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Mineralys Therapeutics Presents New Data from the Phase 3 Launch-HTN Trial of Lorundrostat in Participants with Hypertension and Chronic Kidney Disease at European Meeting on Hypertension and Cardiovascular Protection (ESH 2026)

– Post hoc analysis from pivotal Launch-HTN trial shows statistically significant and clinically meaningful reductions in blood pressure in participants with chronic kidney disease –

– In participants with chronic kidney disease and baseline albuminuria, lorundrostat significantly reduced urine albumin-to-creatinine ratio –

– Lorundrostat demonstrated a favorable safety profile in participants with and without chronic kidney disease over 12 weeks –

RADNOR, Pa., May 30, 2026 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a biopharmaceutical company focused on developing medicines to target hypertension and related comorbidities such as chronic kidney disease (CKD), obstructive sleep apnea (OSA) and other diseases driven by dysregulated aldosterone, today presented new clinical data for lorundrostat at the 35th European Meeting on Hypertension and Cardiovascular Protection (ESH 2026**)** in Gdańsk, Poland.

“Despite the availability of current therapies, up to 75 percent of patients with chronic kidney disease still have uncontrolled or resistant blood pressure, contributing to a high risk of cardiovascular events and kidney disease progression,” said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “These results, together with our Explore-CKD trial findings, demonstrate lorundrostat’s potential to address the compounded burden of hypertension and CKD, underscoring its promise as an important potential treatment option for this difficult-to-treat population with high unmet need.”

The analysis evaluated the efficacy and safety of once-daily lorundrostat 50 mg by CKD status among 800 participants with uncontrolled or resistant hypertension enrolled in the randomized, double-blind, placebo-controlled Phase 3 Launch-HTN trial. Among participants with CKD (n=192), 71% were receiving three or more anti-hypertensive medications at baseline, compared with 56% of those without CKD. In addition, 31% of participants with CKD had systolic blood pressure (SBP) ≥160 mmHg at baseline, versus 17% of participants without CKD.

Lorundrostat demonstrated significant reductions in SBP that were comparable between CKD and non-CKD participants. At week 12, placebo-adjusted SBP reductions were 9.6

mmHg in participants with CKD (p=0.0022) and 12.2 mmHg in those without CKD (p<0.0001). A greater proportion of lorundrostat-treated participants also achieved target SBP of <130 mmHg at week 12 compared with placebo, both among CKD participants (44% vs 18%) and non-CKD participants (48% vs 22%).

Lorundrostat treatment was also associated with a significant placebo-adjusted reduction in urinary albumin-to-creatinine ratio (UACR) among 84 participants with CKD and baseline albuminuria, achieving a 52.2% placebo-adjusted reduction at 12 weeks (p<0.0001). Lorundrostat had a favorable safety profile in both CKD and non-CKD participants with low rates of confirmed hyperkalemia, 2.4% and 0% respectively.

“These findings are compelling because they show that lorundrostat achieves comparable blood pressure reductions regardless of kidney disease status, while also significantly reducing albuminuria, a key marker of kidney injury and disease progression, in these patients,” said Dr. Liffert Vogt, Professor of Nephrology and Renal Transplantation at Amsterdam University Medical Center and University of Amsterdam. “Aldosterone is a key driver of both chronic kidney disease and difficult-to-treat hypertension, and these findings demonstrate the potential for lorundrostat to provide needed cardiorenal protection for these patients.”

Previous data from the Explore-CKD trial, presented atASN Kidney Week 2025, showed that adding lorundrostat to standard-of-care therapy reduced both blood pressure and albuminuria in participants with hypertension and CKD. Across both the Launch-HTN and Explore-CKD trials, lorundrostat demonstrated clinically meaningful blood pressure reductions in participants with hypertension, including those in high-risk populations with CKD, obesity and Black or African American participants.

Lorundrostat is currently under review by the U.S. Food and Drug Administration, with a Prescription Drug User Fee Act (PDUFA) target date of December 22, 2026.

About Launch-HTN
Launch-HTN (NCT06153693) was a global, randomized Phase 3 double-blind, placebo-controlled trial of adults whose blood pressure remained uncontrolled despite being on two to five antihypertensive medications. Participants were assigned to one of three groups: placebo; lorundrostat 50 mg once daily; or lorundrostat 50 mg once daily with the option to increase to 100 mg at week six. The primary endpoint was change from baseline in SBP at 6 weeks versus placebo, measured by automated office blood pressure monitoring.

About Chronic Kidney Disease (CKD)
CKD, which is characterized by the gradual loss of kidney function, is estimated to affect more than 10% of the global population and is one of the leading causes of mortality worldwide. According to the U.S. Centers for Disease Control and Prevention (CDC), more than 1 in 10 of adults aged 18 or older (37 million people) are estimated to have CKD. Approximately 21% of adults with high blood pressure are estimated to have CKD. The relationship between these conditions is tightly linked: sustained hypertension may contribute to impaired kidney function, and progressive decrease in kidney function may lead to worsening blood pressure (BP) control. When CKD is present in patients with hypertension, the risk of cardiovascular disease and mortality rises significantly.

Emerging evidence points to dysregulated aldosterone as a key driver of both diseases.

Excess aldosterone promotes sodium retention, vascular inflammation and fibrosis, contributing to both uncontrolled BP and kidney injury. Despite the availability of existing therapies, a significant proportion of patients remain uncontrolled or undertreated. Early detection and targeted interventions that address underlying mechanisms, such as aldosterone dysregulation, may offer the potential to slow CKD progression, reduce cardiovascular risk and improve long-term outcomes. Without effective management, CKD can advance to kidney failure, requiring dialysis or transplantation.

About Hypertension
Having sustained, elevated blood pressure (BP) (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 hypertensive patients achieve their BP 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 CKD, OSA 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, an observed half-life of 10-12 hours and demonstrated a 40-70% reduction in plasma aldosterone concentration in hypertensive participants.

Mineralys has now completed six late-stage clinical trials of lorundrostat supporting the efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. This 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 BP by lorundrostat. Lorundrostat was generally 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 CKD, OSA 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, Twitter 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 our current beliefs and expectations and include, but are not limited to, statements regarding: the potential therapeutic benefits of lorundrostat; the anticipated timing of the U.S. Food and Drug Administration's (FDA) review of our accepted

New Drug Application (NDA) and any subsequent regulatory approval of lorundrostat; and the planned future clinical development of lorundrostat and the timing thereof. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: topline results that we report are based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; any delays in the FDA's review of our accepted NDA, including as a result of a government shutdown or reductions in agency funding or personnel, the results of our clinical trials, including the Advance-HTN and Launch-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 our NDA submission; our future performance is dependent entirely on the success of lorundrostat; potential delays in the commencement, enrollment and completion of clinical trials and nonclinical studies; our 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; our ability to maintain undisrupted business operations due to any pandemic or future public health concerns; regulatory developments in the United States and foreign countries; our reliance on our exclusive license with Tanabe Pharma Corporation to provide us with intellectual property rights to develop and commercialize lorundrostat; and other risks described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our 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 we undertake 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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