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Mineralys Therapeutics Announces Expansion of Planned Phase 2 Trial of Lorundrostat Alone and in Combination with SGLT2 Inhibitor to Treat Patients with Chronic Kidney Disease (CKD)

– Plan to initiate a Phase 2 proof of concept trial of lorundrostat alone and in combination with an SGLT2 inhibitor for CKD in the second half of 2023 –

– Profiling trial of safety in individuals with stage 3b and 4 CKD to support the hypertension indication will be run in parallel –

– The program builds on the established role of aldosterone in the progression of CKD –

RADNOR, Pa., July 17, 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 details of an expanded two-part Phase 2 clinical trial for lorundrostat as a potential therapy to treat patients with Stage 2 to 4 chronic kidney disease (CKD), which is expected to start enrolling patients in the second half of 2023.

“We are excited to move ahead with this trial to evaluate lorundrostat as a treatment for CKD. This trial builds upon the amelioration of aldosterone-mediated uncontrolled hypertension we observed in our Target-HTN trial of lorundrostat. Over 35 million adults in the U.S. suffer from chronic kidney disease and given the role of aldosterone in CKD, we believe lorundrostat may provide significant clinical benefit,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “This trial will allow us to evaluate the safety, efficacy and tolerability of lorundrostat alone and in combination with an SGLT2 inhibitor in CKD.”

“Aldosterone contributes to the development and progression of chronic kidney disease through genomic and non-genomic signaling. The use of lorundrostat, an aldosterone synthase inhibitor or ASI, to inhibit aldosterone production may represent a more complete solution and promising approach to treat CKD patients,” stated David Rodman, M.D. FAHA, Chief Medical Officer of Mineralys Therapeutics. “There is a growing consensus for the use of an SGLT2 inhibitor as a component of CKD treatment. However, for patients with moderate or severe CKD, a high risk of progression to end-stage disease remains. There is reason for optimism that lorundrostat, with an SGLT2 inhibitor, may provide additive clinical benefit, further reducing the rate of CKD progression.”

The planned Phase 2 clinical trial will be conducted in two parts, including an initial proof-of-concept portion (Part A) and a profiling portion (Part B).

Part A is a randomized, double-blind, placebo-controlled trial that will consist of two treatment periods. Part A will enroll up to 100 subjects with mild to moderate CKD, eGFR 45-90 ml/min/1.73m^2, with persistent albuminuria despite treatment with an ACE inhibitor or ARB. Subjects will receive either once daily combination treatment of lorundrostat 50 mg plus dapagliflozin 10 mg or placebo for 12 weeks. This will be followed by a second 12-week treatment period, during which subjects in the active arm will receive lorundrostat only treatment of 50 mg. Part A of the trial will evaluate the benefit of lorundrostat on proteinuria in this population.

Part B is an open-label, single arm, dose escalation trial that will enroll up to 20 subjects with moderate to severe CKD with and without hypertension, eGFR 25-44 ml/min/1.73m^2 despite treatment with an ACEi or ARB. Subjects will receive four weeks of treatment, once daily of lorundrostat at 25 mg, followed by an increase in dose to lorundrostat 50 mg for another four weeks. Part B of the trial will characterize the safety profile of lorundrostat in a more renally compromised population.

As this is an exploratory trial, interim data analyses may be conducted at one or more time points. Topline data from this trial is anticipated between Q4 2024 and Q1 2025.

About Chronic Kidney Disease
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. Center 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 chronic kidney disease. 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.

About Mineralys
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 developing for cardiorenal conditions affected by abnormally elevated aldosterone, including hypertension and chronic kidney disease. 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 (ASIs) 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 chronic kidney disease; 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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