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Mineralys Therapeutics Announces First Patient Dosed in the ADVANCE-HTN Pivotal Trial of Lorundrostat for the Treatment of Uncontrolled and Resistant Hypertension

– Topline data from the trial are expected in the first half of 2024 –

– A second, pivotal trial of lorundrostat in uncontrolled and resistant hypertension expected to commence enrollment in the second half of 2023 –

RADNOR, Pa., May 02, 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 the first patient dosed in the ADVANCE-HTN pivotal trial to evaluate the safety and efficacy of lorundrostat for the treatment of uncontrolled hypertension (uHTN) and resistant hypertension (rHTN) when used as an add-on therapy to standardized background treatment of two or three antihypertensive medications. The topline data from this trial are expected in the first half of 2024.

“The ADVANCE-HTN trial marks an important milestone for Mineralys as we initiate our pivotal program for lorundrostat. Over half of all treated hypertension patients fail to achieve their goal blood pressure and many continue to experience increased cardiorenal morbidity and mortality risk. Abnormal aldosterone production is considered a key driver in uncontrolled and resistant hypertension,” stated Jon Congleton, Chief Executive Officer of Mineralys. “Lorundrostat has already shown an encouraging clinical benefit and was well-tolerated in the Target-HTN Phase 2 trial, which demonstrated that the inhibition of aldosterone production led to substantial blood pressure reduction among all trial participants – and particularly in the subset of individuals with obesity. We believe lorundrostat has the potential to play an important role in offering a targeted treatment approach for hypertension.”

The randomized, double-blind, placebo-controlled ADVANCE-HTN trial will enroll up to approximately 300 eligible adult participants who will be randomized to 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 four. The primary endpoint of the trial is change in systolic blood pressure versus placebo after 12 weeks of treatment, as measured by 24-hour ambulatory blood pressure monitoring.

This is the first of two clinical trials under the planned pivotal program to evaluate the safety and efficacy of lorundrostat for the treatment of uHTN and rHTN. The second pivotal trial, a Phase 3 trial in a larger population of uHTN and rHTN subjects, is expected to begin

enrolling in the second half of 2023, with data anticipated in mid-2025. Patients from both studies will be offered the opportunity to participate in an open label extension trial after completion of these trials. In addition, 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 and rHTN in a chronic kidney disease (CKD) population in mid-2023. Topline data from the CKD trial is expected in the first half of 2024.

Uncontrolled and resistant hypertension represent a significant unmet need within the approximately 115 million patients in the U.S. who have high blood pressure. More than half of hypertensive patients fail to achieve their blood pressure goals despite treatment, and approximately 20 million treated patients have systolic blood pressure greater than 140 mmHg.

In November 2022, Mineralys presented results of its Target-HTN Phase 2 trial demonstrating that lorundrostat lowered the systolic blood pressure of patients with uHTN and rHTN at a clinically meaningful and statistically significant level, with a mean placebo-adjusted reduction in systolic blood pressure of 9.6 mmHg and 7.8 mmHg with a 50 mg or 100 mg QD dose, respectively. Additionally, treatment with lorundrostat demonstrated a robust effect in obese patients, who, studies show, tend to have abnormal aldosterone biology. Mineralys believes the approach of reducing aldosterone production can provide an effective, targeted approach for the control of hypertension, especially in the rapidly growing subset of hypertensive individuals with obesity.

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 and resistant 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 and resistant hypertensive subjects, once-daily lorundrostat demonstrated clinically meaningful blood pressure reduction in individuals with uncontrolled and resistant 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 and 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 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; 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; regulatory developments in the United States and foreign countries; our reliance on our exclusive license with Mitsubishi Tanabe 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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