PRESS RELEASE
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Cereno Scientific

Cereno Scientific Achieves Key Clinical Milestone as First Patient Is Dosed in Global Phase IIb EPIMODE Trial of CS1 in PAH

Cereno Scientific (Nasdaq First North: CRNO B), an innovative biotech pioneering treatments to enhance and extend life for rare cardiovascular and pulmonary diseases, today announced that the first patient has been randomized and dosed in EPIMODE, the Company's global Phase IIb trial evaluating lead drug candidate CS1 in pulmonary arterial hypertension (PAH). First Patient In (FPI) marks the formal initiation of EPIMODE, with the trial now entering randomized treatment to further evaluate CS1's efficacy and optimal dose, alongside safety and tolerability, while assessing its potential as a disease-modifying treatment for PAH.

The first patient has now completed screening, been randomized and received the first dose of study treatment, marking the transition into randomized treatment in EPIMODE. This significant milestone follows the activation of the first clinical site in August 2026 and the initiation of patient screening. In parallel, activation of additional specialist PAH centers continues across North America, Europe and South America to expand patient recruitment capacity.

"First patient randomization and dosing is an important milestone for EPIMODE. We have made substantial progress across the broader trial network, working closely with our CRO, investigators and clinical teams to prepare and activate additional specialist PAH centers. Regulatory, contractual and operational start-up activities are progressing across the planned countries in North America, Europe and South America. Our focus is on ensuring that participating sites are ready to identify potentially eligible patients in advance, where permitted, and move promptly into screening and randomization once operational and all necessary approvals are in place, progressively expanding recruitment capacity across the global network," said Rahul Agrawal, CMO and Head of R&D at Cereno Scientific.

A key step toward evaluating CS1's disease-modifying potential

EPIMODE represents an important next step in the development of CS1, designed to evaluate whether the encouraging efficacy signals observed in the completed Phase IIa trial can be demonstrated in a larger, randomized and placebo-controlled setting.

PAH is a serious, progressive disease in which structural changes in the pulmonary blood vessels increase resistance to blood flow and place growing strain on the right side of the heart. Despite advances in treatment, significant medical needs remain. CS1 is being developed as an oral, once-daily treatment added to existing standard of care, with the potential to address underlying mechanisms driving disease progression, including vascular remodeling, fibrosis and inflammation.

In the completed Phase IIa trial, CS1 successfully met its primary endpoint demonstrating a favorable safety and tolerability profile together with exploratory efficacy signals, including improvements in right-heart function, functional class, risk score and patient quality of life, as well as early signs consistent with reverse vascular remodeling.

The subsequent 12-month Expanded Access Program (EAP) also met its primary objective of evaluating long-term safety and tolerability, confirming a favorable profile consistent with Phase IIa and extending the accumulated clinical treatment experience to approximately 15 months. Among the six patients who completed 12 months of treatment, the majority maintained or improved their clinical status across several clinically relevant functional and biomarker measures.

Together, these findings provide an encouraging clinical foundation for EPIMODE, which is designed to generate the controlled evidence needed to assess CS1's efficacy, identify the optimal dose for continued development and further investigate its potential to modify the underlying disease process in PAH.

The trial's primary endpoint is change in pulmonary vascular resistance (PVR) after nine months of treatment. PVR measures resistance to blood flow through the lungs and is a key measure of the vascular changes that place strain on the right side of the heart in PAH.

A distinguishing feature of EPIMODE is its two-stage design. Following the initial nine-month treatment period, patients are re-randomized, enabling the study to assess how treatment effects develop when CS1 treatment is continued, initiated or withdrawn. Patients initially assigned to placebo transition to active CS1 treatment during the second period.

This design is particularly relevant to evaluating CS1's potential disease-modifying effects, as it may provide insights into the durability of treatment benefits and whether observed effects extend beyond an immediate treatment response. These insights, alongside the primary efficacy results, are intended to help define CS1's differentiated therapeutic profile and inform its continued clinical development.

With randomized patient treatment now underway, Cereno Scientific has achieved a key operational milestone and is progressing toward the clinical data that will be central to evaluating CS1's potential in PAH.

"Reaching first-patient dosing is a significant achievement for Cereno Scientific and our lead clinical development program. It marks the transition from extensive preparations to randomized patient treatment and delivers on an important near-term priority. We have built an encouraging clinical foundation for CS1 through Phase IIa and the subsequent Expanded Access Program, and EPIMODE is the next important step in evaluating that potential in a larger, controlled trial. What makes CS1 particularly promising is its potential to offer a different approach to PAH treatment by targeting the underlying mechanisms that drive disease progression. EPIMODE is designed not only to evaluate efficacy and identify the optimal dose, but also to investigate the durability of treatment effects and further assess CS1's disease-modifying potential. Our focus is

now on expanding patient recruitment and advancing toward the clinical results that will guide the next stage of CS1's development. Ultimately, our goal is to develop a treatment that can extend and enhance the lives of people living with this serious and progressive disease," said Sten R. Sörensen, CEO of Cereno Scientific.

Next milestones in EPIMODE

Cereno Scientific continues to advance site activation and recruitment preparations across the planned clinical sites in North America, Europe and South America. The Company expects up to 15 clinical sites to be activated by the end of 2026 and more than half of the planned global site network by the end of Q1 2027.

Based on the current site activation and recruitment plan, the Company continues to target completion of patient recruitment during 2027 and topline results in Q4 2028, subject to recruitment progress and securing the financing required to execute the trial as planned.

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This information is information that Cereno Scientific is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-11-18 19:00 CET.

About the EPIMODE trial
EPIMODE is a global, randomized, double-blind, placebo-controlled, dose-finding Phase IIb trial designed to evaluate the efficacy of CS1 when added to standard of care and identify the optimal dose for continued development, alongside evaluating safety and tolerability and further assessing CS1's potential disease-modifying effects. The primary endpoint is pulmonary vascular resistance (PVR) measured after the first treatment period of nine months. PVR is a key measure of resistance in the blood vessels of the lungs and is a fundamental measure in PAH, where increased pulmonary resistance and pressure place strain on the right side of the heart. Other measures will also be evaluated including right-heart function, functional capacity, risk evaluation, biomarker changes, clinical worsening, patient-reported outcomes, and pharmacokinetics. A differentiated two-stage trial design is utilized that enables the assessment of how treatment effects develop following continued CS1 treatment or a switch between CS1 and placebo, providing additional insights into the potential durability of CS1's disease-modifying treatment profile. The trial is designed to enroll approximately 126 patients across approximately 68 investigational sites in 12 countries in North America, Europe and South America. The top-line results are anticipated in Q4 2028, subject to recruitment timelines. The Phase IIb trial has been named EPIMODE, reflecting the scientific foundation of the CS1 program and Cereno Scientific's focus on epigenetic modulation in cardiopulmonary diseases. More information is available on Clinicaltrials.gov: **NCT07761572**.

About CS1

CS1 is Cereno Scientific's lead clinical-stage drug candidate, an HDAC inhibitor acting through epigenetic modulation with a novel therapeutic approach targeting underlying disease-driving mechanisms in pulmonary arterial hypertension (PAH), including vascular remodeling, fibrosis and inflammation. CS1 is being developed as an oral, once-daily, potentially disease-modifying treatment for PAH, intended for use as an add-on to standard of care. In a completed Phase IIa trial, CS1 demonstrated a favorable safety and tolerability profile together with efficacy signals suggesting improvements in right-heart function, functional class, risk score and patient quality of life. The data also provided early signs consistent with reverse vascular remodeling, a finding that supports CS1's potential to address underlying drivers of disease progression in PAH. Long-term follow-up data from the completed 12-month Expanded Access Program (EAP) confirmed a favorable safety and tolerability profile over up to 15 months of treatment experience, consistent with observations in the Phase IIa trial, and showed that a majority of patients completing treatment maintained or improved clinical status. CS1 is currently being evaluated in the EPIMODE trial, a larger, placebo-controlled global Phase IIb trial. CS1 has been granted Orphan Drug Designation (ODD) by the FDA and the European Commission for the treatment of PAH, as well as FDA Fast Track designation.

About Cereno Scientific AB

Cereno Scientific is pioneering treatments to enhance and extend life. The company’s innovative pipeline offers disease-modifying drug candidates to empower people suffering from rare cardiovascular and pulmonary diseases to live life to the fullest.

Lead candidate CS1 is an HDAC inhibitor that works through epigenetic modulation and represents a novel therapeutic approach by targeting the underlying mechanisms of pulmonary arterial hypertension (PAH). CS1 is a well-tolerated oral therapy with a favorable safety profile that has shown encouraging efficacy signals in a Phase IIa trial in patients with PAH, including improvements in right heart function, functional class, risk score and patient quality of life, with early signs consistent with reverse vascular remodeling. An Expanded Access Program confirmed CS1 to be well-tolerated with a favorable safety profile over 12 months of treatment and showed that a majority of patients completing treatment maintained or improved clinical status. CS1 is currently being evaluated in EPIMODE, a global, placebo-controlled Phase IIb trial in PAH. CS014 is a new chemical entity and HDAC inhibitor with a multimodal mechanism of action as an epigenetic modulator having the potential to address the underlying pathophysiology of a range of cardiovascular and pulmonary diseases with high unmet needs. CS014 showed a favorable safety and tolerability profile in Phase I, and is being advanced through a streamlined, FDA-aligned pathway toward Phase IIb in pulmonary hypertension associated with interstitial lung disease (PH-ILD). Cereno Scientific is also advancing the preclinical program CS585, an oral, highly potent and selective prostacyclin (IP) receptor agonist shown to prevent thrombosis without increased bleeding risk, currently being evaluated in antiphospholipid syndrome (APS).

The Company is headquartered in GoCo Health Innovation City in Gothenburg, Sweden, and has a US subsidiary, Cereno Scientific Inc., located in Kendall Square, Boston. Cereno Scientific is listed on the Nasdaq First North (CRNO B). The Company’s Certified Adviser is DNB Carnegie Investment Bank AB, **certifiedadviser@carnegie.se**. More information can be found on **www.cerenoscientific.com**.

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