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Mineralys Therapeutics Completes Enrollment in Phase 2 EXPLORE-OSA Trial of Lorundrostat in Obstructive Sleep Apnea and Hypertension

~ Topline results from the EXPLORE-OSA trial are anticipated in 1Q 2026~

RADNOR, Pa., Sept. 30, 2025 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension and related comorbidities such as chronic kidney disease (CKD), obstructive sleep apnea (OSA) and other diseases driven by dysregulated aldosterone, today announced that it has completed enrollment in its Phase 2 EXPLORE-OSA trial of lorundrostat in participants with moderate-to-severe OSA and hypertension.

“Obstructive sleep apnea and high blood pressure are biologically linked, with blood pressure rising during upper airway obstruction during sleep. In dosing lorundrostat at bedtime, we believe it will suppress the majority of aldosterone produced during sleep while maintaining 24-hour blood pressure control,” said David Rodman, MD, Chief Medical Officer of Mineralys Therapeutics. “Episodes of nocturnal hypertension are underdiagnosed and lack an effective treatment. This is particularly concerning for patients that also suffer from comorbid OSA, where available treatments – which are limited to weight loss and the use of positive airway pressure – may not be sufficiently effective in minimizing the impact on major adverse clinical outcomes. Consequently, there remains a significant unmet need for more effective and targeted treatment options for patients suffering with OSA and hypertension.”

Now that participant enrollment is complete, the Company anticipates analyzing and reporting top-line results of the EXPLORE-OSA trial in the first quarter of 2026. If the trial is successful, the Company believes these data will complement the previously announced positive topline data from its EXPLORE-CKD trial. Demonstrating positive results in these two patient populations would continue to expand the opportunity for lorundrostat in treating hypertension patients with these comorbidities.

About EXPLORE-OSA
The EXPLORE-OSA trial (NCT06785454) is a randomized, Phase 2 double-blind, placebo-controlled, crossover trial. This proof-of-concept trial was designed to evaluate the efficacy, safety, and tolerability of lorundrostat in overweight or obese adults with moderate-to-severe obstructive sleep apnea (OSA) and hypertension. Participants in EXPLORE-OSA will receive 50 mg of oral, once daily (QD) lorundrostat and placebo in sequential treatment periods, with continuous monitoring of blood pressure during overnight polysomnography. The primary efficacy endpoint of the trial is absolute change from baseline in apnea-hypopnea index (AHI) after four weeks of active treatment compared to placebo. Key secondary endpoints include changes in blood pressure, nighttime blood pressure and additional sleep and cardiovascular health measures.

About Obstructive Sleep Apnea
Obstructive sleep apnea (OSA) is characterized by repetitive overnight hypoxic episodes and subsequent sleep fragmentation due to a complete or partial collapse of the upper airway. Moderate OSA is defined as having between 15 and 30 breathing pauses (apnea or hypopnea events) per hour of sleep, while severe OSA indicates more than 30 breathing pauses per hour. OSA impacts almost one billion people globally, including 425 million moderate-to-severe cases. Around 80% of adults with OSA are undiagnosed. As of 2015, undiagnosed OSA is estimated to cost the United States approximately $149.6 billion annually from comorbid disease, workplace accidents, motor vehicle accidents and loss of workplace productivity.

Between 30-50% of adults with hypertension have OSA, and this number increases to between 70-80% in adults with rHTN. Additionally, untreated moderate-to-severe OSA increases the risk of rHTN. Along with hypertension, OSA is a major risk factor of cardiovascular disease, type-2 diabetes mellitus and stroke.

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 United States. In 2022, more than 685,000 deaths in the United States included hypertension as a primary or contributing cause. Hypertension and related health issues resulted in an estimated annual economic burden of about $219 billion in the United States in 2019.

Less than 50% of hypertension patients achieve their blood pressure goal with currently available medications. Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 30% 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 (uHTN) or resistant hypertension (rHTN), as well as chronic kidney disease (CKD) and obstructive sleep apnea (OSA). 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 a 40-70% reduction in plasma aldosterone concentration in hypertensive subjects.

About Mineralys
Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, chronic kidney disease (CKD), obstructive sleep apnea (OSA) 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 the treatment of cardiorenal conditions affected by dysregulated aldosterone, including hypertension, CKD, and OSA. Mineralys is based in Radnor, Pennsylvania, and was founded by Catalys Pacific. For more information, please visit https://mineralystx.com. Follow Mineralys on LinkedIn, Twitter and Bluesky.

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 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 submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA); the anticipated timing of NDA submission and a potential pre-NDA meeting with the FDA; the Company's ability to evaluate lorundrostat as a potential treatment for CKD, OSA, uHTN or rHTN; the planned future clinical development of lorundrostat and the timing thereof; and the expected timing of commencement and enrollment of participants 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: topline results that we report are based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; 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; the results of our clinical trials, including the Advance-HTN and Launch-HTN trials, may not be deemed sufficient by the FDA to serve as the basis for an NDA submission or regulatory approval of lorundrostat; 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; macroeconomic trends and uncertainty with regard to high interest rates, elevated inflation, tariffs, and the potential for a local and/or global economic recession; 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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