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Mineralys Therapeutics Presents Subgroup Analyses of Phase 3 Launch-HTN Trial Demonstrating Efficacy and Safety of Lorundrostat in Hypertension Participants with High Unmet Medical Need

~Pivotal Launch-HTN trial of novel aldosterone synthase inhibitor lorundrostat enrolled a diverse range of participants with uncontrolled or resistant hypertension~

~Subgroups - including Black or African American adults, older adults, women, and participants with comorbid obesity – face heightened risk of poor cardiovascular outcomes and represent high unmet need~

~Lorundrostat demonstrated significant and clinically meaningful blood pressure reductions across all participant subgroups, with a favorable safety and tolerability profile~

RADNOR, Pa., Sept. 05, 2025 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage 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 announced new subgroup analyses from the Phase 3 Launch-HTN trial, evaluating the blood pressure–lowering efficacy and safety of lorundrostat in difficult-to-treat and high-risk patient populations with high unmet medical need. The results were presented at the American Heart Association (AHA) Hypertension Scientific Sessions in Baltimore, MD, September 4-7, 2025.

“In our Phase 3 Launch-HTN trial we were intentional about recruiting a diverse patient population, including those at high-risk. These participants continue to face uncontrolled hypertension despite treatment with existing therapies,” said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “Lorundrostat demonstrated a clinically meaningful blood pressure reduction across the full study population, including these difficult-to-treat groups. Importantly, the safety and tolerability profile was consistent with our topline results, reinforcing the potential of lorundrostat as a transformative therapeutic for patients living with uncontrolled or resistant hypertension.”

Launch-HTN is the largest global Phase 3 trial to date in uncontrolled or resistant hypertension, enrolling a diverse group of participants with high cardiovascular risk, including Black/African American (29%), adults aged ≥65 years (41%), women (47%), participants with obesity (63%), and those requiring three or more background antihypertensive medications (60%). Across all of these subgroups, lorundrostat 50 mg

demonstrated consistent, statistically significant, and clinically meaningful reductions in blood pressure compared with placebo.

"Hypertension remains the leading modifiable risk factor for cardiovascular disease. These findings from the Launch-HTN study highlight the potential of lorundrostat to address a critical unmet medical need and improve blood pressure control in high-risk patient cohorts, including: Black and African American patients, patients 65 yrs or older, females, patients with comorbid obesity and patients on 3 or more anti-hypertensives," said Dr. Manish Saxena, MBBS, Hypertension Specialist and Clinical Co-Director at William Harvey Heart Centre, Barts Health NHS Trust and QMUL. "With consistent blood pressure lowering effect across diverse, high-risk subgroups, lorundrostat could help improve outcomes for patients and reduce the burden of hypertension on the healthcare system."

Table. Subgroup Analysis of AOSBP Change for Lorundrostat 50 mg vs Placebo at Week 6

	LSM Reduction in AOSBP, mmHg		
Characteristic	**Lorundrostat 50 mg (n=808)**	**Placebo (n=270)**	**LSM Difference (90%CI), Lorundrostat vs Placebo**
Age			
≥75 y	-18.2	-6.6	-11.6 (-17.4, -5.8); p=0.0011
65-74 y	-16.7	-9.8	-6.9 (-11.4, -2.4); p=0.0109
<65 y	-16.9	-7.6	-9.3 (-13.2, -5.4); p<0.0001
Race			
Black/African American	-15.1	-8.3	-6.7 (-11.6, -1.9); p<0.0222
White	-17.1	-8.0	-9.2 (-12.8, -5.6); p<0.0001
Sex			
Female	-16.8	-7.4	-9.4 (-13.6, -5.3); p=0.0002
Male	-17.0	-8.2	-8.8 (-12.6, -5.1); p<0.0001
BMI, kg/m^2			
≥30	-16.5	-6.9	-9.6 (-13.3, -5.8); p<0.0001
<30	-17.9	-9.5	-8.4 (-12.6, -4.3); p=0.0009
Antihypertensive therapies			
≥3	-17.2	-8.1	-9.0 (-12.7, -5.4); p<0.0001
2	-16.1	-7.2	-8.8 (-13.2, -4.5); p=0.0009

AOSBP, automated office systolic blood pressure; LSM, least-squares mean.

Safety and tolerability outcomes were favorable across all groups in the trial, with results consistent with the overall study population. No new safety signals were observed, and adverse events were generally mild or moderate in severity.

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.

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 (-11.6 mmHg placebo adjusted; p-

value < 0.0001).

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.

Mineralys is moving forward with a New Drug Application (NDA) filing strategy and has scheduled a pre-NDA meeting with the FDA in the fourth quarter of 2025 and plans to file the NDA in the fourth quarter of 2025 or the first quarter of 2026.

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 Launch-HTN

The Launch-HTN trial (NCT06153693) was a global, randomized, double-blinded, placebo-controlled Phase 3 trial, which enrolled eligible adult participants who failed to achieve their blood pressure goal despite being on two to five background antihypertensive medications. Eligible participants were randomized to one of three arms: placebo, lorundrostat 50 mg once daily (QD), and lorundrostat 50 mg QD and then titrated to 100 mg QD, as needed, at week six. The primary endpoint of the trial was the change from baseline in systolic blood pressure versus placebo after six weeks of treatment, as measured by AOBP monitoring.

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 aldosterone synthase inhibitors 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 anticipated timing of NDA submission and a potential pre-NDA meeting with the 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.

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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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