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Mineralys Therapeutics Presents Late-Breaking Data on Lorundrostat and Heart Failure Risk Biomarkers at The Endocrine Society Annual Meeting (ENDO 2026)

– Lorundrostat was associated with significant reductions in heart failure risk biomarkers in a proteomic analysis of data from participants with uncontrolled hypertension –

– Coordinated reductions in biomarkers of fibrosis and heart failure suggest lorundrostat may favorably modulate the physiological processes that drive heart failure –

RADNOR, Pa., June 14, 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 (OSA) and other diseases driven by dysregulated aldosterone, today presented new data on the effect of lorundrostat on heart failure (HF) risk biomarkers. This post hoc analysis of circulating proteomic data from participants enrolled in the Company's Launch-HTN and Advance-HTN trials was presented in a late-breaking poster presentation at ENDO 2026, the Endocrine Society's annual meeting in Chicago, Illinois.

"People with uncontrolled hypertension are at particular risk of heart failure, a condition where more effective treatments are still needed[i]," said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. "Aldosterone plays a well-established role[ii] in driving this disease, and these findings suggest that lorundrostat may act on the biological processes that contribute to heart failure, supporting further evaluation of its therapeutic potential in this setting."

This analysis characterized the systemic pharmacodynamic (PD) effects of lorundrostat and generated hypotheses regarding its potential modulation of pathways implicated in HF pathophysiology by profiling circulating protein biomarkers at baseline and after 12 weeks from 1,004 participants enrolled in the pivotal Phase 3 Launch-HTN and Phase 2b Advance-HTN trials.

The PD analysis confirmed that lorundrostat was associated with significant increases in renin and decreases in angiotensinogen, reflecting target engagement of the renin-angiotensin-aldosterone system (RAAS). Lorundrostat was associated with significant reductions in 6 of 11 recently published candidate causal risk biomarkers of incident HF, including NT-proBNP, consistent with the hypothesis that RAAS inhibition favorably modulates processes involved in HF risk.[iii]

Compared to placebo, lorundrostat treatment led to coordinated changes in key biomarkers: reductions in markers of scarring and heart failure risk and increases in markers of

hemostasis and protease inhibitor activity. These changes occurred together, suggesting a broad, consistent effect on disease pathways—particularly reducing harmful fibrosis—rather than isolated, random shifts.

These results provide biological plausibility and support further evaluation of the therapeutic potential of lorundrostat in heart failure.

Lorundrostat is currently under review by the U.S. Food and Drug Administration, 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, Phase 3 double-blind, placebo-controlled 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 Advance-HTN
The Advance-HTN trial (NCT05769608) was a randomized, Phase 2 double-blind, placebo-controlled clinical trial that evaluated the efficacy and safety of lorundrostat for the treatment of uncontrolled hypertension or resistant hypertension, when used as an add-on therapy to a standardized background treatment of two or three antihypertensive medications in adult participants. Participants who met screening criteria had their existing hypertension medications discontinued and started on a standard regimen of an angiotensin II receptor blocker (ARB) and a diuretic, if previously on two medications, or a standard regimen of ARB, diuretic and calcium channel blocker if previously on three to five medications. Participants who remained hypertensive despite the standardized regimen were then randomized into three cohorts and treated for 12 weeks: lorundrostat 50 mg once-daily; lorundrostat 50 mg once-daily with the option to increase to 100 mg once-daily at week four based on prespecified criteria; or placebo. The primary endpoint was the change in 24-hour ambulatory systolic blood pressure at week 12 from baseline for active cohorts versus placebo.

About Hypertension
Having sustained, elevated blood pressure (BP) (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 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 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, an observed half-life of 10-12 hours and demonstrated a 40-70% reduction in plasma aldosterone concentration in participants with hypertension.

Mineralys has now completed six late-stage clinical trials of lorundrostat supporting the efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. This includes two pivotal, registrational trials: the Phase 3 Launch-HTN trial and the Phase 2 Advance-HTN trials of lorundrostat, 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, 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 anticipated timing of the U.S. Food and Drug Administration's (FDA) review of the Company's accepted New Drug Application (NDA) and any subsequent regulatory approval of lorundrostat; and the planned future clinical development of lorundrostat and the timing thereof. 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; any delays in the FDA's review of our accepted NDA, 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 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 our NDA submission; 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; 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 other trade policies, 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 Tanabe Pharma Corporation 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

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