May 15, 2023

Mineralys Therapeutics Reports First Quarter 2023 Financial Results and Provides Corporate Update

– Commenced patient dosing in lorundrostat pivotal clinical program, for the treatment of patients with uncontrolled or resistant hypertension in April 2023 –

– Plan to initiate the second pivotal trial to evaluate the safety and efficacy of lorundrostat for the treatment of uncontrolled or resistant hypertension in the second half of 2023 –

– Plan to initiate a Phase 2 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uncontrolled or resistant hypertension in a chronic kidney disease (CKD) population –

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

RADNOR, Pa., May 15, 2023 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target diseases driven by abnormally elevated aldosterone, today announced financial results for the quarter ending March 31, 2023, and provided a corporate update.

“This year is off to a strong start as we continued to build momentum developing lorundrostat for the targeted treatment of hypertension. Most recently we started dosing patients in our confirmatory pivotal Advance-HTN trial evaluating the safety and efficacy of lorundrostat for the treatment of uncontrolled or resistant hypertension. We expect this trial to readout topline data in the first half of 2024,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “In addition, we plan to initiate a second lorundrostat pivotal trial named Launch-HTN in the second half of 2023, which is expected to readout topline data in mid-2025. We believe our current cash, cash equivalents and investments will fund our planned clinical studies and support our operations through mid-2025.”

Recent Corporate and Clinical Highlights

- **Initiated pivotal Advance-HTN trial** – In April 2023, the Company initiated patient dosing in the Advance-HTN Phase 2 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), when used as an add-on therapy to standardized background treatment of two or three antihypertensive medications in up to approximately 300 adult subjects. The topline data from this trial is expected in the first half of 2024.
- **Target-HTN trial presented at ACC.23/WCC** – In March 2023, the Company presented positive data from the Target-HTN Phase 2 trial that demonstrated a clinically meaningful reduction in blood pressure. The presented data included a pre-specified analysis of lorundrostat treatment in hypertensive subjects with a body mass index (BMI) ≥30 kg/m^2 (obese) that demonstrated statistically significant reduction in

placebo-adjusted systolic blood pressure that was larger than that observed in the group as a whole or the subset of subjects with BMI <30kg/m^2.

In addition to our presentation of results in hypertensive individuals, Mineralys also reported full Phase 1 healthy volunteer safety, PK and PK/PD results at the ACC.23/WCC meeting. This study, conducted by Mitsubishi Tanabe Pharma, characterized single and multiple ascending doses of lorundrostat in subjects for up to 7 days of treatment with a dose exceeding the anticipated clinical dose by 3.5- to 7-fold. As with the Target-HTN trial, lorundrostat was well-tolerated and had the predicted effect of suppressing aldosterone in a dose-dependent fashion without inhibiting cortisol.

Key Upcoming Milestones

- **CKD profiling trial** – In mid-2023, the Company plans to initiate a randomized, double-blind, placebo-controlled Phase 2 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN or rHTN in a chronic kidney disease (CKD) population. Topline data from this trial is expected in the first half of 2024.
- **Phase 3 pivotal Launch-HTN trial** – In the second half of 2023, the Company plans to initiate a randomized, double-blind, placebo-controlled Phase 3 trial to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to prescribed background treatment of two or more antihypertensive medications in up to approximately 1,000 adult subjects. The topline data from this trial is expected in mid-2025.
- **Open-label extension trial for long-term safety exposure**– In mid-2023, the Company plans to initiate an open-label extension trial to obtain additional safety data - all subjects in the pivotal hypertension program, including the Advance-HTN and Launch-HTN trials will be given the opportunity to participate.

First Quarter 2023 Financial Highlights

Research and Development (R&D) expenses were $12.3 million for the quarter ended March 31, 2023, compared to $6.8 million for the quarter ended March 31, 2022. The increase in R&D expenses was primarily due to increases in the 2023 period of $4.0 million in license fees under a license agreement with Mitsubishi Tanabe Pharma upon achieving a development milestone of lorundrostat in March 2023, $0.9 million in higher compensation expense as a result of additions to headcount, $0.7 million in clinical supply, manufacturing and regulatory costs and $0.5 million in other research and development expenses, partially offset by a decrease of $0.6 million in preclinical and clinical costs, driven by the timing of research and development activities and clinical trials of lorundrostat in each quarter.

General and Administrative (G&A) expenses were $2.6 million for the quarter ended March 31, 2023, compared to $0.8 million for the quarter ended March 31, 2022. The increase in G&A expenses was primarily due to $0.8 million in higher compensation expense as a result of additions to headcount, $0.5 million in higher professional fees associated with operating as a public company, $0.4 million in higher other administrative expenses and $0.2 million associated with new director and officer insurance policies.

Net loss was $12.6 million for the quarter ended March 31, 2023, compared to $7.6 million for the quarter ended March 31, 2022. The increase was primarily attributable to the factors impacting the Company’s expenses described above.

Cash, cash equivalents and investments were $301.8 million as of March 31, 2023, compared to $110.1 million as of December 31, 2022. The Company believes that its cash, cash equivalents and investments as of March 31, 2023 will be sufficient to allow the Company to fund the planned clinical studies, as well as support corporate operations through mid-2025.

Conference Call
The Company's management team will host a conference call at 4:30 p.m. ET on Monday, May 15, 2023. To access the call, please dial 1-877-704-4453 in the U.S. or 1-201-389-0920 outside the U.S., followed by the conference ID: 13737778. 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 Lorundrostat
Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension. 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* and an observed half-life of 10-12 hours. In a Phase 2, proof-of-concept study (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 Therapeutics
Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target 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 initially developing for the treatment of patients with uncontrolled or resistant hypertension. Mineralys Therapeutics is based in Radnor, PA, 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 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 FDA; the planned future clinical development of lorundrostat and the timing thereof; and expected timing of 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 March 31,

	2023	2022
Operating expenses:		
Research and development	$ 12,293	$ 6,778
General and administrative	2,645	791
Total operating expenses	14,938	7,569
Loss from operations	(14,938)	(7,569)
Other income:		
Interest income, net	2,329	—
Change in fair value of convertible notes	—	—
Other income	1	—
Total other income, net	2,330	—
Net loss	$ (12,608)	$ (7,569)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.51)	$ (1.48)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	24,764,469	5,123,634

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

	March 31, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 301,761	$ 110,110
Total assets	$ 306,435	$ 114,442
Total liabilities	$ 10,560	$ 8,067
Total stockholders' equity (deficit)	$ 295,875	$ (52,269)

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Source: Mineralys Therapeutics, Inc.