



NewAmsterdam Pharma Doses First Participant in Phase 2b SPINOZA Trial Evaluating Obicetrapib in Preclinical Alzheimer's Disease

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- SPINOZA is studying obicetrapib in adults with biomarker evidence suggestive of preclinical Alzheimer's disease who do not have noticeable memory or functional symptoms-

- The study will evaluate changes in blood-based biomarkers associated with Alzheimer's disease, including p-tau 217, and additional cognitive and functional measures-

NAARDEN, the Netherlands and MIAMI, Sept. 29, 2026 (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 the dosing of the first participant in SPINOZA, a Phase 2b clinical trial evaluating obicetrapib in individuals with preclinical Alzheimer's disease.

"The first participant dosed in SPINOZA marks an important milestone for NewAmsterdam as we expand the clinical evaluation of obicetrapib in Alzheimer's disease," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam Pharma. "Alzheimer's disease pathology typically begins years before clinical symptom onset, creating an opportunity for intervention. The commencement of this trial is an important step in our effort to understand whether obicetrapib may affect biological changes associated with the disease before noticeable symptoms develop. The findings from our BROADWAY Alzheimer's disease biomarker analysis, together with the growing body of evidence linking lipid metabolism to Alzheimer's disease pathology, provide a strong scientific rationale for further evaluating the effect of obicetrapib on biomarkers associated with disease progression and neurodegeneration."

SPINOZA is a Phase 2b, randomized, double-blind, placebo-controlled, parallel-group study designed to evaluate the efficacy and safety of obicetrapib in approximately 400 participants with preclinical Alzheimer's disease. Eligible participants have biomarker evidence consistent with early Alzheimer's disease pathology and carry ApoE4/E4, ApoE3/E4 or ApoE3/E3 genotypes. Participants will be randomized 1:1, stratified by genotype, to receive obicetrapib 10 mg or placebo for 52 weeks. Following completion of the double-blind treatment period, participants may enter a 26-week open-label extension study during which all participants will receive obicetrapib.

The SPINOZA trial design was informed by findings from the prespecified Alzheimer's disease biomarker analysis in the Company's Phase 3 BROADWAY trial, which demonstrated the strongest observed biomarker response in ApoE4/E4 participants and supportive signals across additional genotype-defined populations. These findings informed the genotype-stratified design of SPINOZA and the selection of enrollment criteria intended to further evaluate the effects of obicetrapib on biomarkers associated with Alzheimer's disease pathology and neurodegeneration. SPINOZA further expands NewAmsterdam's clinical development program for obicetrapib alongside its ongoing Phase 3 REMBRANDT, RUBENS and PREVAIL clinical trials.

People interested in learning more about the SPINOZA trial can visit spinoza.longboat.com. Additional eligibility criteria apply, and eligibility can only be determined by the study team following the required screening assessments.

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, BROADWAY 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 commenced the Phase 3 PREVAIL cardiovascular outcomes trial in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of MACE. The Company 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, have been exclusively granted to the Menarini Group, an Italy-based, leading international pharmaceutical and diagnostics company.

About the Phase 2b SPINOZA Trial

The SPINOZA trial is a Phase 2b, randomized, double-blind, placebo-controlled, parallel-group study evaluating the effect of obicetrapib on plasma p-tau217 and other biomarkers associated with Alzheimer's disease pathology and neurodegeneration in approximately 400 participants with preclinical Alzheimer's disease.

Eligible participants are adults aged 55 to 85 years with preclinical Alzheimer's disease (Stage 1 or Stage 2) as defined by FDA guidance for Early Alzheimer's Disease drug development, a Mini-Mental State Examination (MMSE) score of at least 27, a global Clinical Dementia Rating (CDR) score of 0.5 or lower, and biomarker evidence of Alzheimer's disease pathology. Enrollment is restricted to participants with ApoE4/E4, ApoE3/E4, or ApoE3/E3 genotypes. Participants will be randomized 1:1 to receive obicetrapib 10 mg or placebo, stratified by genotype.

The primary efficacy endpoint is change from baseline to Week 52 in plasma phosphorylated tau 217 (p-tau217), a biomarker associated with Alzheimer's disease pathology. Secondary endpoints include changes in plasma Alzheimer's disease biomarkers, including Aβ42/Aβ40, p-tau217/Aβ42, p-tau217/Aβ42/40 and BD-tau, as well as change from baseline to Week 52 in the Preclinical Alzheimer's Cognitive Composite 5 (PACC5) score.

Following completion of the 52-week double-blind treatment period, eligible participants may choose to enter an open-label extension lasting at least 26 weeks, during which all participants will receive obicetrapib.

BROADWAY Alzheimer's Analysis

In BROADWAY, a pre-specified analysis was designed to assess plasma biomarkers of Alzheimer's disease in patients enrolled in the BROADWAY trial and evaluated the effects of longer duration of therapy (12 months) with a prespecified ApoE population, based on phenotypic analysis. The analysis included 1,535 patients, including 367 ApoE4 carriers (ApoE3/E4 or ApoE4/E4), whose ApoE status was able to be determined. Because this analysis was based on a subset of patients from BROADWAY (which was designed to evaluate LDL-C reductions in an ASCVD and/or HeFH population), the AD analysis was not controlled for baseline differences between the treatment and placebo populations, but statistical analyses were adjusted for baseline biomarker values and age. The absolute and percent change over 12 months in p-tau217, a key biomarker of AD pathology, was measured among patients with baseline and end of study datapoints above the lower limit of quantitation. Additional outcome measures included NFL, GFAP, p-tau181, and A β 42/40 ratio absolute and percent change over 12 months. NewAmsterdam observed statistically significant lower absolute changes in p-tau217 compared to placebo over 12 months in both the full analysis set ($p=0.025$; $n=1,535$) and in ApoE4 carriers ($p=0.022$; $n=367$) as well as favorable trends in the other AD biomarkers. Although a safety analysis was not performed in the AD analysis population, in BROADWAY obicetrapib was observed to be well-tolerated, with safety results comparable to placebo.

About NewAmsterdam

NewAmsterdam Pharma (Nasdaq: NAMS) is a late-stage biopharmaceutical company dedicated to building a new standard of care for people living with cardiometabolic and neurodegenerative diseases. The Company is advancing therapies designed to address a significant unmet need for safe, well-tolerated, and convenient treatment options that lower LDL-C while advancing innovation beyond a single marker to better address cardiovascular risk. In multiple Phase 3 trials, NewAmsterdam is investigating obicetrapib, an oral, low-dose, once-daily CETP inhibitor, alone and as a fixed-dose combination with ezetimibe, in patients at risk of cardiovascular disease with elevated LDL-C. Guided by its mission, the Company challenges convention with courage, translates deep biological insight into meaningful patient impact, and delivers with rigor, precision, and purpose.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995 and are subject to the "safe harbor" provisions created thereunder. All statements that are not historical facts are hereby identified as forward-looking statements for this purposes and include, among others, statements relating to: the therapeutic potential of the Company's product candidate; the design, progression, timing and objectives of the Company's clinical trials, including the SPINOZA trial; and other statements regarding the Company's future operations, prospects, objectives, strategies and other future events. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. These forward-looking statements are based upon management's current expectations and assumptions. Actual results or events could differ materially and adversely from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various risks, uncertainties and other factors, including, among others: uncertainties inherent in research and development, in the initiation and advancement of clinical trials and in the clinical development of obicetrapib in preclinical Alzheimer's disease; whether results of early clinical trials and analyses will be indicative of the results of later clinical trials and analyses; risks to clinical trial site initiation, patient enrollment and follow-up; changes in domestic and foreign business, market, financial, political, and legal conditions; and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, that are described in greater detail in the sections entitled "Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 18, 2026 and in its Quarterly Report on Form 10-Q filed with the SEC on August 5, 2026, as well as in other filings the Company may make with the SEC in the future, which are available at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date of this press release, and the Company expressly disclaims any obligation to update any forward-looking statements contained herein, whether because of new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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