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# Mineralys Therapeutics Announces Publication of Phase 2 Explore-CKD Trial Results for Lorundrostat in Kidney International

*- Explore-CKD met its primary endpoint; lorundrostat 25 mg once daily added to an SGLT2 inhibitor achieved a statistically significant reduction in systolic blood pressure at four weeks -*

*- New hormonal and urinary protein data show a 41.5% reduction in serum aldosterone with additional significant reductions in albuminuria and proteinuria -*

RADNOR, Pa., Oct. 28, 2026 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a biopharmaceutical company focused on developing medicines to target hypertension and aldosterone-related adverse outcomes in comorbid conditions such as chronic kidney disease (CKD), obstructive sleep apnea and other diseases driven by dysregulated aldosterone, today announced that the full results from the Phase 2 Explore-CKD trial of lorundrostat in participants with uncontrolled hypertension, CKD and albuminuria have been published in *Kidney International* and are available online.

The Explore-CKD trial evaluated the efficacy and safety of lorundrostat, an aldosterone synthase inhibitor, added to guideline-directed background therapy in 59 participants with uncontrolled hypertension, stage 1 to 3b CKD and albuminuria (albumin loss in the urine), an early manifestation of kidney damage.

“Chronic kidney disease and hypertension are pathologically linked, and approximately 76% of patients with both CKD and hypertension have uncontrolled blood pressure despite treatment with multiple antihypertensive medications,” said Matthew R. Weir, MD, Director of the Division of Nephrology at the University of Maryland Medical Center, Professor of Medicine at the University of Maryland School of Medicine, lead author of the publication and scientific consultant for Mineralys. “The Explore-CKD results demonstrate that lorundrostat may help CKD patients reduce otherwise uncontrolled high blood pressure and potentially improve their kidney function.”

"With this publication we have additional peer-reviewed evidence demonstrating the potential benefits of lorundrostat for people living with uncontrolled or resistant hypertension and CKD, a population that is especially difficult to treat," said Terry Ferguson, MD, Chief Medical Officer of Mineralys Therapeutics. "There were consistent reductions in urinary protein loss, along with the expected reductions in serum aldosterone levels. Further evaluation of lorundrostat as a therapeutic approach for lowering blood pressure and reducing albuminuria in participants with CKD will follow shortly, with longer-term data from Explore-CKD participants enrolled in the Transform-HTN open-label extension study.”

**Key Findings from Explore-CKD**

Explore-CKD randomized 59 participants at 42 sites in the United States. Participants had a mean age of 64.6 years and a mean body mass index of 33.1 kg/m2, and 76% had type 2 diabetes. Of the participants, 30.5% were female, 16.9% were Black or African American and 42.4% were Hispanic or Latino. At baseline, mean automated office systolic blood pressure (AOSBP) was 149 mmHg, UACR (urinary albumin-to-creatinine ratio, an indicator of kidney protein loss) was 516.8 mg/g and mean estimated glomerular filtration rate (eGFR) was 43 mL/min/1.73m2 based on cystatin C. Overall, 64.4% of participants were taking three or more antihypertensive medications.

The primary efficacy endpoint was the change from baseline in systolic blood pressure at week four in the active versus placebo treatment period. At week four, lorundrostat 25 mg once daily achieved a 9.3 mmHg reduction in AOSBP, compared with a 1.8 mmHg reduction for placebo, yielding a placebo-adjusted reduction of 7.5 mmHg (95% CI, -12.3 to -2.7; p=0.0024). Automated office diastolic blood pressure was reduced by 3.9 mmHg with lorundrostat and 1.4 mm Hg with placebo.

Lorundrostat also reduced UACR by 30.5% from baseline and by 25.6% placebo-adjusted (p=0.0015) at week four. The placebo-adjusted reductions were also significant for 24-hour UACR (26.1%; p<0.0001) and 24-hour urine protein-to-creatinine ratio (22.1%; p=0.0002).

Serum aldosterone decreased by 41.5% with lorundrostat and increased by 1.8% with placebo, and plasma renin activity rose by 75.2% and 4.2%, respectively. No clinically meaningful changes in serum cortisol were observed in either treatment sequence.

The nature and incidence of adverse events were similar to those in prior lorundrostat trials and consistent with its mechanism of action.

**About Explore-CKD**

The Explore-CKD trial (NCT06150924) was a randomized, double-blind, placebo-controlled, two-period, two-sequence (2x2) crossover Phase 2 clinical trial. This trial was designed to evaluate blood pressure reduction and safety of 25 mg once-daily lorundrostat when added to background treatment with an ACEi or ARB and an SGLT2 inhibitor for the treatment of hypertension in participants with CKD with an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m2 and albuminuria (UACR of 200-5,000 mg/g). The primary efficacy endpoint of the trial was change from baseline in systolic blood pressure at week four in the active versus placebo treatment period. Exploratory endpoints included change from baseline in UACR and eGFR at week four in the active versus placebo treatment period.

**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 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 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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