August 13, 2024

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

– Advance-HTN trial is approximately 90% enrolled; trial is anticipated to deliver topline data in Q1 2025 –

– Enrollment ahead of schedule in Phase 3 pivotal Launch-HTN trial and on track to deliver topline data as anticipated in 2H 2025 –

– Ongoing Explore-CKD Phase 2 trial is ramping up enrollment under the amended protocol and is anticipated to deliver topline data in 1H 2025 –

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

RADNOR, Pa., Aug. 13, 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 second quarter ending June 30, 2024, and provided a corporate update.

“During the first half of 2024, we continued to make progress executing our pivotal development program for lorundrostat to treat uHTN or rHTN. Considering the current pace of enrollment in the Advance-HTN trial, which is approximately 90 percent enrolled, we anticipate announcing topline data during the first quarter of 2025. To our knowledge, this will be one of the most rigorous trials ever completed for an aldosterone targeted therapy,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “In addition, we have significantly ramped up enrollment in our pivotal Launch-HTN trial, which is well ahead of schedule compared to our enrollment projections.”

Recent Clinical Highlights and Upcoming Milestones

- **Pivotal Advance-HTN Trial** – Based on the anticipated timing of full enrollment, the Company is guiding to announce top-line data in the first quarter of 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 of two or three antihypertensive medications. In August 2024, the Company met with the FDA and aligned on maintaining the primary endpoint for the Advance-HTN trial as the change in 24-hour ambulatory systolic blood pressure (BP) at week twelve from baseline for active cohorts versus placebo.

- **Pivotal Launch-HTN Phase 3 Trial** – Enrollment in the Launch-HTN Phase 3 trial is ahead of schedule, with topline data on track to be available in the second 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.

- **Explore-CKD Phase 2 Trial** – The ongoing trial 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. The amended protocol is implemented, enrollment is ramping up and we anticipate topline data in the first half of 2025.

- **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.

Second Quarter 2024 Financial Highlights

Cash, cash equivalents and investments were $311.1 million as of June 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 June 30, 2024 were $39.3 million, compared to $11.9 million for the quarter ended June 30, 2023. The increase in R&D expenses was primarily due to increases of $22.8 million in preclinical and clinical costs driven by the initiation of the lorundrostat pivotal program in the second quarter of 2023 and the Explore-CKD trial in the fourth quarter of 2023, $2.6 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 $5.9 million for the quarter ended June 30, 2024, compared to $3.9 million for the quarter ended June 30, 2023. The increase in G&A expenses was primarily due to $1.5 million in higher compensation expense resulting from additions to headcount, increases in salaries and accrued bonuses and increased stock-based compensation and $0.5 million in higher professional fees and other administrative expenses.

Total other income, net was $4.2 million for the quarter ended June 30, 2024, compared to $3.6 million for the quarter ended June 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 $41.0 million for the quarter ended June 30, 2024, compared to $12.1 million for the quarter ended June 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 Tuesday, August 13, 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: 13747982. 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.

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 uncontrolled hypertension and 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 individuals with uncontrolled hypertension, 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 the Advance-HTN and the planned Phase 3 clinical trial of lorundrostat 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 or uncontrolled hypertension; 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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 39,273	$ 11,884	$ 70,027	$ 24,177
General and administrative	5,895	3,851	10,503	6,496
Total operating expenses	45,168	15,735	80,530	30,673
Loss from operations	(45,168)	(15,735)	(80,530)	(30,673)
Interest income, net	4,152	3,593	8,005	5,922
Other income	2	1	3	2
Total other income, net	4,154	3,594	8,008	5,924
Net loss	$ (41,014)	$ (12,141)	$ (72,522)	$ (24,749)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.83)	$ (0.31)	$ (1.54)	$ (0.77)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	49,356,287	39,754,981	47,178,288	32,301,136

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and investments	$ 311,115	$ 239,049
Total assets	$ 318,492	$ 251,636
Total liabilities	$ 28,397	$ 10,482
Total stockholders' equity	$ 290,095	$ 241,154

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Source: Mineralys Therapeutics, Inc.