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Mineralys Therapeutics Presents New Lorundrostat Data in Participants with Hypertension and Chronic Kidney Disease at ASN Kidney Week 2026

In the large, pivotal Phase 3 Launch-HTN trial, lorundrostat achieved similar significant blood pressure reductions in participants with and without CKD, with consistent reductions across Stages 1-3 CKD

In participants with CKD, lorundrostat also reduced albuminuria by 52% versus placebo, validating similar findings in a prior trial in participants with established CKD

RADNOR, Pa., Oct. 22, 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 and other diseases driven by dysregulated aldosterone, today presented new clinical data for lorundrostat at the American Society of Nephrology (ASN) Kidney Week 2026 in Denver, Colorado. The data were shared in an oral presentation delivered by Liffert Vogt, MD, PhD.

In this analysis, lorundrostat provided statistically significant and clinically meaningful reductions in systolic blood pressure (SBP) that were similar between participants with Stages 1 to 3 CKD and those without CKD. At week 12, lorundrostat reduced placebo-adjusted SBP by 9.6 mmHg in participants with CKD ($p=0.0022$) and 12.2 mmHg in those without CKD ($p<0.0001$). In participants with CKD, SBP reductions were seen as early as week 2. A greater proportion of lorundrostat-treated participants reached the target SBP below 130 mmHg at week 12 compared with placebo, both among participants with CKD (44% vs. 18%) and those without CKD (48% vs. 22%).

Among participants with CKD and baseline albuminuria (protein in the urine, an indicator of kidney damage), lorundrostat reduced urine albumin-to-creatinine ratio (UACR, a way to quantitate the amount of protein in the urine) by 52.2% versus placebo at week 12 ($p<0.0001$). This adds to findings from the prior Explore-CKD trial, which showed UACR reductions with lorundrostat in participants with more severe degrees of albuminuria. Lorundrostat had an acceptable safety profile in both CKD and non-CKD participants, with low rates of confirmed hyperkalemia (2.4% and 0%, respectively).

“These results are encouraging. Besides impacting blood pressure in participants with and without kidney disease, treatment with lorundrostat showed a meaningful reduction in albuminuria, a key marker for cardiovascular and kidney risk control,” said Dr. Vogt, Professor of Clinical Nephrology and Renal Physiology at Amsterdam University Medical Center and the University of Amsterdam. “In patients with chronic kidney disease, high blood pressure and albuminuria are two of the most important risk factors we can modify, and

lorundrostat improved both in this trial."

"CKD affects approximately 37 million adults in the U.S., and up to 75% of patients with CKD have uncontrolled hypertension. Aldosterone is a common driver of both hypertension and CKD, and lorundrostat is designed to reduce aldosterone at the source," said Terry Ferguson, MD, Chief Medical Officer of Mineralys Therapeutics. "In Launch-HTN, lorundrostat provided similar blood pressure reductions in participants with or without CKD, and it not only did so across a broad spectrum of the disease, but it did it in a way that reduced albuminuria." Lorundrostat is currently under review by the U.S. Food and Drug Administration for the treatment of hypertension in combination with other antihypertensive drugs, with a Prescription Drug User Fee Act (PDUFA) target date of December 22, 2026.

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 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 hypertensive 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 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 (14%) adults aged 18 or older (approximately 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. 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 blood pressure 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 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 anticipated timing of the Food and Drug Administration's (FDA) review of Mineralys' accepted new drug application (NDA) and 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 FDA's review of Mineralys' accepted 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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