December 12, 2025

Mineralys Therapeutics' Phase 3 Launch-HTN Trial of Lorundrostat Recognized in Inaugural Journal of the American Medical Association (JAMA) "Research of the Year" Roundup

– Launch-HTN, the largest trial of an aldosterone synthase inhibitor conducted among participants with uncontrolled or treatment-resistant hypertension, was one of nine studies selected as most impactful of 2025 by JAMA editors –

RADNOR, Pa., Dec. 12, 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, announced today that the manuscript highlighting the Company's Phase 3 Launch-HTN clinical trial evaluating lorundrostat for the treatment of uncontrolled or treatment-resistant hypertension, was featured in JAMA*'s* inaugural "Research of the Year Roundup," a curated collection of the most impactful studies published between October 2024 and September 2025.

In introducing this first-ever "Research of the Year Roundup," JAMA noted that its top editors were asked to nominate their favorite studies based on their importance and impact. The list of nine selected studies spans diverse topics - from hypertension, to dementia and the use of artificial intelligence (AI) - and, according to JAMA, reflects clinical conditions that are of great importance to patients, clinicians, and to the public health community.

Among this select group, JAMA profiled Mineralys' Launch-HTN trial under the banner "New Hope for Treatment-Resistant Hypertension." The Launch-HTN trial evaluated the efficacy and safety of lorundrostat, a novel aldosterone synthase inhibitor (ASI), when added to existing background antihypertensive 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. Launch-HTN recruited a diverse population as reflected in the high proportion of female, Black or African American and elderly participants in the trial.

JAMA highlighted several key findings from the Launch-HTN trial:

- Lorundrostat's mechanism targets excess aldosterone production, a root cause of hypertension. Unlike existing aldosterone blockers that obstruct the hormone receptor, lorundrostat inhibits the enzyme that produces aldosterone itself, offering a novel mechanism of action.
- When added to existing background treatment, lorundrostat 50 mg dosed once daily

demonstrated clinically meaningful, statistically significant mean reductions in automated office blood pressure (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, noting that while hyponatremia, hyperkalemia, and reduced kidney function occurred more frequently in the treatment arm, discontinuation rates due to adverse events remained below 1%.

In the "Research of the Year" article, JAMA's Executive Editor Gregory Curfman, MD, emphasized the importance of advancing care for the large segment of patients whose hypertension remains uncontrolled despite being on multiple medications, noting that lorundrostat "opens a new approach to the treatment of uncontrolled hypertension, which may affect up to 40% of patients." The article also points out that, until now, patients have had limited options despite facing heightened cardiovascular risks, including myocardial infarction, stroke, or chronic kidney disease.

"We are honored that JAMA has recognized Launch-HTN as one of its Research of the Year studies," said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. "This acknowledgment underscores the significant clinical need faced by millions of people living with uncontrolled or treatment-resistant hypertension. The results of Launch-HTN reflect the dedication of our investigators, participants, and team, and reinforce our commitment to bringing forward a differentiated therapy to address a root cause of hypertension."

The manuscript titled, "Lorundrostat in Participants with Uncontrolled and Treatment-Resistant Hypertension" was featured in JAMA's June 30, 2025 issue. Lorundrostat continues to be evaluated in the ongoing Transform-HTN open-label extension trial, which is assessing long-term safety and durability of response. The Company also completed enrollment in Explore-OSA, the first trial to evaluate lorundrostat in participants with hypertension and moderate-to-severe OSA. Lorundrostat is the only ASI being studied to address both apnea-hypopnea index (AHI) and nighttime systolic blood pressure in this population, with data anticipated in the first quarter of 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 systolic BP at six weeks versus placebo, measured by automated office blood pressure monitoring.

About Hypertension

Having sustained, elevated blood pressure (or hypertension) (BP) 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 hypertension 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 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 participants.

The Company has now completed four successful clinical trials of lorundrostat supporting the efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. The Company has completed two pivotal, registrational trials, including 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 well tolerated in both trials with a favorable safety profile.

About Mineralys

Mineralys Therapeutics is a clinical-stage 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 a 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 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 the FDA's review of the same; 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; any delays in the FDA's review of our planned NDA submission, 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 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.

Contact:
Investor Relations
investorrelations@mineralystx.com

Media Relations
Melyssa Weible
Elixir Health Public Relations
Email: mweible@elixirhealthpr.com

MINERALYS

Source: Mineralys Therapeutics, Inc.