March 9, 2026

Mineralys Therapeutics Announces FDA Acceptance of NDA for Lorundrostat for Treatment of Adults with Hypertension and Topline Explore-OSA Trial Results

– The FDA assigned a PDUFA target action date of December 22, 2026 –

– The NDA is based on positive data from a successful clinical program demonstrating favorable safety and blood pressure reduction in adults with hypertension –

– Topline results from the Phase 2 Explore-OSA exploratory trial did not reduce AHI; demonstrated a clinically meaningful reduction in blood pressure and favorable safety and tolerability in this population with difficult to control hypertension –

RADNOR, Pa., March 09, 2026 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a 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, announced today that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for lorundrostat for the treatment of adult patients with hypertension in combination with other antihypertensive drugs. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of December 22, 2026.

“The FDA’s acceptance of our NDA for lorundrostat marks an important milestone in our efforts to address the clinically significant need faced by millions of patients living with uncontrolled or resistant hypertension,” said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “While the Explore-OSA trial did not demonstrate a reduction in AHI, the blood pressure reductions and safety profile were clinically meaningful, especially for this difficult to control population. We believe lorundrostat has the potential to become an important new treatment option for resistant and uncontrolled hypertension, and we look forward to working with the FDA as we advance toward potential approval.”

Explore-OSA Trial Topline Results

The Explore-OSA trial was a Phase 2 exploratory trial of lorundrostat in forty-eight participants with an average body mass index (BMI) of 38.2 kg/m^2, an average apnea-hypopnea index (AHI) of 48.5 events/hr and an average systolic blood pressure (BP) of 142.3 mmHg (range 131-175 mmHg). After four weeks of treatment, lorundrostat 50 mg dosed in the evening did not demonstrate a clinically meaningful difference relative to placebo on the apnea-hypopnea index (AHI), the primary endpoint.

At week four, the trial demonstrated an 11.1 mmHg ($p < 0.0001$) and a 1.0 mmHg (p = NS) BP reduction with lorundrostat and placebo, respectively, in the pre-planned parallel arm

analysis of the first period. There was a 6.2 mmHg placebo-adjusted reduction ($p < 0.0003$) in BP in the crossover analysis.

Lorundrostat demonstrated a favorable safety profile and was well tolerated, with no serum potassium excursions above 5.5 mmol/L. Analysis is ongoing for other endpoints in the trial and will be reported in future publications or medical meetings.

About Launch-HTN

Launch-HTN (NCT06153693) was a global, randomized Phase 3 double-blind, placebo-controlled trial of adults whose blood pressure (BP) remained uncontrolled despite being on two to five antihypertensive medications. Participants were assigned to one of three groups: placebo; lorundrostat 50 mg once daily; or lorundrostat 50 mg once daily with the option to increase to 100 mg at week six. The primary endpoint was change from baseline in systolic BP at six weeks versus placebo, measured by automated office blood pressure monitoring.

About Advance-HTN

Advance-HTN (NCT05769608) was a randomized, double-blind, placebo-controlled Phase 2 clinical trial that evaluated the efficacy and safety of lorundrostat for the treatment of uncontrolled or resistant hypertension, when used as an add-on therapy to a standardized background treatment of two or three antihypertensive medications in adult participants. Participants who met screening criteria had their existing hypertension medications discontinued and started on a standard regimen of an angiotensin II receptor blocker (ARB) and a diuretic, if previously on two medications, or a standard regimen of ARB, diuretic and calcium channel blocker if previously on three to five medications. Participants who remained hypertensive despite the standardized regimen were then randomized into three cohorts and treated for twelve weeks: lorundrostat 50 mg once daily, lorundrostat 50 mg once daily and an option to titrate to 100 mg once daily at week four based on defined criteria, or placebo. The trial's primary endpoint was the change in 24-hour ambulatory systolic blood pressure at week twelve from baseline for active cohorts versus placebo.

About Explore-OSA

The Explore-OSA trial (NCT06785454) was a Phase 2 randomized, 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 OSA and hypertension. Participants in Explore-OSA received 50 mg of oral, once daily (QD) lorundrostat and placebo in sequential treatment periods, with continuous monitoring of BP during overnight polysomnography. The primary efficacy endpoint of the trial was absolute change from baseline in apnea-hypopnea index (AHI) after four weeks of active treatment compared to placebo. The first secondary endpoint was AOBP, and additional endpoints were nighttime BP and sleep and cardiovascular health measures.

About 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 to severe OSA is associated with increased production of aldosterone and increased nighttime BP; standard treatment with positive airway pressure is not sufficient for BP reduction. OSA

impacts almost one billion people globally, including 425 million moderate-to-severe cases. Around 80% of adults with OSA are undiagnosed. As of 2025, untreated OSA is estimated to cost the United States more than $150 billion annually when considering direct medical expenses, productivity losses and accident-related costs.

Between 30-50% of adults with hypertension have OSA, and this number increases to between 70-80% in adults with resistant hypertension (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 (BP 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 BP 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 CKD and 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 participants.

The Company has now completed five successful Phase 2/3 clinical trials of lorundrostat supporting the efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN and rHTN. This includes two pivotal, registrational trials, including the Phase 3 Launch-HTN trial and Phase 2 Advance-HTN trial, which support the robust, durable and clinically meaningful reductions in systolic BP by lorundrostat. Lorundrostat was well tolerated in both trials with a favorable safety profile.

About Mineralys

Mineralys Therapeutics is a biopharmaceutical company focused on developing medicines to target hypertension and related comorbidities such as CKD, OSA and other diseases driven by dysregulated aldosterone. Its initial product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor. 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 timing and results of review of additional endpoints evaluated in the Explore-OSA clinical trial; the anticipated timing of the FDA's review of the Company's accepted NDA and any subsequent regulatory approval 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: 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; any delays in the FDA's review of our accepted NDA, including as a result of a government shutdown or reductions in agency funding or personnel, 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 regulatory approval of lorundrostat;later developments with the FDA may be inconsistent with the feedback from prior meetings, including whether the proposed pivotal program will support registration of lorundrostat following submission of an NDA and the FDA's review of the same; 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; macroeconomic trends and uncertainty with regard to high interest rates, elevated inflation, tariffs and other trade policies, 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 Tanabe Pharma Corporation 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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