NewAmsterdam Pharma Doses First Patient in PREVAIL, the Cardiovascular Outcomes Trial of Obicetrapib in Adults with Atherosclerotic Cardiovascular Disease (ASCVD)

March 1, 2022

- PREVAIL evaluates whether obicetrapib, a novel cholesteryl ester transfer protein (CETP) inhibitor, lowers the risk of adverse cardiovascular outcomes (MACE) in individuals with Atherosclerotic Cardiovascular Disease (ASCVD) who are not adequately controlled despite maximally tolerated lipid-modifying therapies
- PREVAIL is being conducted in parallel with NewAmsterdam's BROADWAY Phase 3 study
- The Company is expected to complete enrollment for PREVAIL in the first half of 2023 and announce data in the first quarter of 2026

Naarden, the Netherlands and Miami, USA; March 1, 2022 -- NewAmsterdam Pharma (NAP), a clinical-stage company focused on the research and development of transformative therapies for cardiometabolic diseases, today announced dose administration for the first patient in its PREVAIL study, a global Phase 3 cardiovascular outcomes trial of the novel cholesteryl ester transfer protein (CETP) inhibitor obicetrapib. PREVAIL is a placebo-controlled, double-blind, randomized study in participants with a history of atherosclerotic cardiovascular disease (ASCVD) who do not have adequate control of their low-density lipoprotein cholesterol (LDL-c) despite being on maximally tolerated lipid-modifying therapies. Today's announcement follows the recent announcement of NewAmsterdam dosing the first patient in its BROADWAY trial, Phase 3 study of obicetrapib's LDL-c lowering efficacy.

"The beginning of the Phase 3 PREVAIL cardiovascular outcomes trial is another major step forward in the development of the latest-generation CETP inhibitor," said Professor Stephen Nicholls of Monash University, Principal Investigator of the PREVAIL trial. "Over 100 million individuals globally are not achieving their LDL-c goals despite currently available lipid lowering therapies. With PREVAIL we aim to demonstrate the impact that obicetrapib's LDL-c lowering efficacy can provide on patient outcomes in order to help individuals live longer, healthier lives."

"Starting our cardiovascular outcomes trial in parallel with our Phase 3 BROADWAY lipid lowering study, in addition to further studies we intend to start in 2022, underscores NewAmsterdam's commitment to demonstrating the potential for obicetrapib — a simple, low-dose, once daily oral therapy — for patients struggling to meet their targets despite their current lipid modifying therapies," said Michael Davidson, MD, chief executive officer of NewAmsterdam Pharma. "We are thrilled NewAmsterdam will be positioned to share cardiovascular outcomes data just two years after we expect to release our Phase 3 BROADWAY lipid lowering data. We believe these trials will provide a robust package of evidence for obicetrapib's benefits to patients."

The primary objective of the PREVAIL trial is to evaluate the effect of obicetrapib on the risk of major adverse cardiovascular events (MACE), including cardiovascular (CV) death, non-fatal myocardial infraction, non-fatal stroke, or non-elective coronary revascularization. Secondary objectives include evaluating the effect of obicetrapib on all-cause mortality, total CV events, new-onset diabetes mellitus (NODM), and change in LDL-c, non-HDL-c, and ApoB levels.

A total of 9,000 patients will be randomized to placebo or 10 mg obicetrapib dosed as a once daily oral treatment. Enrollment is expected to be completed in the first half of 2023.

About Obicetrapib

Obicetrapib is a selective cholesteryl ester transfer protein (CETP) inhibitor in development for lowering low-density lipoprotein cholesterol (LDL-c) and preventing major adverse cardiovascular events. More than 100 million people globally are not achieving LDL-c goals despite the current available standard of care. Obicetrapib was previously tested in ROSE and TULIP[1] randomized double-blind, placebo-controlled Phase 2 trials. Results from the ROSE trial, presented in November 2021 at the AHA Scientific Sessions, demonstrated that patients on statin therapy who received 5 mg of obicetrapib saw an LDL-c reduction of 42%. Patients who were part of the 10 mg cohort experienced a 51% reduction versus baseline, while the placebo cohort experienced a 7% reduction versus baseline. Both doses were well tolerated, with no serious adverse effects in the two cohorts and two serious AEs in the placebo arm.

About NewAmsterdam Pharma

Founded in 2019 by the venture capital firm Forbion and John Kastelein, NewAmsterdam Pharma is a privately held, clinical-stage company focused on the research and development of transformative therapies for metabolic diseases. Its mission is to improve patient care in populations. In April 2020, NewAmsterdam acquired Dezima Pharma from Amgen, including all rights for obicetrapib (formerly AMG 899, now TA-8995) a selective cholesteryl ester transfer protein (CETP) inhibitor. In January 2021, NewAmsterdam Pharma closed a $196M (€161M) Series A financing led by Morningside Ventures and Ascendant BioCapital with participation from Forbion, Kaiser Foundation Hospitals, BVF Partners L.P., Population Health Partners, LSP Dementia Fund, Peter Thiel, Janus Henderson Investors, Medpace, GL Capital, JVC Investment Partners, and Presight Capital. The Company is investigating obicetrapib as the preferred LDL-c lowering therapy for patients with ASCVD/FH on maximally tolerated statin therapy as well as for the treatment of Alzheimer's disease and diabetes. NewAmsterdam Pharma is headquartered in Naarden, The Netherlands. For more

information, please visit: www.newamsterdampharma.com.

[1] Hovingh, G. K., Kastelein, J. J. P., van Deventer, S. J. H., Round, P., Ford, J., Saleheen, D., Rader, D. J., Brewer, H. B., & Barter, P. J. (2015). Cholesterol ester transfer protein inhibition by TA-8995 in patients with mild dyslipidaemia (TULIP): a randomised, double-blind, placebo-controlled phase 2 trial. In The Lancet (Vol. 386, Issue 9992, pp. 452–460). Elsevier BV. https://doi.org/10.1016/s0140-6736(15)60158-1