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Mineralys Therapeutics Presents Positive Lorundrostat Results from the Phase 2 Target-HTN Trial at ACC.23/WCC

Lorundrostat demonstrated clinically meaningful blood pressure reduction in individuals with uncontrolled hypertension

Obesity was predictive of an enhanced response to lorundrostat with placebo-adjusted systolic BP reduction of 16.7 mmHg with 50mg once-daily dosing

Additional clinical trial expected to begin in first half of 2023

RADNOR, Pa., March 04, 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 positive data from the Target-HTN Phase 2 study that demonstrated clinically meaningful blood pressure reduction with once-daily dosing of lorundrostat at the American College of Cardiology's 72nd Annual Scientific Session together with the World Congress of Cardiology (ACC.23/WCC) going on now in New Orleans, LA. In a pre-specified analysis, hypertensive subjects with a BMI ≥30 kg/m2, demonstrated a statistically significant reduction of placebo-adjusted change in systolic blood pressure (BP) of 16.7 mmHg (p=0.002) with 50mg QD and a reduction of 12.3 mmHg (p=0.030) with 100 mg QD in Part 1 of the study.

"We continue to be excited by the compelling data from our Target-HTN trial. As detailed in the poster presentation at ACC.23/WCC today, the latest subgroup analysis of obese patients further supports our hypothesis of the linkage between obesity, aldosterone and hypertension," stated Jon Congleton, Chief Executive Officer of Mineralys. "The prevalence of uncontrolled hypertension continues to grow, and with the rate of obesity rapidly rising in tandem, these data underscore our confidence that targeting the underlying cause of hypertension, abnormal aldosterone biology, has the potential to position lorundrostat earlier in the treatment paradigm."

The data from this sub-analysis of the Phase 2 study were presented in a moderated poster titled, "Highly Effective Blood Pressure Lowering with lorundrostat, a New Aldosterone Synthase Inhibitor, in Individuals with Obesity and RAAS Dysregulation" at the ACC.23/WCC. The poster is available on the Company's website here.

"Current hypertension treatments were developed and introduced several decades ago, when the incidence of obesity was below 20 percent and abnormal aldosterone production affected less than 10 percent of the U.S. population. As rates of hypertension and obesity continue to evolve, so must our approach to treatment," said David Rodman, M.D., Chief Medical Officer of Mineralys. "Our hypothesis when starting Target-HTN was that obesity, abnormal aldosterone biology and hypertension were linked intrinsically. In finding that lorundrostat demonstrated clinically meaningful improvement in obese individuals, we've

validated our initial thinking, and now have data that will be crucial for developing future trials and bringing lorundrostat to market."

Initial topline results from the Target-HTN Phase 2 trial demonstrated that treatment with lorundrostat at doses of 50 mg and 100 mg once daily (QD) led to a statistically significant reduction in systolic BP in inadequately controlled hypertensive patients on at least two background antihypertensive medications. Robust placebo-adjusted reductions in systolic BP and diastolic BP were observed in the office, as well as in the home with 24-hour ambulatory blood pressure monitoring demonstrating reduction of 24-hour average systolic BP, night-time systolic BP, and central systolic BP.

"High blood pressure is the world's leading cause of cardiovascular morbidity and mortality, and the link between elevated nighttime blood pressure and cardiovascular risk is well established in medical literature," said Luke Laffin, M.D., cardiologist, Cleveland Clinic's Heart, Vascular & Thoracic Institute, and lead investigator of the Target-HTN trial. "In the Target-HTN trial, we saw statistically significant reductions in overnight blood pressure which is key in controlling hypertension and reducing the risk of morbidity and mortality. These findings are an encouraging demonstration of the potential of lorundrostat to evolve and impact the way in which we treat hypertension as clinicians."

The Target-HTN (NCT05001945) study was a Phase 2 randomized, double-blind, placebo-controlled, dose-ranging, multicenter trial conducted in the U.S. The trial was designed to evaluate the safety, efficacy, and tolerability of orally administered lorundrostat on BP for the treatment of uncontrolled and resistant hypertension when used as add-on therapy to stable background treatment of two or more antihypertensive agents in 200 male and female subjects 18 years of age or older. Five active doses of lorundrostat (12.5 mg QD, 50 mg QD, 100 mg QD, 12.5 mg twice daily [BID], and 25 mg BID) were compared to placebo in hypertensive subjects. 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.

During ACC.23/WCC, the Company will also present Phase 1 data for lorundrostat that is included in a poster titled, "First-In-Human Study of lorundrostat, a Potent and Highly Selective Aldosterone Synthase Inhibitor". The poster will be made available on the Company's website here on March 5, 2023.

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 and 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 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 is initially developing for the treatment of patients with uncontrolled hypertension. Mineralys 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 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; and the planned future clinical development of lorundrostat and the timing thereof;. 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; our ability to maintain undisrupted business operations due to the COVID-19 pandemic or any other pandemic or future public health concerns; 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 prior filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our in our Prospectus dated February 9, 2023 filed with the SEC on February 10, 2023, 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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