September 23, 2026

Mineralys Therapeutics' Transform-HTN Open-Label Extension Trial Data Selected for Late-Breaking Presentation at American Heart Association Scientific Sessions 2026

RADNOR, Pa., Sept. 23, 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 (CKD), obstructive sleep apnea (OSA) and other diseases driven by dysregulated aldosterone, today announced that new long-term efficacy and safety data from the Company's ongoing Transform-HTN open-label extension trial of the aldosterone synthase inhibitor lorundrostat will be featured in a late-breaking science presentation at the American Heart Association Scientific Sessions 2026, taking place November 6-9 in Chicago, IL.

Details for the Presentation:

Title:	Transform-HTN: Long-Term Efficacy and Safety of Lorundrostat, a Novel Aldosterone Synthase Inhibitor, in Uncontrolled Hypertension
Presenter:	Manish Saxena MBBS, Deputy Clinical Co-Director of Queen Mary University of London's William Harvey Heart Centre, and Hypertension Specialist at Barts Health NHS Trust
Session Time:	Sunday, November 8, 3:30 pm CT
Session Title:	Old Meds, New Meds and BP Goals: Optimizing Antihypertensive Therapy
Session Location:	Learning Studio 2, Science and Technology Hall, South Hall

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 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 hypertensive 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 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 CKD, OSA 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 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 Food and Drug Administration's (FDA) review of Mineralys' accepted new drug application (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 may not be able to reach agreement on the proposed termination of its license agreement with Tanabe on its expected timeframe, or at all; 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; Mineralys' reliance on its exclusive license with Tanabe to provide Mineralys with intellectual property rights to develop and commercialize lorundrostat; 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.

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