Mineralys Therapeutics

Fact Sheet

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MINERALYS THERAPEUTICS

QUICK REFERENCE

Mineralys Therapeutics Inc.
Nasdaq: MLYS
www.MINERALYSTX.com

BUSINESS SUMMARY

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.

SCIENCE

Lorundrostat targets aldosterone-driven hypertension by inhibiting the enzyme that catalyzes the final steps of aldosterone synthesis. Our goal is to decrease levels of aldosterone by selectively inhibiting aldosterone synthesis without affecting cortisol synthesis. Lorundrostat has 374-fold selectivity for inhibiting aldosterone synthesis over cortisol synthesis.

Treatment of Hypertension with Lorundrostat
In a phase 2 clinical trial, lorundrostat was effective in reducing blood pressure in people with uncontrolled hypertension taking at least 2 medications, including those on 3 or more medications (treatment-resistant hypertension), and lorundrostat was well tolerated.

Aldosterone works by binding to the mineralocorticoid receptor (MR) within cells of the kidney and other organs. In the classic MR pathway, aldosterone promotes sodium and water reabsorption and potassium excretion, which drives blood volume and BP. In addition to MR-mediated effects, aldosterone also signals through non-MR mediated pathways, such as G protein-coupled receptors.

Cardio-Renal-Metabolic Syndrome
Hypertension and other CRMS diseases are major contributors to premature morbidity and mortality and are linked to dysregulated aldosterone.

Aldosterone synthase inhibitor therapy targets aldosterone-dependent hypertension, including obesity-related aldosterone-dependent hypertension.
Given that elevated blood pressure is associated with an increased risk of CRMS morbidity, including cardiovascular events, stroke, and heart failure,28 a treatment approach targeting inhibition of aldosterone synthesis could potentially improve rates of blood pressure control in people with dysregulated aldosterone and reduce the risk for CRMS events.

CONTACT INFORMATION

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Recent Press Releases *(Headlines and Excerpts)*

Mineralys Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

- ***Anticipate topline data from pivotal Advance-HTN trial in March 2025 and pivotal Phase 3 Launch-HTN trial in mid first half of 2025***
- ***Completed enrollment in Explore-CKD Phase 2 trial and anticipate delivering topline data in Q2 2025***
- ***Initiating Phase 2 trial to evaluate lorundrostat for the treatment of patients with moderate-to-severe obstructive sleep apnea (OSA) and hypertension***
- ***Conference call today at 8:30 a.m. ET***

Feb. 12, 2025 -- Mineralys Therapeutics, Inc. announced financial results for the fourth quarter and full year ending December 31, 2024, and provided a corporate update.

Recent Clinical Highlights and Upcoming Milestones

- Pivotal Advance-HTN Trial – Anticipate reporting topline data in March 2025. The trial is evaluating the efficacy and safety of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN), when used as an add-on therapy to a standardized background treatment. The trial's primary endpoint is the change in 24-hour ambulatory systolic blood pressure at week twelve from baseline for each active cohort versus placebo.
- Pivotal Launch-HTN Phase 3 Trial – Anticipate reporting topline data in mid first half of 2025. This is the second ongoing pivotal trial of lorundrostat for the treatment of subjects with uHTN or rHTN as add-on therapy, who fail to achieve blood pressure control on their existing, prescribed background treatment of two to five antihypertensive medications. The primary endpoint of the trial is change from baseline in systolic blood pressure versus placebo after six weeks of treatment, as measured by automated office blood pressure monitoring.
- Transform-HTN Open-Label Extension Trial – The Company's ongoing open-label extension trial allows subjects to continue to receive lorundrostat and obtain additional safety and efficacy data.
- Explore-CKD Phase 2 Trial – Enrollment completed and topline data is anticipated in the second quarter of 2025. The trial is designed to evaluate the safety and efficacy of lorundrostat when added to background treatment with SGLT2 inhibitor as a potential therapy to treat patients with uHTN or rHTN and Stage 2 to 3b CKD.
- Explore-OSA Phase 2 Trial – Initiation planned in the first quarter of 2025. The trial is designed to evaluate the safety and efficacy of lorundrostat in the treatment of overweight and obese subjects with moderate-to-severe OSA and hypertension.

Mineralys Therapeutics Completes Enrollment in Explore-CKD Phase 2 Trial of Lorundrostat for the Treatment of Hypertension in Subjects with Stage 2 to 3b CKD and Albuminuria

- ***Continues to anticipate announcing topline data from Explore-CKD trial in Q2 2025***

Feb. 04, 2025 -- Mineralys Therapeutics, Inc. announced that it has completed enrollment in the Explore-CKD Phase 2 trial evaluating the efficacy and safety of lorundrostat for the treatment of hypertension in subjects with CKD and albuminuria, despite receiving stable treatment with an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB) and an SGLT2 inhibitor.

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***

Jan. 08, 2025 -- Mineralys Therapeutics, Inc. 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.

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