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Mineralys Therapeutics Announces Late-Breaking Presentation of Data from the Launch-HTN Pivotal Trial of Lorundrostat in Uncontrolled or Resistant Hypertension at 34th European Meeting on Hypertension and Cardiovascular Protection (ESH 2025)

– Largest hypertension trial of an aldosterone synthase inhibitor to date demonstrated the efficacy of lorundrostat in over 1,000 participants with uncontrolled or resistant hypertension in a real-world setting –

– Lorundrostat 50 mg dosed once daily demonstrated clinically meaningful and sustained reductions in systolic blood pressure, with a 16.9 mmHg reduction at Week 6 (-9.1 mmHg placebo adjusted) and a 19.0 mmHg reduction at Week 12 (-11.7mm placebo adjusted) –

– Lorundrostat demonstrated a favorable safety and tolerability profile –

RADNOR, Pa., May 24, 2025 (GLOBE NEWSWIRE) -- Mineralys Therapeutics, Inc. (Nasdaq: MLYS), 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, today announced detailed results from the pivotal Phase 3 Launch-HTN trial in over 1,000 participants with uncontrolled hypertension (uHTN) or resistant hypertension (rHTN) who were taking two to five antihypertensive medications. When added to existing background treatment, lorundrostat 50 mg dosed once daily demonstrated clinically meaningful and sustained reductions in automatized office systolic blood pressure, with a 16.9 mmHg reduction at Week 6 (-9.1 mmHg placebo adjusted; p-value < 0.0001) and a 19 mmHg reduction at Week 12 (-11.7mm placebo adjusted; p-value < 0.0001). Additionally, lorundrostat demonstrated a favorable safety and tolerability profile.

“The detailed results from Launch-HTN, which was designed to reflect treatment in the real-world setting, mark a pivotal milestone in our mission to deliver the first targeted aldosterone synthase inhibitor to the millions of people suffering from uncontrolled or resistant hypertension,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “With these findings in hand, we now have data from two pivotal trials in distinct-but-complementary populations that reinforce the promise of a new treatment approach for hypertension that directly addresses the dysregulated aldosterone pathway – a key driver of the condition in many patients.”

“The Launch-HTN trial provides substantial evidence supporting lorundrostat’s potential as a well-tolerated, effective treatment for patients with uncontrolled or resistant hypertension,

with consistent blood pressure reductions across a large and diverse patient population," stated Manish Saxena MBBS, Deputy Clinical Co-Director of Queen Mary University of London's William Harvey Research Institute and Hypertension Specialist at Barts Health NHS Trust. "The clinically meaningful and sustained reductions in systolic blood pressure observed with lorundrostat are especially important, as long-term control is key to lowering the risk of serious cardiovascular, renal, and metabolic complications. The consistency of results seen in the lorundrostat development program – which includes multiple trials across differentiated patient populations – supports its potential to have a broad role in future hypertension care."

Results from Launch-HTN were presented in a late-breaking session at the 34th European Meeting on Hypertension and Cardiovascular Protection (ESH 2025) on Saturday, May 24, 2025, at 10:00am CEST.

Efficacy Results from Launch-HTN

The Launch-HTN trial was a global, randomized, double-blinded, placebo-controlled Phase 3 trial, which enrolled eligible adult participants who failed to achieve their blood pressure goal despite being on two to five antihypertensive medications. Launch-HTN reflects the real-world setting for clinicians by utilizing automated office blood pressure (AOBP) measurement and allowing participants to stay on their existing medications. The trial met its endpoints demonstrating clinically meaningful, statistically significant mean reduction from baseline in placebo-adjusted systolic blood pressure at week six and the benefit was sustained with potential further reduction through week 12.

Primary Endpoint	**50 mg** *(n=808)*	
Change in AOBP at Week 6	-16.9 mmHg absolute change	
	-9.1 mmHg placebo-adjusted change ($p < 0.0001$)	
Pre-Defined Endpoint	**50 mg** *(n=538)*	**50 to 100 mg** *(n=270)*
Change in AOBP at Week 12	-19.0 mmHg absolute change	-15.7 mmHg absolute change
	-11.7 mmHg placebo-adjusted change ($p < 0.0001$)	-8.4 mmHg placebo-adjusted change ($p = 0.0016$)

Safety and Tolerability Results

Lorundrostat demonstrated a favorable safety and tolerability profile in the Launch-HTN trial. The anticipated on-target effects on serum electrolytes, increased serum potassium and reduced serum sodium were modest and rapidly reversible upon discontinuation of lorundrostat. Suppression of cortisol production was not observed and there was a very low incidence of drug-related serious adverse events resulting in discontinuation or dose-adjustment of study medication.

- Treatment-emergent serious adverse events (SAEs) occurred in 12 participants (2.2%) and two participants (0.7%) in the 50 mg and 50 mg with optional dose escalation to 100 mg arms, respectively, compared with eight participants (3.0%) in the placebo arm.
- There was only one participant (0.1%) in the trial with treatment-related SAE that occurred in the 50 mg arm.

- The incidence of hyperkalemia (serum potassium >6.0 mmol/L) at the scheduled study visit was 1.1% and 1.5% in the 50 mg and 50 to 100 mg arms, respectively. After per-protocol exclusion of factitious results, the values for confirmed hyperkalemia were 0.6% and 1.1%, respectively.

Launch-HTN was the second of two pivotal trials evaluating lorundrostat in participants with uHTN or rHTN. Detailed results from the first pivotal trial (Advance-HTN) in participants who would normally be treated by specialists were recently published in *The New England Journal of Medicine (NEJM)*. Advance-HTN results were first presented at the American College of Cardiology's Annual Scientific Session & Expo (ACC.25) in March 2025.

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 U.S. 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 U.S. 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 uHTN or 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 subjects.

In a Phase 2, proof-of-concept trial (Target-HTN) in uncontrolled or resistant hypertensive participants, once-daily lorundrostat demonstrated statistically significant and clinically meaningful systolic blood pressure reduction in both AOBP and 24-hour ambulatory systolic 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 SAE possibly related to study drug being hyponatremia.

About Launch-HTN

The Launch-HTN trial (NCT06153693) was a global, randomized, double-blinded, placebo-controlled Phase 3 trial, which enrolled eligible adult participants who failed to achieve their blood pressure goal despite being on two to five background antihypertensive medications. Eligible participants were randomized to one of three arms: placebo, lorundrostat 50 mg once daily (QD), and lorundrostat 50 mg QD and then titrated to 100 mg QD, as needed, at week six. The primary endpoint of the trial was the change from baseline in systolic blood pressure versus placebo after six weeks of treatment, as measured by AOBP monitoring.

About Advance-HTN

The Advance-HTN trial (NCT05769608) was a randomized, double-blind, placebo-controlled Phase 2 clinical trial that evaluated the efficacy and safety of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to a standardized background treatment of two or three antihypertensive medications in adult participants. Participants who meet 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 QD, lorundrostat 50 mg QD and an option to titrate to 100 mg QD 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 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 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 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 U.S. Food and Drug Administration (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 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: 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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