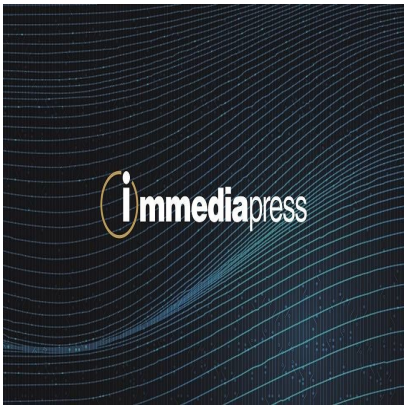

Menarini Group and NewAmsterdam Pharma Receive European Commission Approval for UbesloÂ® (Obicetrapib Monotherapy) and EvlarcoÂ® (Obicetrapib Plus Ezetimibe Fixed-Dose Combination)

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

â?? First-in-Class approval supported by Phase 3 BROADWAY, BROOKLYN, and TANDEM trials demonstrating significant LDL-C reductions with favorable tolerability profile â??

â?? First global regulatory approval of obicetrapib marks a defining milestone for NewAmsterdam and Menarini, expanding treatment options for patients with elevated LDL-C â??

FLORENCE, Italy, NAARDEN, Netherlands and MIAMI, Sept. 21, 2026 /PRNewswire/ â?? NewAmsterdam Pharma Company N.V. (Nasdaq: NAMS or â??NewAmsterdamâ?• or the â??Companyâ?•), a late-stage, clinical biopharmaceutical company developing oral, non-statin medicines for patients at risk of cardiovascular disease (â??CVDâ?•) with elevated low-density lipoprotein cholesterol (â??LDL-Câ?•), for whom existing therapies are not sufficiently effective or well-tolerated, along with partner Menarini Group (â??Menariniâ?•), today announced that the European Commission (EC) has granted marketing authorization for UbesloÂ® (obicetrapib 10 mg monotherapy) and EvlarcoÂ® (10 mg obicetrapib plus 10 mg ezetimibe fixed-dose combination) for patients with primary hypercholesterolaemia, both heterozygous familial (â??HeFHâ?•) and non-familial or mixed dyslipidaemia, marking the first regulatory approval of obicetrapib worldwide.

â??The European Commission approval of Ubeslo and Evlarco marks a major milestone for NewAmsterdam as the first regulatory approval of obicetrapib globally, a novel oral therapy, and validates years of work focused on delivering a potential new treatment option for patients who continue to struggle to achieve recommended LDL-C levels despite previously available therapies,â?• said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam Pharma. â??This first-in-class approval reflects the strength of the clinical evidence supporting obicetrapib, the dedication of our team and partners, and our commitment to addressing one of the largest unmet needs in cardiovascular

medicine. Together with Menarini, we look forward to bringing Ubeslo and Evlarco to patients across Europe and building on this important milestone as we advance our vision of making obicetrapib available to patients around the world.â?•

The European Commission approval follows the positive opinion adopted by the European Medicines Agencyâ??s Committee for Medicinal Products for Human Use (CHMP) and is supported by data from NewAmsterdamâ??s comprehensive clinical development program evaluating obicetrapib, including the Phase 3 BROADWAY, BROOKLYN and TANDEM trials, which demonstrated statistically significant LDL-C reductions of up to 40% with obicetrapib monotherapy versus placebo and approximately 50% with obicetrapib combined with ezetimibe versus placebo, with a tolerability profile comparable to placebo. NewAmsterdam and Menarini continue to advance the clinical development of obicetrapib through multiple ongoing Phase 3 trials, including PREVAIL, a cardiovascular outcomes trial, as well as REMBRANDT and RUBENS.

â??This approval represents an important advancement for patients across Europe who require additional LDL-C lowering despite available therapies,â?• said Elcin Barker Ergun, Chief Executive Officer of Menarini Group. â??We are proud to reach this significant achievement alongside NewAmsterdam and look forward to leveraging our well-established commercial capabilities and deep cardiovascular expertise to bring Ubeslo and Evlarco to healthcare providers and eligible patients throughout Europe.â?•

Under the partiesâ?? licensing agreement, Menarini holds exclusive commercialization rights for obicetrapib in Europe and is responsible for regulatory interactions and commercialization activities throughout the region. NewAmsterdam is entitled to tiered double-digit percentage royalties ranging from the low double-digits to mid-twenties on net sales in the Menarini Territory and up to an additional â?¬833 million upon the achievement of various clinical, regulatory and commercial milestones.

For full details on the approved indications, contraindications, warnings, and precautions please refer to the Summary of Product Characteristics (SmPC) which will be made available on the European Medicines Agency websites at:https://www.ema.europa.eu/en/medicines/human/EPAR/ubeslo https://www.ema.europa.eu/en/medicines/human/EPAR/evlarco

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 Companyâ??s Phase 2 trials, ROSE2, TULIP, ROSE, and OCEAN, as well as the Companyâ??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 Major Adverse Cardiovascular Events (â??MACEâ?•). 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 Cardiovascular Disease

Cardiovascular disease remains the leading cause of death globally, despite the availability of lipid-lowering therapies (â??LLTsâ?•). By 2050 more than 184 million U.S. adults are expected to be affected by CVD and hypertension, including 27 million with coronary heart disease and 19 million with stroke. In the United States from 2019 through 2022, CVD age-adjusted mortality rates increased by 9%, reversing the trend observed since 2010 and undoing nearly a decade of progress. Despite the availability of high-intensity statins and non-statin LLTs, LDL-C target level attainment remains low, contributing to residual cardiovascular risk, and underscoring a significant clinical need for improved therapeutic regimens. Even with 269 million LLT prescriptions written over the last 12 months, 30 million under-treated US adults are not at their risk-based LDL-C goal, of which 13 million have ASCVD. Less than 1 in 4 patients with ASCVD achieve an LDL-C goal of less than 70 mg/dL and only 10% of very high risk ASCVD patients achieve the goal below 55 mg/dL. In addition to the 30 million under-treated U.S. adults, there are 10 million patients diagnosed with elevated LDL-C who are not taking any LLTs including statins. Beyond LDL-C, additional factors are at play, such as lifestyle choices, tobacco use, and obesity, as well as inflammation, thrombosis, triglyceride levels, elevated Lp(a) levels, and type 2 diabetes.

About NewAmsterdam

NewAmsterdam Pharma (Nasdaq: NAMS) is a late-stage biopharmaceutical company dedicated to build a new standard of care for people living with cardiometabolic disease. 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.

About Menarini Group

The Menarini Group, with headquarters in Florence, is present in 140 countries worldwide to date, with $5.5 billion in consolidated turnover and more than 17,000 employees. Menariniâ??s products are present in the most important treatment areas, including those of cardiometabolic, oncology, gastroenterology, diabetology, pneumology, and anti-inflammatory/analgesic products. Through its commitment to R&D and high-quality manufacturing activities, Menarini continuously contributes to patientsâ?? health worldwide, maintaining the highest quality standards.

Forward-Looking Statements

This press release contains â??forward-lookingâ?• statements within the meaning of the United States Private Securities Litigation Reform Act of 1995 and are subject to the â??safe harborâ?• provisions created thereunder. All statements that are not historical facts are hereby identified as forwarding-looking statements for this purposes and include, among others, statements relating to: the therapeutic potential of obicetrapib; expected availability of Ubeslo and Evlarco across Europe; the Companyâ??s licensing agreement with Menarini and entitlement to potential future payments thereunder; the continued advancement of clinical development of obicetrapib through multiple ongoing Phase 3 trials; and other statements regarding the Companyâ??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 managementâ??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: whether projections regarding clinical outcomes will reflect actual results in clinical use of Ubeslo and Evlarco; risks related to the Companyâ??s ability to achieve its business plans, objectives and milestones, including those related to its licensing agreement with Menarini; challenges inherent to the clinical development and launch of new drug products; risks related to the Companyâ??s reliance on third parties; and other important factors, any of which could cause the Companyâ??s actual results to differ from those contained in the forward-looking statements, that are described in greater detail in the sections entitled â??Risk Factorsâ?• in the Companyâ??s Annual Report on Form 10-K filed with the Securities and Exchange Commission (â??SECâ?•) 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.

BROADWAY (NCT05142722)BROOKLYN (NCT05425745)OCEAN NCT04770389PREVAIL (NCT05202509)REMBRANDT (NCT06305559)ROSE NCT04753606ROSE2 NCT05266586RUBENS (NCT07219602)TANDEM (NCT06005597)TULIP NCT01970215

(Translations: in the event of any discrepancy, the English language version prevails)

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Categoria

1. Comunicati

Tag

1. ImmediaPress

Data di creazione
Settembre 21, 2026
Autore
redazione