PRESS RELEASE
13 August 2026 08:00:00 CEST

Cereno Scientific

Cereno Scientific Activates First Clinical Site in Global Phase IIb EPIMODE Trial of CS1 in PAH, Enabling Patient Recruitment

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 clinical site has been activated in the Company's global Phase IIb EPIMODE trial evaluating lead drug candidate CS1 in pulmonary arterial hypertension (PAH). The extensive study preparations are now translating into site-level clinical execution, with the first EPIMODE site operationally cleared to begin screening and recruitment. This marks a concrete step toward first patient randomization and dosing and establishes the foundation for recruitment capacity to expand as additional specialist PAH centers are activated.

Potential participants can now enter the screening process, during which they are assessed against the trial's eligibility criteria and, if eligible, may proceed to randomization and first dosing. Further regulatory and site-level preparations, submissions and activations will continue across the planned global clinical network. As additional specialist PAH centers become active, recruitment capacity is expected to expand across the global network, enabling patient identification, screening and subsequent randomization to progress at an increasing number of sites. Top-line results are anticipated in Q4 2028, based on the planned recruitment timeline.

"Activating the first clinical site is an important operational step that enables patient screening to begin in the EPIMODE trial. Despite important advances in the treatment of PAH, there remains a need for therapies that go beyond managing symptoms and hemodynamics and address the underlying disease biology. With EPIMODE, we aim to rigorously evaluate whether CS1's epigenetic approach can contribute to that next step. Building on the encouraging observations from our Phase IIa trial and Expanded Access Program, the study is designed not only to assess efficacy and dose response, but also to deepen our understanding of CS1's potential disease-modifying effects. The strong engagement from participating PAH investigators during our investigator meeting reinforces our belief that this is an important scientific question for the field," said Rahul Agrawal, CMO and Head of R&D at Cereno Scientific.

From study preparation to active trial execution
Since obtaining clearance to start the Phase IIb trial from the FDA in December 2025, Cereno Scientific, its contract research organization (CRO) and other partners have undertaken an intensive, sustained and highly coordinated effort to complete the extensive regulatory, contractual, logistical and site-level work to enable active patient recruitment in the EPIMODE trial.

For each participating site, this work includes regulatory and ethics approvals, clinical site agreements, investigator onboarding and training, clinical supply and laboratory logistics, data systems set-up and confirmation that participating sites are operationally cleared to identify, screen and randomize potential patients. Many of these activities must be completed sequentially at the individual site level before patient recruitment can begin.

Activation of the first clinical site demonstrates that the extensive study preparations have successfully translated into operational clinical capacity. At the same time, preparations and activation activities continue for planned clinical sites across the global trial network. As further centers become active, patient identification, screening, randomization and treatment will progressively accelerate.

This is the point at which the extensive work carried out since the completion of the Phase IIa trial, including a Type C meeting with the FDA, protocol development and obtaining Fast Track designation, begins to translate into trial execution.

In practical terms, the first activated site is now operationally cleared to begin the identification and screening of potential patients for participation in the EPIMODE trial. This is the first step in establishing recruitment capacity across the global EPIMODE clinical site network and moves the trial toward first patient randomization and dosing.

Preparation and execution supported by a top-tier global CRO
Following an extensive procurement process, Cereno Scientific selected an industry-leading global contract research organization (CRO) with substantial experience in PAH clinical trials. The CRO brings disease-area expertise, an established network of experienced investigators, access to well-characterized patient populations, and the global infrastructure required to support a study of EPIMODE's scope.

This expertise is particularly important in a rare disease such as PAH, where effective study execution depends on identifying specialist centers with relevant clinical expertise, access to potential participants and the operational experience to screen, randomize, treat and retain patients in accordance with the study protocol.

The EPIMODE trial is further supported by Professor Marc Humbert, one of the world's leading experts in PAH, with decades of experience in patient care, clinical research, and international treatment guidelines development. He serves as the trial's principal investigator (PI) and Chair of its Clinical Steering Committee, which includes additional internationally recognized experts in PAH and cardiovascular disease who provide guidance and support to the trial.

Together with the CRO, Cereno is implementing a site strategy designed to prioritize experienced PAH centers with appropriate patient access and recruitment potential. The objective is to support high-quality clinical execution and progressively expand recruitment capacity and execution as additional clinical sites complete activation.

Clinical foundation of EPIMODE
EPIMODE builds on two important sets of clinical observations: the completed Phase IIa trial and the completed 12-month Expanded Access Program (EAP). In the 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, as well as early signs consistent with reverse vascular remodeling.

The EAP provided additional long-term treatment experience with CS1 and met its primary endpoint of safety and tolerability. A majority of patients who completed 12 months of treatment maintained or improved their clinical status, while the favorable safety and tolerability profile remained consistent with the Phase IIa observations. In a progressive disease such as PAH, where patients worsen over time despite available treatment, these longer-term observations are supportive and strengthen the rationale for evaluating CS1 in the larger, randomized and placebo-controlled EPIMODE trial.

A unique Phase IIb design built to assess dose, efficacy and disease-modifying potential
EPIMODE is a global, randomized, double-blind, placebo-controlled and dose-finding Phase IIb trial evaluating CS1 as an add-on to stable standard of care treatment in patients with PAH. The trial is designed to evaluate efficacy, safety and tolerability, determine the optimal dose for further development, and provide additional insight into CS1's potential disease-modifying effects.

The trial name EPIMODE reflects the company's scientific focus on epigenetic modulation in cardiopulmonary diseases, and the trial's objective to evaluate CS1's effects on the mechanisms involved in the underlying disease biology of PAH.

The study uses a differentiated two-stage design. During the first treatment period of 9 months, participants are assigned to one of two CS1 dose levels or placebo. Participants are subsequently re-randomized in the second period: those initially receiving CS1 may continue treatment or switch to placebo, while those initially receiving placebo transition to either of the two doses of active CS1 treatment. This design means that all participants receive active treatment during part of the study. It also enables Cereno to assess how treatment effects develop following continued CS1 treatment or a switch between CS1 and placebo, providing additional insights into the potential of CS1's disease-modifying effects.

The primary endpoint in the trial is change in pulmonary vascular resistance (PVR) measured by right-heart catheterization after the first treatment period of 9 months. PVR is a central hemodynamic measure in PAH, reflecting the resistance to blood flow through the pulmonary circulation and the strain placed on the right side of the heart. The study will also evaluate other measures including right-heart function, functional capacity, risk evaluation, biomarker changes, clinical worsening, patient-reported outcomes, and pharmacokinetics. The study period is 56 weeks.

Strengthened strategic value and continued momentum
Activation of the first clinical site represents an important operational value inflection point for CS1 and enables the start of screening and recruitment of patients for the EPIMODE trial. It demonstrates that the extensive start-up activities are translating into execution and advances the program toward generating randomized and controlled clinical data needed to further define CS1's clinical profile, with the aim of reducing remaining clinical uncertainty and support continued development and partnering activities. This strengthens CS1's clinical maturity, strategic value and relevance in ongoing discussions with potential partners and in the evaluation of broader strategic opportunities. Together, these developments position CS1 for a period of increasing clinical activity as the EPIMODE trial progresses through additional site activations, patient recruitment and toward first patient randomization and dosing.

This operational progress comes at a strategically important time for Cereno Scientific, as CS1 advances toward randomized Phase IIb treatment while the Company's financial flexibility and partnering position have strengthened. The recently completed SEK 60 million directed share issue at a premium has strengthened the Company's financial flexibility and negotiating position, enabling the Company to continue advancing its programs from a position of greater strength while partnering discussions progress. At the same time, the completion of dosing and participant visits in CS014's FDA-aligned PK-bridging study has created an additional potential near-term value driver and further strengthened the depth and strategic relevance across Cereno's HDAC inhibitor platform.

"This is an important and long-awaited operational milestone for Cereno Scientific, for our lead program and largest value driver CS1, and ultimately, for people living with PAH. Activation of the first clinical site demonstrates that the extensive planning and preparations required to initiate a larger, randomized and placebo-controlled Phase IIb trial are now translating into site-level clinical execution. The activated site can now begin screening and recruitment, moving the EPIMODE trial toward first patient randomization and dosing while also additional sites progress toward activation. Together with our strengthened financial position, ongoing partnering activities and progress across the pipeline, this reinforces Cereno Scientific's momentum as we enter an active period of operational and clinical milestones," said Sten R. Sörensen, CEO of Cereno Scientific.

For further information, please contact:
Tove Bergenholt, Head of IR & Communications
Email: **tove.bergenholt@cerenoscientific.com**
Phone: +46 73- 236 62 46

About the EPIMODE trial
EPIMODE is a global, randomized, double-blind, placebo-controlled, dose-finding Phase IIb trial that will evaluate the efficacy, safety and tolerability of CS1 when added to standard of care, while also further assessing CS1's potential disease-modifying effects and identifying the optimal dose for continued development. The primary endpoint is pulmonary vascular resistance (PVR) measured after a 9-month treatment period. PVR is a central hemodynamic measure in PAH, reflecting the resistance to blood flow through the pulmonary circulation and the strain placed on the right side of the heart. By using PVR as the primary endpoint, EPIMODE is designed to further evaluate whether CS1 may impact important disease-driving mechanisms in PAH. 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 Clinicaltrial.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. 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**.