# NewAmsterdam Pharma Presents Full Data from Phase 2 ROSE2 Trial Evaluating Obicetrapib in Combination with Ezetimibe as an Adjunct to High-Intensity Statin Therapy at NLA Scientific Sessions 2023

June 3, 2023

*– Met Primary Endpoint with 63.4% Median Reduction in LDL-C (p<0.0001) –*

*– 87.1% of Patients Treated with Combination of Obicetrapib and Ezetimibe Met Guideline-Recommended LDL-C Goal of <55 mg/dL compared to 0% of Patients Treated with Placebo (p<0.05) –*

*– New Data Demonstrate Statistically Significant and Clinically Meaningful Improvements in Additional Lipid and Lipoprotein Parameters Predictive of Cardiovascular Disease Risk, Such as LDL Particles and Lipoprotein(a) –*

*– Favorable Safety and Tolerability Observed –*

*– Selected Fixed-Dose Combination Tablet Formula; Phase 3 Trial Expected to Initiate 1Q 2024 –*

*– Management to Host Conference Call at 8:00 a.m. ET on Monday, June 5, 2023 –*

NAARDEN, the Netherlands and MIAMI, June 03, 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 full results of 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. The data are being presented in an oral late-breaker presentation today at the National Lipid Association ("NLA") Scientific Sessions 2023 and will be published concurrently in the *Journal of Clinical Lipidology*.

ROSE2 met its primary and secondary endpoints, with statistically significant and clinically meaningful reductions in LDL-C and apolipoprotein B ("ApoB") observed. Statistically significant improvements in lipoprotein(a) ("Lp(a)"), non-HDL cholesterol ("non-HDL-C") and total and small LDL particles were also observed. In addition, the combination of obicetrapib and ezetimibe was observed to be well-tolerated, with a safety profile observed to be comparable to placebo. With these data in hand, the Company has selected a formulation for a fixed-dose combination tablet and intends to advance the compound into a Phase 3 trial in the first quarter of 2024.

"The 2022 ACC Expert Consensus Decision Pathway has recommended that very high risk patients with LDL-C above 55mg/dl need additional therapy to maximize proven risk reduction. With these new recommendations, many more patients will fail to achieve guideline-mandated LDL-C goals, demonstrating the limitations of existing therapeutics and the critical need for new options," said Christie M. Ballantyne, M.D., Chief of Cardiovascular Research and Professor at Baylor College of Medicine and principal investigator on the clinical trial. "The data presented today are highly encouraging, showing that the combination of obicetrapib and ezetimibe delivers robust impacts on multiple atherogenic lipid parameters. I believe the observed reductions in LDL-C, ApoB, Lp(a) and total and small LDL particles are potentially predictive of profound reductions in the risk of cardiovascular events and look forward to further characterizing the combination obicetrapib and ezetimibe regimen in a Phase 3 trial."

"The ROSE2 data build on our prior clinical experience, supporting the potential for obicetrapib to become a new standard-of-care combined safely with existing options to deliver improved outcomes to the millions of very high-risk patients in need. We are particularly encouraged by the new goal attainment data announced today, through which we observed that 87 percent of patients treated with the combination regimen of obicetrapib and ezetimibe met the most aggressive guideline-mandated LDL-C target of <55 mg/dL," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam, "We have selected a fixed-dose combination tablet formula and look forward to advancing it into a Phase 3 trial, targeted to commence in the first quarter of 2024. In addition, we continue to progress our ongoing BROADWAY, BROOKLYN and PREVAIL trials according to plan. We believe that clinicians and patients are seeking oral options in addition to maximally tolerated statin therapy to reduce the risk of cardiovascular disease. Obicetrapib 10mg as monotherapy and in a fixed dose combination with ezetimibe, if successful in our Phase 3 trials, could well be the therapeutic solution that is so sorely needed."

**Full Data from the Phase 2 ROSE2 Clinical Trial of Obicetrapib and Ezetimibe**

ROSE2 (NCT05266586) was designed as a placebo-controlled, double-blind, randomized Phase 2 clinical trial 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. Patients were randomized to receive combination therapy, obicetrapib 10 mg or placebo for a 12 week treatment period. A total of 119 patients enrolled in ROSE2, of which 97 were included in the on-treatment analysis. Patients presented at baseline with a fasting LDL-C greater than 70 mg/dL and triglycerides ("TG") less than 400 mg/dL and all were receiving a stable dose of high-intensity statin therapy.

The primary endpoint was the percent change from baseline to week 12 in Friedewald-calculated LDL-C for the obicetrapib plus ezetimibe combination treatment group compared with placebo. Secondary efficacy endpoints included the percent changes from baseline to week 12 in LDL-C for obicetrapib monotherapy compared with placebo and in ApoB for the obicetrapib plus ezetimibe combination compared with placebo and the obicetrapib monotherapy compared with placebo. Exploratory endpoints included the percent changes from baseline to week 12 in Lp(a), non-HDL-C, HDL-C, total and small LDL particles assessed by NMR, and the proportion of patients at the end of treatment who achieved LDL-C levels below 100 mg/dL, 70 mg/dL and 55 mg/dL for the obicetrapib plus ezetimibe combination and obicetrapib monotherapy groups compared with placebo.

The p-value for the LS mean for each endpoint compared to placebo was <0.0001. The table below shows the median percent change from baseline

in patients receiving the combination of obicetrapib and ezetimibe, obicetrapib monotherapy and placebo.

| Median percent change from baseline | **Placebo (n=40)** | **Obicetrapib 10mg (n=26)** | **Obicetrapib 10 mg + Ezetimibe 10 mg (n=31)** |
|---|---|---|---|
| **Friedewald-calculated LDL-C** | -6.4 | -43.5 | -63.4 |
| **ApoB** | -2.1 | -24.2 | -34.4 |
| **Non-HDL-C** | -5.6 | -37.5 | -55.6 |
| **Total LDL particles** | -5.7 | -54.8 | -72.1 |
| **Small LDL particles** | -8.3 | -92.7 | -95.4 |
| **LDL particle size** | -0.5 | 1.5 | 1.8 |

The combination of obicetrapib plus ezetimibe resulted in significantly more patients achieving LDL-C levels of less than 100, less than 70 and less than 55 mg/dL than the placebo group (100%, 93.5% and 87.1% vs. 66.7%, 16.7% and 0.0%, respectively) ($p<0.05$ vs. placebo for all). In addition, we observed a median reduction in Lp(a) of 47.2% and 40.2% in the monotherapy and combination arms, respectively.

Treatment with the combination of obicetrapib and ezetimibe was observed to be generally well-tolerated, with a safety profile comparable to placebo. Adverse events were generally mild to moderate, with the most prevalent adverse events being nausea, urinary tract infection and headache, and no drug-related, treatment-emergent serious adverse events were observed.

“We are particularly encouraged by the new lipid particle analysis, in which we observed reductions in Lp(a) and both total and small LDL particles in patients who received the combination of obicetrapib and ezetimibe,” said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. “An observed reduction of almost 50% in Lp(a) levels and associated reduction of 95% in the highly atherogenic small LDL particles are potentially clinically relevant, as LDL particles are believed to be one of the most robust predictors of cardiovascular disease risk. Together, these data further reinforce the potential for obicetrapib to transform the treatment landscape.”

Under the terms of NewAmsterdam’s licensing agreement with the Menarini Group, data from the ROSE2 trial triggered a clinical success milestone payment to NewAmsterdam, which was received in April 2023.

**Conference Call Information**
NewAmsterdam will host a live conference call on Monday, June 5, 2023 beginning at 8:00 a.m. ET to review the full data from the Phase 2 ROSE2 clinical trial. Participants may register for the conference call here. While not required, it is recommended that participants join the call ten minutes prior to the scheduled start.

A live webcast of the call will also be available under “Events & Presentations” in the Investors & News section of the Company’s website at https://ir.newamsterdampharma.com.

**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 63% 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 and completed enrollment of BROOKLYN ahead of schedule in April 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 (“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, 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 63% 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,” “will,” “continue,” “anticipate,” “intend,” “expect,” “predict,” “potential,” “seek,” “target” 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 clinical trials and the timing for enrolling patients (including commencement of its Phase 3 trial), the timing and forums for announcing data and the achievement and 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 Company's public filings with the U.S. Securities and 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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