February 12, 2025

Mineralys Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

– Anticipate topline data from pivotal Advance-HTN trial in March 2025 and pivotal Phase 3 Launch-HTN trial in mid first half of 2025 –

– Completed enrollment in Explore-CKD Phase 2 trial and anticipate delivering topline data in Q2 2025 –

– Initiating Phase 2 trial to evaluate lorundrostat for the treatment of patients with moderate-to-severe obstructive sleep apnea (OSA) and hypertension –

– Conference call today at 8:30 a.m. ET –

RADNOR, Pa., Feb. 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 fourth quarter and full year ending December 31, 2024, and provided a corporate update.

“This past year was important for the development of lorundrostat, and the entire Mineralys team contributed to the execution of our clinical strategy. Over the course of the next several months we anticipate delivering topline data from our pivotal program to treat patients with uncontrolled or resistant hypertension,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “Our clinical development program is focused on high-risk patients with poorly controlled hypertension who may benefit from this novel treatment. Based on the extensive medical data showing the impact dysregulated aldosterone can have on the human body, we believe that targeting aldosterone with lorundrostat can have a positive impact on millions of patients’ lives.”

Recent Clinical Highlights and Upcoming Milestones

- **Pivotal Advance-HTN Trial** – Anticipate reporting topline data in March 2025. The trial is evaluating the efficacy and safety of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), when used as an add-on therapy to a standardized background treatment. The trial’s primary endpoint is the change in 24-hour ambulatory systolic blood pressure at week twelve from baseline for each active cohort versus placebo.

- **Pivotal Launch-HTN Phase 3 Trial** – Anticipate reporting topline data in mid first half of 2025. This is the second ongoing pivotal trial of lorundrostat for the treatment of subjects with uHTN or rHTN as add-on therapy, who fail to achieve blood pressure control on their existing, prescribed background treatment of two to five

antihypertensive medications. The primary endpoint of the trial is change from baseline in systolic blood pressure versus placebo after six weeks of treatment, as measured by automated office blood pressure monitoring.

- **Transform-HTN Open-Label Extension Trial** – The Company's ongoing open-label extension trial allows subjects to continue to receive lorundrostat and obtain additional safety and efficacy data.

- **Explore-CKD Phase 2 Trial** – Enrollment completed and topline data is 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 SGLT2 inhibitor as a potential therapy to treat patients with uHTN or rHTN and Stage 2 to 3b CKD.

- **Explore-OSA Phase 2 Trial** – Initiation planned in the first quarter of 2025. The trial is designed to evaluate the safety and efficacy of lorundrostat in the treatment of overweight and obese subjects with moderate-to-severe OSA and hypertension.

Fourth Quarter and Full Year 2024 Financial Highlights

Cash, cash equivalents and investments were $198.2 million as of December 31, 2024, compared to $239.0 million as of December 31, 2023. The Company believes that its current cash, cash equivalents and investments will be sufficient to fund its planned clinical studies, as well as support corporate operations, through the first quarter of 2026.

Research and Development (R&D) expenses for the year ended December 31, 2024 were $168.6 million, compared to $70.4 million for the year ended December 31, 2023. R&D expenses for the quarter ended December 31, 2024, were $44.6 million, compared to $23.7 million for the quarter ended December 31, 2023. The annual increase in R&D expenses was primarily due to increases of $88.7 million in preclinical and clinical costs, driven by the initiation of the lorundrostat pivotal program in the second quarter of 2023, $10.6 million in clinical supply, manufacturing and regulatory costs, $7.0 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation, and $0.9 million in other research and development expenses, partially offset by a decrease of $9.0 million in license fees associated with development milestone payments in 2023 that did not recur in 2024.

General and Administrative (G&A) expenses were $23.8 million for the year ended December 31, 2024, compared to $14.3 million for the year ended December 31, 2023. G&A expenses were $7.2 million for the quarter ended December 31, 2024, compared to $4.0 million for the quarter ended December 31, 2023. The annual increase in G&A expenses was primarily due to $6.6 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation, $2.6 million in higher professional fees and $0.3 million in higher other administrative expenses.

Total other income, net was $14.6 million for the year ended December 31, 2024, compared to $12.8 million for the year ended December 31, 2023. Total other income, net was $2.8 million for the quarter ended December 31, 2024, compared to $3.3 million for the quarter ended December 31, 2023. The annual increase was primarily attributable to increased interest earned on the Company's investments in money market funds and U.S. treasuries.

Net loss was $177.8 million for the year ended December 31, 2024, compared to $71.9 million for the year ended December 31, 2023. Net loss was $48.9 million for the quarter ended December 31, 2024, compared to $24.4 million for the quarter ended December 31, 2023. The annual 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 8:30 a.m. ET on Wednesday, February 12, 2025. To access the call, please dial 1-800-717-1738 in the U.S. or 1-646-307-1865 outside the U.S. 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 U.S. In 2020, more than 670,000 deaths in the U.S. included hypertension as a primary or contributing cause. Hypertension and related health issues resulted in an average annual economic burden of about $130 billion each year in the U.S., averaged over 12 years from 2003 to 2014.

Less than 50 percent of hypertension patients achieve their blood pressure goal with currently available medications. Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 25 percent 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 resistant hypertension. Additionally, untreated moderate-to-

severe OSA increases the risk of resistant hypertension. 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 and 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 approximately a 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 clinically meaningful blood pressure reduction in both automated office blood pressure measurement and 24-hour ambulatory blood pressure monitoring. Adverse events observed were a modest increase in serum potassium, decrease in estimated glomerular filtration rate, 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 United States 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: 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; 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; 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
Tom Weible
Elixir Health Public Relations
Phone: (1) 515-707-9678
Email: tweible@elixirhealthpr.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 44,569	$ 23,685	$ 168,581	$ 70,361
General and administrative	7,198	4,026	23,822	14,296
Total operating expenses	51,767	27,711	192,403	84,657
Loss from operations	(51,767)	(27,711)	(192,403)	(84,657)
Interest income, net	2,809	3,321	14,588	12,756
Other income	12	1	5	3
Total other income, net	2,821	3,322	14,593	12,759
Net loss	$ (48,946)	$ (24,389)	$ (177,810)	$ (71,898)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.98)	$ (0.61)	$ (3.66)	$ (1.99)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	49,957,912	40,093,242	48,539,795	36,188,254

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

	December 31,	
	2024	**2023**
Cash, cash equivalents and investments	$ 198,187	$ 239,049
Total assets	$ 205,903	$ 251,636
Total liabilities	$ 14,646	$ 10,482
Total stockholders' equity	$ 191,257	$ 241,154

Source: Mineralys Therapeutics, Inc.