October 30, 2024

Mineralys Therapeutics Completes Enrollment Ahead of Schedule in Launch-HTN, the Second Pivotal Trial of Lorundrostat for the Treatment of Hypertension

– Topline data now anticipated in mid first half of 2025 –

– Management to host virtual KOL event today to discuss the unmet need in hypertension, as well as a review of the ongoing pivotal clinical program for lorundrostat in hypertension –

RADNOR, Pa., Oct. 30, 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 prevalent cardiovascular diseases driven by dysregulated aldosterone, today announced that it has completed enrollment in the Launch-HTN trial ahead of schedule. Launch-HTN is the second of two trials under the planned pivotal program evaluating the efficacy and safety of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN). The Company expects the trial to be completed earlier than planned, with topline data now anticipated in mid first half of 2025.

“Due to the high interest among treating physicians and patients in the Launch-HTN trial, we have completed enrollment earlier than planned. This trial is designed to model the real-world treatment of uHTN and rHTN using lorundrostat in the primary care setting,” stated David Rodman, MD, Chief Medical Officer of Mineralys Therapeutics. “We look forward to sharing the topline data from the trial, which are now expected to be available in mid first half of 2025. We greatly appreciate the enthusiasm and commitment that participating trial investigators and trial participants have shown to the development program for lorundrostat.”

The Launch-HTN trial (NCT06153693), a global, randomized, double-blinded, placebo-controlled Phase 3 trial, enrolled eligible adult participants who failed to achieve their blood pressure goal despite being on two to five background antihypertensive medications. Eligible subjects were randomized to one of three arms: placebo, lorundrostat 50 mg once daily (QD), and lorundrostat 50 mg QD and then titrated to 100 mg QD, as needed, at week six. 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.

KOL Event Details

The Company will host a virtual KOL event for investors at 10:00 am ET today, October 30th. To register for the event, click here. This event will provide expert perspectives on the

currently available treatment options for uHTN and rHTN, as well as a review of the ongoing pivotal clinical program for lorundrostat, including the Advance-HTN and Launch-HTN trials.

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 Lorundrostat

Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uHTN 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 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 Company's plan to announce top line data for Launch-HTN in mid first half of 2025; 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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Source: Mineralys Therapeutics, Inc.