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Mineralys Therapeutics Announces Phase 2 Clinical Trial of Lorundrostat for Obstructive Sleep Apnea in Patients with Hypertension

– Estimated 54 million people suffer from obstructive sleep apnea in the U.S. including 30-50% of adults with hypertension, both conditions associated with excess morbidity and mortality –

– Obstructive sleep apnea represents Mineralys' third precision, targeted indication for lorundrostat, further expanding its market potential in aldosterone-driven diseases –

– Initiation of the trial anticipated in the first quarter of 2025 –

RADNOR, Pa., Jan. 08, 2025 (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 diseases driven by dysregulated aldosterone, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) Application for a Phase 2 clinical trial to evaluate the effect of lorundrostat in the treatment of subjects with moderate-to-severe obstructive sleep apnea (OSA) and hypertension. The Company anticipates initiating the trial in the first quarter of 2025.

"We are pleased to announce the OSA clinical development program for lorundrostat. This program aligns with our strategy to develop lorundrostat in conditions driven by dysregulated aldosterone, with poor cardiovascular outcomes and few treatment options," stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. "We believe suppression of aldosterone production by lorundrostat has the potential to reduce the nocturnal hypertension driving adverse cardiovascular outcomes. In addition, lorundrostat is anticipated to reduce the severity of upper airway obstruction and associated OSA symptoms such as daytime sleepiness and cognitive impairment."

"Obstructive sleep apnea carries significant physiological and psychological impacts on health. Along with trouble sleeping, excessive daytime sleepiness and snoring from repetitive upper airway closure, patients frequently experience significant surges in blood pressure overnight contributing to the daytime hypertension that most are struggling to control," stated Reena Mehra, MD, MS, a sleep disorders researcher and physician and new member of the Mineralys Scientific Advisory Board. "We designed the OSA trial in collaboration with a group of thought leaders in sleep apnea treatment in order to incorporate state-of-the-art technology, register sites with expertise in sleep medicine, and pinpoint the right participants to ensure high-quality data that are reflective of real-world unmet needs facing these patients. I look forward to conducting this innovative trial with Mineralys and our academic partners over the coming months."

The planned Phase 2 clinical trial is a placebo-controlled, crossover study to evaluate the safety and efficacy of lorundrostat 50mg taken once daily in the evening in approximately 40 subjects with moderate-to-severe OSA. Subjects will be at least 18 years old, with a BMI ≥27 kg/m^2, and the trial will be conducted across approximately 40 sites.

The key objective of this trial is to validate the hypothesis that lorundrostat both alleviates the severity of upper airway obstruction and reduces nocturnal hypertension. The primary outcome measure is absolute change in the frequency of apnea-hypopnea episodes. The key secondary objective is to quantify blood pressure throughout the night using continuous BP monitoring during performance of a standard sleep study without the benefit of CPAP. Standard patient reported outcomes, specific to OSA will also be assessed.

The Company believes that its current cash, cash equivalents and investments will be sufficient to fund its planned clinical trials, and support its corporate operations through the first quarter of 2026.

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 resistant hypertension. Additionally, untreated moderate-to-severe OSA increases the risk of resistant hypertension. Along with hypertension, OSA is a major risk factor of cardiovascular disease, type-2 diabetes mellitus and stroke.

About Lorundrostat

Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension (uHTN) and resistant hypertension (rHTN) as well as chronic kidney disease (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, 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 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 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 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, rHTN or OSA in patients with hypertension; 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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