November 11, 2024

Mineralys Therapeutics Reports Third Quarter 2024 Financial Results and Provides Corporate Update

– Completed enrollment in pivotal Advance-HTN trial and anticipate topline data in March 2025 –

– Completed enrollment ahead of schedule in pivotal Phase 3 Launch-HTN trial and anticipate delivering topline data in mid first half of 2025 –

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

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

RADNOR, Pa., Nov. 11, 2024 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, chronic kidney disease (CKD) and other diseases driven by dysregulated aldosterone, today announced financial results for the third quarter ending September 30, 2024, and provided a corporate update.

“The past several months were very productive for our team, as we made significant progress advancing our pivotal clinical program for lorundrostat for the treatment of uncontrolled hypertension or resistant hypertension,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “We are excited that the two pivotal trials from this program are fully enrolled and on track to deliver topline data during the first half of 2025. Pending positive data from these trials, this pivotal program will be the foundation for our NDA submission to the FDA.”

Recent Clinical Highlights and Upcoming Milestones

- **Pivotal Advance-HTN Trial** – Enrollment has been completed and topline data is anticipated 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. Key characteristics of subjects enrolled in the Advance-HTN trial include: more than 66% have a BMI equal to or greater than 30kg/m^2, more than 40% are women, and more than 50% of Black or African American race. The Company believes the diversity of Advance-HTN could offer data and insights on characteristics of patients who would see the most benefit from lorundrostat. The trial’s primary endpoint is the change in 24-hour ambulatory systolic blood pressure at week twelve from baseline for active cohorts versus placebo.
- **Pivotal Launch-HTN Phase 3 Trial** – Enrollment has been completed ahead of schedule and topline data is anticipated 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.

- **Explore-CKD Phase 2 Trial** – Enrollment is ongoing 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.
- **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.

Third Quarter 2024 Financial Highlights

Cash, cash equivalents and investments were $263.6 million as of September 30, 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, into 2026.

Research and Development (R&D) expenses for the quarter ended September 30, 2024 were $54.0 million, compared to $22.5 million for the quarter ended September 30, 2023. The increase in R&D expenses was primarily due to increases of $26.1 million in preclinical and clinical costs driven by the initiation of the lorundrostat pivotal program in the second quarter of 2023, $3.4 million in clinical supply, manufacturing and regulatory costs, $1.7 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation and $0.3 million in other research and development expenses.

General and Administrative (G&A) expenses were $6.1 million for the quarter ended September 30, 2024, compared to $3.8 million for the quarter ended September 30, 2023. The increase in G&A expenses was primarily due to $1.7 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation and $0.8 million in higher professional fees, partially offset by a decrease of $0.2 million in other administrative expenses.

Total other income, net was $3.8 million for the quarter ended September 30, 2024, compared to $3.5 million for the quarter ended September 30, 2023. The increase was primarily attributable to increased interest earned on the Company's investments in money market funds and U.S. treasuries.

Net loss was $56.3 million for the quarter ended September 30, 2024, compared to $22.8 million for the quarter ended September 30, 2023. 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, November 11, 2024. To access the call, please dial 1-877-407-9127 in the U.S. or 1-201-

689-8574 outside the U.S., followed by the conference ID: 13749121. 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 Chronic Kidney Disease (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 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. 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 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 cardiorenal conditions affected by dysregulated aldosterone, including hypertension and CKD. 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, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 53,985	$ 22,499	$ 124,012	$ 46,676
General and administrative	6,121	3,774	16,624	10,270
Total operating expenses	60,106	26,273	140,636	56,946
Loss from operations	(60,106)	(26,273)	(140,636)	(56,946)
Interest income, net	3,774	3,513	11,779	9,435
Other income (expense)	(10)	—	(7)	2
Total other income, net	3,764	3,513	11,772	9,437
Net loss	$ (56,342)	$ (22,760)	$ (128,864)	$ (47,509)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.13)	$ (0.57)	$ (2.68)	$ (1.36)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	49,815,186	39,930,748	48,063,638	34,872,287

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

	September 30, 2024	**December 31, 2023**
Cash, cash equivalents and investments	$ 263,603	$ 239,049
Total assets	$ 268,253	$ 251,636
Total liabilities	$ 31,321	$ 10,482
Total stockholders' equity	$ 236,932	$ 241,154

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Source: Mineralys Therapeutics, Inc.