November 8, 2026

Mineralys Therapeutics Presents New Late-Breaking Data from Transform-HTN Open-Label Extension Trial of Lorundrostat in Hypertension at AHA Scientific Sessions 2026

– In the largest long-term hypertension trial of an aldosterone synthase inhibitor to date, lorundrostat demonstrated sustained reduction in automated office systolic blood pressure (AOSBP) of 17.8 mmHg at Week 48 from Launch-HTN baseline –

– 56% of participants reached AOSBP below 130 mmHg at Week 48 –

– Long-term treatment with lorundrostat was well tolerated, with no new clinically relevant safety findings beyond Launch-HTN –

– U.S. FDA review of lorundrostat is underway, with a PDUFA target date of December 22, 2026 –

RADNOR, Pa., Nov. 08, 2026 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a biopharmaceutical company focused on developing medicines to target hypertension and aldosterone-related adverse outcomes in comorbid conditions such as chronic kidney disease, obstructive sleep apnea and other diseases driven by dysregulated aldosterone, today announced long-term results from the Transform-HTN open-label extension trial of lorundrostat in participants with uncontrolled or resistant hypertension, demonstrating sustained reductions in AOSBP following lorundrostat treatment in Launch-HTN. The results were presented in a late-breaking oral session at the American Heart Association (AHA) Scientific Sessions 2026 in Chicago, IL, on Sunday, November 8, 2026, at 3:35 p.m. CT.

“For patients whose blood pressure remains uncontrolled despite multiple medications, particularly those in high-risk populations disproportionately affected by hypertension, the question in practice is whether a treatment can deliver both rapid and sustained blood pressure control,” said Manish Saxena, MBBS, Clinical Co-Director of Queen Mary University of London’s William Harvey Clinical Research Centre and Hypertension Specialist at Barts Health NHS Trust. “In Transform-HTN, lorundrostat demonstrated sustained blood pressure reductions for nearly a year, with more than half of participants achieving the guideline-recommended systolic blood pressure target of less than 130 mmHg, an important goal for reducing long-term cardiovascular and kidney risks.”

Efficacy Results from Transform-HTN

In this open-label extension trial, lorundrostat demonstrated a clinically meaningful 17.8

mmHg absolute reduction in AOSBP from the Launch-HTN baseline through 48 weeks ($p<0.0001$), supporting sustained blood pressure control. More than half of participants achieved systolic blood pressure below 130 mmHg at the end of the analysis period. Results were similar among participants taking two background antihypertensive medications and those taking three or more.

Endpoint	Lorundrostat
Mean change in AOSBP from Launch-HTN baseline to Week 48 (n=504)	−17.8 mmHg
Proportion reaching AOSBP <130 mmHg at Week 48, overall	56.0%

Safety and Tolerability Results

Lorundrostat was well tolerated during the 36-week open-label extension, with no new clinically relevant safety findings compared with Launch-HTN. Of the 632 participants, 583 (92%) completed 48 weeks of follow-up.

- Serious adverse events occurred in 27 participants (4.3%). Investigators considered two of these (0.3%) treatment-related. Thirty-seven participants (5.9%) discontinued the trial drug because of an adverse event, including 10 (1.6%) for hyperkalemia.
- Hyperkalemia requiring a trial drug modification (dose reduction, interruption, or discontinuation) occurred in 32 participants (5.1%).

Consistent with lorundrostat's mechanism of action, serum potassium increased and eGFR decreased early in treatment; both remained stable through the open-label period to Week 48.

"Across multiple large clinical trials that included a diverse set of patients, lorundrostat has repeatedly demonstrated its potential to improve blood pressure control in patients with difficult-to-treat hypertension, while also being consistently well tolerated," said Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. "As we advance toward a potential FDA approval, these findings further strengthen the evidence supporting lorundrostat as an important new treatment option, with demonstrated durability of blood pressure reduction in the patients who need additional treatment options most."

Lorundrostat is currently under review by the U.S. Food and Drug Administration for the treatment of hypertension in combination with other antihypertensive drugs, with a Prescription Drug User Fee Act (PDUFA) target date of December 22, 2026.

Transform-HTN Trial Design

The results presented at AHA were from participants assigned to both lorundrostat arms in the 12-week, double-blind, placebo-controlled Launch-HTN trial who transitioned into Transform-HTN. Of the 808 participants from Launch-HTN's lorundrostat treatment arms, 632 participants were eligible and enrolled in Transform-HTN. These participants received an additional 36 weeks of lorundrostat while continuing their existing antihypertensive medications. The open-label starting lorundrostat dose was 50 mg once daily, or 25 mg if the previously blinded treatment dose was reduced. The efficacy analysis (n=504) excluded participants randomized to placebo in a four-week randomized treatment withdrawal sub-

study between Weeks 24 and 28. The safety analysis (n=632) included participants receiving at least one dose of lorundrostat in the open-label extension.

Participants had a mean age of 61 years; 46% were women, 25% were Black or African American and 39% were Hispanic or Latino. Nearly two-thirds (63%) had a BMI of 30 kg/m² or higher; 41% were taking two antihypertensive medications at baseline, while 59% were taking three or more.

About Transform-HTN

Transform-HTN (NCT05968430) is a global open-label extension trial designed to assess the safety, efficacy and tolerability of lorundrostat in participants with hypertension, and includes participants who completed one of three eligible parent studies (Advance-HTN, Launch-HTN or Explore-CKD). Eligible participants were enrolled in the open-label extension study, with a primary endpoint of the change in automated office systolic blood pressure.

About Launch-HTN

The Launch-HTN trial (NCT06153693) was a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial of adults whose blood pressure remained uncontrolled despite being on two to five antihypertensive medications. Participants were assigned to one of three groups: lorundrostat 50 mg once daily; lorundrostat 50 mg once daily with the option to increase to 100 mg at Week 6 based on prespecified criteria; or placebo. The primary endpoint was change from baseline in systolic blood pressure at Week 6 versus placebo, measured by automated office blood pressure monitoring.

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 hypertensive 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 an investigational, proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), as well as related comorbidities, such as chronic kidney disease, obstructive sleep apnea and other diseases driven by dysregulated aldosterone. 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, has an observed half-life of 10-12 hours and demonstrated a 40-70% reduction in plasma aldosterone concentration in participants with hypertension.

Mineralys has completed six late-stage clinical trials of lorundrostat supporting its efficacy and safety profile while also validating aldosterone as an integral therapeutic target in uHTN

and rHTN. The clinical program includes two pivotal, registrational trials, the Phase 3 Launch-HTN trial and Phase 2 Advance-HTN trial, which support the robust, durable and clinically meaningful reductions in systolic blood pressure 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 chronic kidney disease, obstructive sleep apnea and other diseases driven by dysregulated aldosterone. Its initial product candidate, lorundrostat, is an investigational, 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, X 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 Mineralys' current beliefs and expectations and include, but are not limited to, statements regarding the anticipated timing of the Food and Drug Administration's (FDA) review of Mineralys' accepted new drug application (NDA) and the potential therapeutic benefits of lorundrostat. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Mineralys' business, including, without limitation: any delays in the FDA's review of Mineralys' accepted NDA, including as a result of a government shutdown or reductions in agency funding or personnel; the results of Mineralys' clinical trials, including the Launch-HTN and Advance-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 the FDA's review of Mineralys' NDA submission; the risk that future funding under the secured debt facility may not be available on the timeframe Mineralys expects, or at all, including as a result of its failure to meet the conditions required for such funding or failure to comply with the affirmative and negative covenants under the debt facility; Mineralys' future performance is dependent entirely on the success of lorundrostat; potential delays in the commencement, enrollment and completion of clinical trials and nonclinical studies; Mineralys' 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; Mineralys' ability to maintain undisrupted business operations due to any pandemic or future public health concerns; regulatory developments in the United States and foreign countries; and other risks described in Mineralys' filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in its 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 Mineralys undertakes 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.

Contact:

Investor Relations
investorrelations@mineralystx.com

Media Relations
Melyssa Weible
Elixir Health Public Relations
Email: mweible@elixirhealthpr.com



Source: Mineralys Therapeutics, Inc.