March 21, 2024

Mineralys Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

– Enrollment in the two pivotal trials of lorundrostat for the treatment of uHTN or rHTN is on track, with topline data expected for Advance-HTN trial in Q4 2024 and Launch-HTN trial in 2H 2025 –

– Explore-CKD Phase 2 trial, a study for lorundrostat in hypertensive patients with stage 2-3b CKD on track for Q4 2024 to Q1 2025 topline data –

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

RADNOR, Pa., March 21, 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 abnormally elevated aldosterone, today announced financial results for the fourth quarter and full year ending December 31, 2023, and provided a corporate update.

“Throughout 2023 we accomplished key milestones that put us in a position to execute our pivotal development plan for lorundrostat for the treatment of hypertension, as well as adjacent conditions including chronic kidney disease,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “In 2024, we are working towards achieving several clinical events, which we expect to expand the data package for lorundrostat. We believe aldosterone, like obesity, is a significant driver of cardiorenal metabolic conditions and our pursuit of developing an aldosterone targeted approach has the potential to impact millions of patients impacted by these conditions.”

Recent Corporate and Clinical Highlights

- **Pivotal Launch-HTN Phase 3 Trial** – In the fourth quarter of 2023, the Company initiated the Launch-HTN trial, the second ongoing pivotal trial of lorundrostat for the treatment of patients with uHTN or rHTN, when added to subjects’ existing background hypertension treatment.

- **Pivotal Advance-HTN Trial** – The first of the two ongoing pivotal trials, the Advance-HTN trial is evaluating the safety and efficacy of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to an AHA guidelines-based standardized background treatment regimen of either two or three antihypertensive medications.

- **Open-Label Extension Trial** – In mid-2023, the Company initiated an open-label extension trial to allow subjects to continue to receive lorundrostat and obtain additional safety and efficacy data.

- **BMI Data from Target-HTN Phase 2 Trial** – The Company presented data from a new

analysis of serum leptin levels among subjects in the Target-HTN Phase 2 trial, which showed that increased BMI was correlated with both increased leptin and increased aldosterone production. These data expand our understanding of mechanisms that may link the increasing prevalence of obesity to a parallel increase in uncontrolled and resistant hypertension. These data were presented at the American Heart Association (AHA) Scientific Sessions in Q4 2023.

- **Expanded Management Team** – Appointed Minji Kim, Ph.D. as Chief Business Officer. Dr. Kim brings more than two decades of experience in business development, strategic leadership, and scientific research. During her career, she has worked with biotech companies in the U.S. and overseas across broad therapeutic and technical areas.

- **Strengthened Balance Sheet** – Subsequent to the end of the fourth quarter, the Company completed a private placement financing for gross proceeds of approximately $120 million, before deducting fees and expenses.

Key Upcoming Milestones

- **Pivotal Advance-HTN Trial** – Enrollment in the study is on track to announce topline data in the fourth quarter of 2024.

- **Phase 3 pivotal Launch-HTN Trial** – Topline data from this trial is expected in the second half of 2025.

- **Explore-CKD Phase 2 Trial** – The trial design is being modified, including allowing all subjects to use concurrent SGLT2 inhibitors, which have become the standard of care in CKD, and reducing the eGFR cutoff to 30ml/min/1.73m2 for all trial participants, obviating the need for Part B of the trial. The trial remains on track to report topline data in the fourth quarter of 2024 to the first quarter of 2025.

Fourth Quarter and Annual 2023 Financial Highlights

Cash, cash equivalents and investments were $239.0 million as of December 31, 2023, compared to $110.1 million as of December 31, 2022. In February 2024, the Company completed a private placement financing for gross proceeds of approximately $120 million, before deducting offering expenses. 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 were $70.4 million for the year ended December 31, 2023, compared to $26.3 million for the year ended December 31, 2022. R&D expenses for the quarter ended December 31, 2023 were $23.7 million, compared to $7.8 million for the quarter ended December 31, 2022. The annual increase in R&D expenses was primarily due to increases of $21.4 million in preclinical and clinical costs, driven by the initiation of the lorundrostat pivotal program beginning in the second quarter of 2023, $9.0 million in license fees upon achieving development milestones of lorundrostat in 2023, $7.8 million in clinical supply, manufacturing, and regulatory costs, $5.6 million in higher compensation expense resulting from additions to headcount and stock-based compensation and $0.3 million in other research and development expenses.

General and Administrative (G&A) expenses were $14.3 million for the year ended December 31, 2023, compared to $5.2 million for the year ended December 31, 2022. G&A expenses were $4.0 million for the quarter ended December 31, 2023, compared to $2.2 million for the quarter ended December 31, 2022. The annual increase in G&A expenses was primarily due to $3.8 million in higher professional fees associated with operating as a public company, $3.4 million in higher compensation expenses resulting from additions to headcount and stock-based compensation, $1.1 million of higher insurance expenses primarily associated with new director and officer insurance policies and $0.8 million in higher other administrative expenses.

Total other income, net was $12.8 million for the year ended December 31, 2023, compared to $1.7 million for the year ended December 31, 2022. Total other income, net was $3.3 million for the quarter ended December 31, 2023, compared to $0.9 million for the quarter ended December 31, 2022. 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 $71.9 million for the year ended December 31, 2023, compared to $29.8 million for the year ended December 31, 2022. Net loss was $24.4 million for the quarter ended December 31, 2023, compared to $9.1 million for the quarter ended December 31, 2022. 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 Thursday, March 21, 2024. To access the call, please dial 1-888-886-7786 in the U.S. or 1-416-764-8658 outside the U.S., followed by the conference ID: 27947513. 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. Abnormally elevated 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 abnormally elevated 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 abnormally elevated 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.

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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 23,685	$ 7,818	$ 70,361	$ 26,250
General and administrative	4,026	2,190	14,296	5,229
Total operating expenses	27,711	10,008	84,657	31,479
Loss from operations	(27,711)	(10,008)	(84,657)	(31,479)
Interest income, net	3,321	935	12,756	1,676
Other income	1	—	3	4
Total other income, net	3,322	935	12,759	1,680
Net loss	$ (24,389)	$ (9,073)	$ (71,898)	$ (29,799)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (1.74)	$ (1.99)	$ (5.77)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	40,093,242	5,210,456	36,188,254	5,167,296

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

	December 31,	
	2023	**2022**
Cash, cash equivalents and investments	$ 239,049	$ 110,110
Total assets	$ 251,636	$ 114,442
Total liabilities	$ 10,482	$ 8,067
Total stockholders' equity (deficit)	$ 241,154	$ (52,269)



Source: Mineralys Therapeutics, Inc.