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Mineralys Therapeutics Announces Journal of the American Medical Association (JAMA) Publication of Pivotal Phase 3 Launch-HTN Trial for Lorundrostat

– The Launch-HTN trial is the largest trial of an aldosterone synthase inhibitor completed in participants with uncontrolled or treatment resistant hypertension –

– Lorundrostat 50 mg once daily demonstrated clinically meaningful reductions in systolic blood pressure, with a 16.9 mmHg reduction at Week 6 and a 19.0 mmHg reduction at Week 12 –

– Lorundrostat was generally well-tolerated; and treatment-emergent adverse events were mostly mild, transient, and resolved without intervention –

RADNOR, Pa., June 30, 2025 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, chronic kidney disease (CKD), obstructive sleep apnea (OSA) and other diseases driven by dysregulated aldosterone, today announced the publication of the positive results from the pivotal Phase 3 Launch-HTN trial in the *Journal of the American Medical Association (JAMA)*. The manuscript titled "Lorundrostat in Participants with Uncontrolled and Treatment-Resistant Hypertension" is featured in the June 30, 2025 issue.

The Launch-HTN trial evaluated the efficacy and safety of lorundrostat, a novel aldosterone synthase inhibitor (ASI), when added to existing background treatment in 1,083 participants with uncontrolled or treatment resistant hypertension. The trial demonstrated that lorundrostat significantly reduced systolic blood pressure (BP) with a favorable safety and tolerability profile.

"Hypertension remains the most prevalent and preventable driver of cardiovascular disease globally, yet a significant proportion of patients continue to struggle with inadequate blood pressure control. We believe lorundrostat has the potential to be a best-in-class treatment for patients with uncontrolled or treatment resistant hypertension," said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. "We are pleased to have the results of Launch-HTN published in a medical journal as prestigious as JAMA. The consistency of results seen in the lorundrostat development program – which includes multiple trials across differentiated patient populations – supports its potential to have a broad role in future hypertension care."

"Launch-HTN was the largest Phase 3 trial of an ASI in patients with uncontrolled or resistant hypertension, designed to reflect usual clinical practice. It demonstrated consistent blood pressure lowering efficacy and safety with the aldosterone synthase inhibitor, lorundrostat, across a diverse group of patients," said Dr. Manish Saxena, MBBS, Deputy

Clinical Co-Director of Queen Mary University of London's William Harvey Heart Centre, and Hypertension Specialist at Barts Health NHS Trust and lead investigator on the study. "Dysregulated aldosterone, a key factor in driving hypertension in up to 30% of all hypertensive patients, is a consistent feature of treatment-resistant hypertension and related cardiovascular morbidities, such as heart failure and chronic kidney disease, making aldosterone synthase inhibition an attractive treatment target. Lorundrostat, a novel ASI therapy, is a promising development that could help address unmet clinical needs for patients who remain hypertensive despite multiple medications."

Key Findings from Launch-HTN

The Launch-HTN trial was a global, randomized, double-blinded, placebo-controlled Phase 3 trial, which enrolled 1,083 eligible adult participants who failed to achieve their BP goal despite being on two to five antihypertensive medications. Launch-HTN reflects the real-world setting for clinicians by utilizing automated office blood pressure (AOBP) measurements and allowing participants to stay on their existing medications. Authors noted that the trial recruited a diverse population as reflected in the high proportion of females, Black or African American and elderly participants.

When added to existing background treatment, lorundrostat 50 mg dosed once daily demonstrated clinically meaningful, statistically significant mean reductions in AOBP with a 16.9 mmHg reduction at Week 6 (-9.1 mmHg placebo adjusted; p-value < 0.0001) that was sustained with a reduction of 19.0 mmHg at Week 12 (-11.7 mmHg placebo adjusted; p-value < 0.0001). These benefits were consistent across age, sex, race, body mass index, and baseline medication regimen.

Lorundrostat demonstrated a favorable safety and tolerability profile in the Launch-HTN trial. The anticipated on-target effects on serum electrolytes, increased serum potassium and reduced serum sodium were modest and rapidly reversible upon discontinuation of lorundrostat. A confirmed serum potassium level of greater than 6.0 mmol/L occurred in three subjects (0.6%) on lorundrostat 50 mg once daily, as compared to one subject (0.4%) on placebo. Suppression of cortisol production was not observed, and there was a very low incidence of drug-related serious adverse events resulting in discontinuation or dose-adjustment of study medication.

About Hypertension

Having sustained, elevated BP (or hypertension) increases the risk of heart disease, heart attack and stroke, which are leading causes of death in the United States.[1] In 2022, more than 685,000 deaths in the United States included hypertension as a primary or contributing cause.[2] Hypertension and related health issues resulted in an estimated annual economic burden of about $219 billion in the United States in 2019.[3]

Less than 50% of hypertension patients achieve their BP goal with currently available medications.[4] Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 30% of all hypertensive patients.[5]

About Lorundrostat

Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), as well as CKD and OSA. 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 subjects.

About Mineralys Therapeutics

Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, CKD, OSA and other diseases driven by dysregulated aldosterone. Its initial product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor that Mineralys Therapeutics is developing for the treatment of cardiorenal conditions affected by dysregulated aldosterone, including hypertension, CKD, and OSA. 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 Company's expectation that ASIs with an SGLT2 inhibitor may provide additive clinical benefits to patients; the Company's expectation that Advance-HTN and Launch-HTN may serve as pivotal trials in submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA); the Company's ability to evaluate lorundrostat as a potential treatment for CKD, OSA, uHTN or rHTN; the planned future clinical development of lorundrostat and the timing thereof; and the expected timing of commencement and enrollment of participants in clinical trials and topline results from clinical trials. 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; 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; later developments with the FDA may be inconsistent with the feedback from the completed end of Phase 2 meeting, including whether the proposed pivotal program will support registration of lorundrostat which is a review issue with the FDA upon submission of an NDA; 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 an NDA submission or regulatory approval of lorundrostat; 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 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 Mitsubishi Tanabe Pharma 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.

References

[1] CDC. Facts About Hypertension. Centers for Disease Control and Prevention. Updated September 27, 2023. Accessed June 2025.

[2] CDC. Underlying Cause of Death, 1999–2022 Results. CDC WONDER Online Database. Accessed June 2025.

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[5] Brown JM, et al. Primary Aldosteronism and the Pathogenesis of Hypertension.*Physiol Rev*. 2018;98(1):103-137.

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