October 21, 2025

Mineralys Therapeutics Announces Late-Breaking Presentation of Phase 2 Explore-CKD Trial of Lorundrostat at American Society of Nephrology (ASN) Kidney Week 2025

- ***~ Late-breaking Phase 2 trial data evaluating the safety and efficacy of 25 mg of lorundrostat in participants with hypertension and comorbid CKD to be presented~***
- ***~ Phase 3 data of the Launch-HTN Trial of lorundrostat to be included in "Best of Journal of the American Medical Association and the New England Journal of Medicine" presentation~***

RADNOR, Pa., Oct. 21, 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 that data from the Phase 2 Explore-CKD trial evaluating the safety and efficacy of 25 mg of lorundrostat in participants with hypertension and comorbid CKD will be presented in a late-breaking clinical trials session at American Society of Nephrology (ASN) Kidney Week 2025, being held November 6 -9 in Houston, Texas.

Details for the Late-Breaking Clinical Trial Presentation:

Presentation Title:	Lorundrostat, a Novel Aldosterone Synthase Inhibitor (ASI), in Participants with Uncontrolled Hypertension, CKD, and Albuminuria: Results from Explore-CKD
Presenter:	Matthew Weir, MD, Director of the Division of Nephrology at the University of Maryland Medical Center and Professor of Medicine at the University of Maryland School of Medicine
Date/Time:	November 7, 2025, from 5:06 PM to 5:18 PM CST

Matthew Weir, MD, is scientific consultant to the Mineralys Therapeutics, Inc.

In addition, data from Mineralys' Phase 3 Launch-HTN pivotal trial of lorundrostat will be featured at ASN Kidney Week's "Best of the *Journal of the American Medical Association* and the *New England Journal of Medicine"* program presentation, taking place on November 7 from 2:00 PM to 4:00 PM CST in Grand Ballroom A of the George R. Brown Convention Center. Convention. Dr. Manish Saxena, MBBS, Hypertension Specialist and Clinical Co-Director at William Harvey Heart Centre, Barts Health NHS Trust and QMUL, will present "Lorundrostat in Participants with Uncontrolled Hypertension and Treatment Resistant Hypertension – The Launch-HTN Randomized Clinical Trial" as a member of the faculty for ASN. These data were published in the *Journal of the American Medical Association* (JAMA) earlier this year.

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 chronic kidney disease (CKD) and obstructive sleep apnea (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.

About Mineralys
Mineralys Therapeutics is 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. 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.

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