly believe that obicetrapib as a monotherapy or in a fixed-dose combination with ezetimibe has the potential to help patients achieve LDL-C targets.”

“Despite the availability of established therapies, a considerable number of patients still fail to achieve target LDL-C levels, leaving them vulnerable to future cardiovascular events. These top-line results advance our understanding of potential new tools for lipid management for patients at high risk of cardiovascular disease,” said Ashish Sarraju, M.D., Cardiovascular Medicine, Cleveland Clinic.

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

Design of the Pivotal Phase 3 TANDEM Clinical Trial

The pivotal, Phase 3, randomized, double-blind, four-arm, placebo-controlled multicenter study evaluated the effect of 10 mg obicetrapib and 10 mg ezetimibe as a fixed-dose combination on LDL-C levels, compared to both ezetimibe 10 mg and obicetrapib 10 mg monotherapy and to placebo. The study was conducted at sites across the United States, and a total of 407 patients with HeFH and/or ASCVD or ASCVD risk equivalents, who had a baseline LDL-C of at least 70 mg/dL, were randomized 1:1:1:1 to receive 10 mg obicetrapib and 10 mg ezetimibe fixed-dose combination, 10 mg obicetrapib, 10 mg ezetimibe or placebo for an 84-day treatment period. The mean baseline LDL-C for enrolled patients in the obicetrapib-ezetimibe arm was 97 mg/dL despite high intensity statin use reported by approximately 74% of patients during screening. In addition to measuring the co-primary endpoints and secondary endpoints, 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 TANDEM at 8:00 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 of obicetrapib and ezetimibe, including TANDEM. Details on the Company’s pivotal Phase 3 programs are as follows:

- 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 and presented additional data at the American Heart Association Scientific Sessions 2024 in November.
- TANDEM evaluated obicetrapib as part of a fixed-dose combination 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 reported topline data in November 2024.
- BROADWAY is evaluating obicetrapib in adult patients with established 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.
- 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 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 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. The Company began enrolling patients in BROADWAY in January 2022 and completed enrollment of BROADWAY in July 2023. 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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