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Mineralys Therapeutics Presents New Data for Lorundrostat at the American Heart Association Hypertension Scientific Sessions 2026

- New analyses from the pivotal Launch-HTN trial showed that 46% of participants with difficult-to-treat hypertension receiving lorundrostat 50 mg achieved the AHA/ACC Guideline systolic blood pressure target of <130 mmHg at 12 weeks, with more than two-thirds achieving ≥10 mmHg systolic blood pressure reduction -

- In the Explore-OSA trial in participants with obstructive sleep apnea, lorundrostat 50 mg taken once daily in the evening achieved clinically meaningful reductions in morning systolic blood pressure with no measurable change in apnea-hypopnea indices -

RADNOR, Pa., Oct. 09, 2026 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a biopharmaceutical company focused on developing medicines to target hypertension and aldosterone-related outcomes in comorbid conditions such as chronic kidney disease (CKD), obstructive sleep apnea (OSA) and other diseases driven by dysregulated aldosterone, announced today the presentation of a new analysis from its pivotal Phase 3 Launch-HTN trial, showing that at Week 12, 46% of lorundrostat-treated participants achieved the AHA/ACC Guideline recommended office systolic blood pressure (SBP) target of <130 mmHg. These results were presented at the American Heart Association Hypertension Scientific Sessions 2026 (AHA-HTN), taking place October 7-11 in Arlington, VA.

“Hypertension remains the most important risk factor for cardiovascular diseases, as blood pressure control rates remain poor. Participants in Launch-HTN had uncontrolled or treatment-resistant hypertension, despite being treated with two to five antihypertensive therapies. In this new analysis, nearly half of the lorundrostat-treated participants achieved a guideline-recommended SBP below 130 mmHg,” said Manish Saxena, MBBS, principal investigator on the study and Deputy Clinical Co-Director of Queen Mary University of London’s William Harvey Heart Centre, and Hypertension Specialist at Barts Health NHS Trust. “In addition, 70% of lorundrostat-treated participants achieved an SBP reduction of 10 mmHg or more, a level that, if sustained in the long term, is associated with a 20% reduction in the risk of a cardiovascular event. The results of the analysis reinforce the potential of lorundrostat to deliver clinically meaningful reductions in blood pressure in patients with difficult-to-treat hypertension.”

In a separate oral presentation, the finalresults of the Phase 2 Explore-OSA trial of lorundrostat in overweight or obese adults with moderate-to-severe OSA and hypertension were featured. Participants receiving lorundrostat 50 mg once daily in the evening achieved clinically meaningful reductions in morning SBP of 11.1 mmHg at Week 4 ($p<0.0001$), compared with 1.0 mmHg reduction for participants receiving placebo (p=NS), although no

measurable change in apnea-hypopnea indices were observed with lorundrostat. In the study, lorundrostat exhibited a favorable safety and tolerability profile, and there was no evidence of significant safety events, including hyperkalemia (high serum potassium).

“The observed reductions in morning blood pressure in Explore-OSA were consistent with the reductions in our other pivotal trials of lorundrostat in participants with uncontrolled or treatment-resistant hypertension,” said Terry Ferguson, MD, Chief Medical Officer of Mineralys Therapeutics. “Results across lorundrostat trials to date demonstrate a compelling potential for lorundrostat to help a significant proportion of patients with uncontrolled or treatment-resistant hypertension, including those who also have CKD or OSA, reduce their systolic blood pressure to a level that may also reduce their risk of cardiovascular events.”

About Launch-HTN

The Launch-HTN trial (NCT06153693) was a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial of adults whose blood pressure remained uncontrolled despite being on two to five antihypertensive medications. Participants were assigned to one of three groups: lorundrostat 50 mg once daily; lorundrostat 50 mg once daily with the option to increase to 100 mg at week six based on prespecified criteria; or placebo. The primary endpoint was change from baseline in systolic blood pressure at six weeks versus placebo, measured by automated office blood pressure monitoring.

About Explore-OSA

The Explore-OSA trial (NCT06785454) was a randomized, double-blind, placebo-controlled, crossover Phase 2 clinical trial. This proof-of-concept trial was designed to evaluate the efficacy, safety and tolerability of lorundrostat in overweight or obese adults with moderate-to-severe OSA and hypertension. Participants in Explore-OSA received lorundrostat 50 mg once daily and placebo in sequential treatment periods, with continuous monitoring of blood pressure during overnight polysomnography. The primary efficacy endpoint of the trial was absolute change from baseline in apnea-hypopnea index after four weeks of active treatment compared to placebo. The first secondary endpoint was automated office blood pressure, and additional endpoints were nighttime blood pressure and sleep and cardiovascular health measures.

About Obstructive Sleep Apnea

OSA is characterized by repetitive overnight hypoxic episodes and subsequent sleep fragmentation due to a complete or partial collapse of the upper airway. Moderate-to-severe OSA is associated with increased production of aldosterone and increased nighttime blood pressure; standard treatment with positive airway pressure is not sufficient for blood pressure reduction. OSA impacts almost one billion people globally, including 425 million moderate-to-severe cases. Around 80% of adults with OSA are undiagnosed. As of 2025, untreated OSA is estimated to cost the United States more than $150 billion annually when considering direct medical expenses, productivity losses and accident-related costs.

Between 30-50% of adults with hypertension have OSA, and this number increases to between 70-80% in adults with resistant hypertension (rHTN). Additionally, untreated moderate-to-severe OSA increases the risk of rHTN. Along with hypertension, OSA is a major risk factor of cardiovascular disease, type-2 diabetes mellitus and stroke.

About Hypertension

Having sustained, elevated blood pressure (or hypertension) increases the risk of heart disease, heart attack and stroke, which are leading causes of death in the United States. In 2022, more than 685,000 deaths in the United States included hypertension as a primary or contributing cause. Hypertension and related health issues resulted in an estimated annual economic burden of about $219 billion in the United States in 2019.

Less than 50% of hypertension patients achieve their blood pressure goal with currently available medications. Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 30% of all hypertensive patients.

About Lorundrostat

Lorundrostat is an investigational, proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), as well as related comorbidities, such as chronic kidney disease, obstructive sleep apnea and other diseases driven by dysregulated aldosterone. Lorundrostat was designed to reduce aldosterone levels by inhibiting CYP11B2, the enzyme responsible for its production. Lorundrostat has 374-fold selectivity for aldosterone-synthase inhibition versus cortisol-synthase inhibition in vitro, has an observed half-life of 10-12 hours and demonstrated a 40-70% reduction in plasma aldosterone concentration in participants with hypertension.

Mineralys has completed six late-stage clinical trials of lorundrostat supporting its efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. The clinical program includes two pivotal, registrational trials, the Phase 3 Launch-HTN trial and Phase 2 Advance-HTN trial, which support the robust, durable and clinically meaningful reductions in systolic blood pressure by lorundrostat. Lorundrostat was well tolerated in both trials with a favorable safety profile.

About Mineralys

Mineralys Therapeutics is a biopharmaceutical company focused on developing medicines to target hypertension and related comorbidities such as chronic kidney disease, obstructive sleep apnea and other diseases driven by dysregulated aldosterone. Its initial product candidate, lorundrostat, is an investigational, proprietary, orally administered, highly selective aldosterone synthase inhibitor. Mineralys is based in Radnor, Pennsylvania, and was founded by Catalys Pacific. For more information, please visit https://mineralystx.com. Follow Mineralys on LinkedIn, X and Bluesky.

Forward-Looking Statements

Mineralys Therapeutics cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on Mineralys' current beliefs and expectations and include, but are not limited to, statements regarding the potential therapeutic benefits of lorundrostat. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Mineralys' business, including, without limitation: any delays in the Food and Drug Administration's (FDA) review of Mineralys' accepted new drug application

(NDA), including as a result of a government shutdown or reductions in agency funding or personnel; the results of Mineralys' clinical trials, including the Launch-HTN and Advance-HTN trials, may not be deemed sufficient by the FDA to serve as the basis for regulatory approval of lorundrostat; later developments with the FDA may be inconsistent with the feedback from prior meetings, including whether the proposed pivotal program will support registration of lorundrostat following the FDA's review of Mineralys' NDA submission; the risk that future funding under the secured debt facility may not be available on the timeframe Mineralys expects, or at all, including as a result of its failure to meet the conditions required for such funding or failure to comply with the affirmative and negative covenants under the debt facility; Mineralys may not be able to reach agreement on the proposed termination of its license agreement with Tanabe on its expected timeframe, or at all; Mineralys' future performance is dependent entirely on the success of lorundrostat; potential delays in the commencement, enrollment and completion of clinical trials and nonclinical studies; Mineralys' dependence on third parties in connection with manufacturing, research and clinical and nonclinical testing; unexpected adverse side effects or inadequate efficacy of lorundrostat that may limit its development, regulatory approval and/or commercialization; unfavorable results from clinical trials and nonclinical studies; results of prior clinical trials and studies of lorundrostat are not necessarily predictive of future results; macroeconomic trends and uncertainty with regard to high interest rates, elevated inflation, tariffs and other trade policies, and the potential for a local and/or global economic recession; Mineralys' ability to maintain undisrupted business operations due to any pandemic or future public health concerns; regulatory developments in the United States and foreign countries; Mineralys' reliance on its exclusive license with Tanabe to provide Mineralys with intellectual property rights to develop and commercialize lorundrostat; and other risks described in Mineralys' filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in its annual report on Form 10-K, and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Mineralys undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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