



## NewAmsterdam Pharma Announces Positive Topline Results from Phase 2b Dose-Finding Trial Evaluating Obicetrapib in Japanese Patients

June 5, 2023

-- Achieved Primary Endpoint with Statistically Significant 45.8% Median Reduction in LDL-C ( $p < 0.0001$ ) in patients treated with 10mg obicetrapib--

-- 29.7% Median Reduction in Apo B and 37.0% Median Reduction in non-HDL-C from Baseline ( $p < 0.0001$ ) in patients treated with 10mg obicetrapib

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-- Favorable Safety and Tolerability Observed --

-- Data Enable PMDA Regulatory Path Aligned with Rest of World; Plan to Leverage Data from Ongoing Phase 3 BROOKLYN, BROADWAY and PREVAIL Trials to Support Potential Approval in Japan --

-- Management to Host Conference Call Today at 8:00 a.m. E.T. --

NAARDEN, the Netherlands and MIAMI, June 05, 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 statistically significant and clinically meaningful topline results from the Phase 2b dose-finding trial of obicetrapib, the company's oral, low-dose and once-daily cholesteryl ester transfer protein ("CETP") inhibitor, as an adjunct to stable statin therapy in Japanese patients with dyslipidemia. Based on the results observed, NewAmsterdam plans to leverage data from the ongoing Phase 3 BROOKLYN, BROADWAY and PREVAIL clinical trials, if supportive, to pursue regulatory approval in Japan.

"Despite the availability of statins, elevated levels of LDL-C continue to pose a significant public health burden. A considerable number of patients fail to achieve sufficient LDL-C lowering on existing treatment options or are unable to access these therapies due to high costs," said Mariko Harada-Shiba, M.D., Ph.D., Director at the Department of Molecular Innovation in Lipidology at Osaka Medical and Pharmaceutical University. "There are currently millions of people living with atherosclerotic cardiovascular disease ("ASCVD") or heterozygous familial hypercholesterolemia ("HeFH") in Japan. Like in other geographies, there is a significant unmet need for an oral therapy that can help many more patients achieve target LDL-C goals. Based on the data reported today, I believe incorporating obicetrapib, if approved, alongside statin therapy may emerge as a promising treatment approach, and I look forward to partnering with the NewAmsterdam team to advance obicetrapib's development globally."

### Topline Data from the Phase 2b Japan Trial

"After announcing positive data from our ROSE2 trial at the National Lipid Association ("NLA") Scientific Sessions this weekend, we are excited to report strong clinical results from the Phase 2b trial assessing obicetrapib in Japanese patients," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "We are particularly encouraged by the consistency of these results with data observed across our clinical program to-date, which reinforces our belief in obicetrapib as a potentially paradigm-changing medicine. Importantly, we believe these data enable us to pursue a regulatory strategy in Japan aligned with our efforts in the rest of the world and look forward to seeking global approval for obicetrapib, if the data from our three pivotal Phase 3 trials, BROOKLYN, BROADWAY and PREVAIL, is positive. With our operational expertise and a strong partner to support obicetrapib commercialization in Europe, if approved, we believe we are well positioned to significantly improve patient outcomes and to potentially transform healthcare for millions of people who are living with cardiometabolic diseases."

The Phase 2b trial was a placebo-controlled, double-blind, randomized, dose-finding trial to evaluate the efficacy, safety and tolerability of obicetrapib as an adjunct to stable statin therapy in Japanese patients. The trial enrolled 102 adult participants, who were randomized 1:1:1:1 to receive obicetrapib 2.5mg, 5mg, 10mg or placebo for a 56-day treatment period.

Patients treated with obicetrapib 2.5mg, 5mg, or 10mg, achieved a median reduction in LDL-C of 24.8%, 31.9%, and 45.8%, respectively, as compared to patients treated with placebo, who achieved a median reduction in LDL-C of 0.9%. In addition, patients treated with obicetrapib 10mg achieved a median reduction in apolipoprotein B ("Apo B") of 29.7%, compared to a 1.2% reduction in patients treated with placebo, and a median reduction in non-high-density lipoprotein cholesterol ("non-HDL-C") of 37.0%, as compared to a 0.4% reduction in patients treated with placebo. The p-value for each endpoint compared to placebo was  $<0.0001$ . Overall, the different dosages of obicetrapib were observed to be well-tolerated, with a safety profile comparable to placebo.

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

### Conference Call and Webcast

NewAmsterdam will host a conference call today at 8:00 a.m. ET to review these data, as well as the full data from the Phase 2 ROSE2 clinical trial, which were presented on Saturday. To access the live conference call, please register [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 four of the Company's Phase 2 trials, ROSE2, 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](http://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 Company's business and strategic plans, the Company's clinical trials and the timing for enrolling patients, 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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