May 12, 2025

Mineralys Therapeutics Reports First Quarter 2025 Financial Results and Provides Corporate Update

– Pivotal Advance-HTN and Launch-HTN trials successfully achieved statistical significance in primary efficacy endpoints and demonstrated a favorable safety and tolerability profile –

– Anticipate Explore-CKD Phase 2 trial to deliver topline data in Q2 2025 –

– Initiated Explore-OSA Phase 2 Trial in Q1 2025 –

– Conference call today at 4:30 p.m. ET –

RADNOR, Pa., May 12, 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 financial results for the first quarter ended March 31, 2025, and provided a corporate update.

“We are pleased to have recently announced positive topline results from our pivotal trials, Launch-HTN and Advance-HTN, that evaluated lorundrostat’s efficacy and safety as a potential treatment for patients with uncontrolled or resistant hypertension. The Advance-HTN late-breaking presentation at the American College of Cardiology meeting and the recent publication in the New England Journal of Medicine underscore the strength of our clinical data and the potentially transformative nature of lorundrostat. With the success of our two pivotal trials, we are working toward submitting our new drug application with a pre-NDA meeting with the FDA anticipated in the fourth quarter of 2025,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “We are excited to announce the appointment of Eric Warren as our Chief Commercial Officer. Eric’s proven leadership skills, extensive cardiovascular experience and track record of success, will be invaluable to Mineralys as we solidify our commercial and partnering strategy.”

Recent Clinical Highlights and Upcoming Milestones

- **Pivotal Launch-HTN Phase 3 Trial** – The trial met its primary endpoint in evaluating the efficacy and safety of lorundrostat for the treatment of subjects with uncontrolled hypertension (uHTN) or resistant hypertension (rHTN) as add-on therapy, who fail to achieve blood pressure control on their existing medications. The trial reported that the lorundrostat 50 mg dose achieved a 16.9 mmHg reduction in systolic blood pressure, and a 9.1 mmHg placebo-adjusted reduction (p-value < 0.0001), as assessed by automated office blood pressure at week six. This benefit was sustained with potential further reduction through week 12, with a 19.0 mmHg reduction in automated office systolic blood pressure and an 11.7 mmHg placebo-adjusted reduction (p-value <0.0001). The clinical safety results, including adrenocorticotropic hormone (ACTH)-

stimulated and serum cortisol, change in serum potassium, serum sodium, and estimated glomerular filtration rate (eGFR), as well as incidence of hypotension, from the trial support a favorable benefit-risk profile in a “real world” setting. The incidence of hyperkalemia (serum potassium >6.0 mmol/L) at the scheduled study visit was 1.1% and 1.5% in the 50 mg and 50 to 100 mg arms, respectively. After exclusion of factitious test results, the incidence of confirmed hyperkalemia was 0.6% and 1.1%, respectively.
    - The Launch-HTN trial has been accepted as a late-breaking presentation at the 2025 European Society of Hypertension Meeting on Hypertension and Cardiovascular Protection, which is being held in Milan, Italy on May 23-26, 2025.
- **Pivotal Advance-HTN Trial** – Detailed results from the Advance-HTN trial were recently presented in a late-breaking presentation at the American College of Cardiology’s ACC.25 meeting and published on May 8th in the New England Journal of Medicine. The trial met its primary endpoints in evaluating the efficacy and safety of lorundrostat for the treatment of confirmed uHTN or rHTN. The trial reported that the lorundrostat 50 mg dose cohort achieved a 15.4 mmHg absolute reduction in systolic blood pressure and a 7.9 mmHg placebo-adjusted reduction (p-value = 0.001), as assessed by 24-hour ambulatory blood pressure monitoring at 12 weeks. Lorundrostat demonstrated a favorable safety and tolerability profile, with modest changes in serum potassium, serum sodium and eGFR, and a low discontinuation rate. The incidence of hyperkalemia (serum potassium >6.0 mmol/L) at the scheduled study visit was 5.3% and 7.4% in the 50 mg and 50 to 100 mg arms, respectively. After exclusion of factitious test results, the incidence of confirmed hyperkalemia was 2.1% and 3.2%, respectively. These results reinforce lorundrostat’s favorable benefit-risk profile in a high-risk population that would typically be treated by specialists rather than general practitioners.
- **Transform-HTN Open-Label Extension Trial** – The Company’s ongoing open-label extension trial allows subjects to continue to receive lorundrostat and the Company to obtain additional safety and efficacy data.
- **Explore-CKD Phase 2 Trial** – Enrollment has been completed and topline data are anticipated in the second quarter of 2025. The trial is designed to evaluate the safety and efficacy of lorundrostat when added to background treatment with an ACE inhibitor or ARB and a SGLT2 inhibitor for the treatment of hypertension in subjects with Stage 2 to 3b CKD (eGFR greater than or equal to 30 mL/min/1.73m^2) and albuminuria.
- **Explore-OSA Phase 2 Trial** – The Company initiated the trial in the first quarter of 2025, which will evaluate the safety and efficacy of lorundrostat in the treatment of overweight and obese subjects with moderate-to-severe OSA and hypertension.
- **Expanded Management Team –** Appointed Eric Warren as Chief Commercial Officer. Mr. Warren brings more than three decades of commercial leadership experience across multiple healthcare segments with a heavy emphasis on cardiovascular disease. Mr. Warren will lead the Company’s commercial strategy and support future partnering opportunities.
- **Strengthened Balance Sheet** – On March 18, 2025, the Company completed a public equity financing for gross proceeds of approximately $201.2 million, before deducting fees and expenses. The Company reported a total of $343.0 million of cash, cash equivalents and investments as of March 31, 2025.

First Quarter 2025 Financial Highlights

Cash, cash equivalents and investments were $343.0 million as of March 31, 2025, compared to $198.2 million as of December 31, 2024. The Company believes that its current cash, cash equivalents and investments will be sufficient to fund its planned clinical trials and regulatory activities, as well as support corporate operations, into 2027.

Research and Development (R&D) expenses for the quarter ended March 31, 2025 were $37.9 million, compared to $30.8 million for the quarter ended March 31, 2024. The increase in R&D expenses was primarily due to increases of $4.8 million in preclinical and clinical costs and $2.8 million in compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation, partially offset by $0.5 million in lower clinical supply, manufacturing and regulatory costs.

General and Administrative (G&A) expenses were $6.6 million for the quarter ended March 31, 2025, compared to $4.6 million for the quarter ended March 31, 2024. The increase in G&A expenses was primarily due to $1.2 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation, and $0.7 million in higher professional fees.

Total other income, net was $2.2 million for the quarter ended March 31, 2025, compared to $3.9 million for the quarter ended March 31, 2024. The decrease was primarily attributable to decreased interest earned on our investments in money market funds and U.S. treasuries.

Net loss was $42.2 million for the quarter ended March 31, 2025, compared to $31.5 million for the quarter ended March 31, 2024. The increase was primarily attributable to the factors impacting the Company's expenses described above.

Conference Call

The Company's management team will host a conference call at 4:30 p.m. ET on Monday, May 12, 2025. To access the call, please dial 1-800-717-1738 in the United States or 1-646-307-1865 outside the United States. A live webcast of the conference call may be found here. A replay of the call will be available on the "News & Events" page in the Investor Relations section of the Mineralys Therapeutics website (click here).

About Hypertension

Having sustained, elevated blood pressure (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 average annual economic burden of about $219 billion in the United States in 2019.

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

About CKD

CKD, which is characterized by the gradual loss of kidney function, is estimated to affect more than 10% of the global population and is one of the leading causes of mortality worldwide. According to the U.S. Centers for Disease Control and Prevention (CDC), an

estimated 1-in-7 (15%) of U.S. adults have CKD. Diabetes and hypertension are responsible for approximately two-thirds of CKD cases. Early detection and treatment can often keep CKD from getting worse. When CKD progresses, it may eventually lead to kidney failure, which requires dialysis or a kidney transplant to maintain life.

About OSA

OSA is characterized by repetitive overnight hypoxic episodes and subsequent sleep fragmentation due to a complete or partial collapse of the upper airway. Moderate OSA is defined as having between 15 and 30 breathing pauses (apnea or hypopnea events) per hour of sleep, while severe OSA indicates more than 30 breathing pauses per hour. OSA impacts almost one billion people globally, including 425 million moderate-to-severe cases. Around 80% of adults with OSA are undiagnosed. As of 2015, undiagnosed OSA is estimated to cost the United States approximately $149.6 billion annually from comorbid disease, workplace accidents, motor vehicle accidents and loss of workplace productivity.

Between 30-50% of adults with hypertension have OSA, and this number increases to between 70-80% in adults with rHTN. Additionally, untreated moderate-to-severe OSA increases the risk of rHTN. Along with hypertension, OSA is a major risk factor of cardiovascular disease, type-2 diabetes mellitus and stroke.

About Lorundrostat

Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uHTN or 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.

In a Phase 2, proof-of-concept trial (Target-HTN) in uncontrolled or resistant hypertensive subjects, once-daily lorundrostat demonstrated statistically significant and clinically meaningful systolic blood pressure reduction in both automated office systolic blood pressure measurement and 24-hour ambulatory systolic blood pressure monitoring. Adverse events observed were a modest increase in serum potassium, decrease in eGFR, urinary tract infection and hypertension, with one serious adverse event possibly related to study drug being hyponatremia.

About Mineralys

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 and Twitter.

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 any 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 patients 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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Mineralys Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 37,879	$ 30,754
General and administrative	6,568	4,608
Total operating expenses	44,447	35,362
Loss from operations	(44,447)	(35,362)
Interest income, net	2,239	3,853
Other income (expense)	(3)	1
Total other income, net	2,236	3,854
Net loss	$ (42,211)	$ (31,508)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.79)	$ (0.70)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	53,163,551	44,900,755

Mineralys Therapeutics, Inc.
Selected Financial Information
Condensed Balance Sheet Data
(amounts in thousands)
(unaudited)

	March 31, 2025	**December 31, 2024**
Cash, cash equivalents and investments	$ 343,026	$ 198,187
Total assets	$ 354,941	$ 205,903
Total liabilities	$ 13,386	$ 14,646
Total stockholders' equity	$ 341,555	$ 191,257

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Source: Mineralys Therapeutics, Inc.