

Cereno Scientific expects up to 15 sites to be activated by year-end 2026 in the global Phase IIb EPIMODE trial; maintains Q4 2028 timeline for topline results

Cereno Scientific (Nasdaq First North: CRNO B), an innovative biotech pioneering treatments to enhance and extend life for people with rare cardiovascular and pulmonary diseases, today provides an update on the global Phase IIb EPIMODE trial evaluating lead drug candidate CS1 in pulmonary arterial hypertension (PAH). Up to 15 clinical sites are expected to be activated by year-end 2026 as the global trial continues to expand across North America, Europe and South America. Based on the current site activation and recruitment plan, Cereno Scientific continues to anticipate topline results in Q4 2028.

Randomization of the first patient in EPIMODE has taken longer than initially anticipated following a prolonged trial start-up phase. An unforeseen patient-related event also contributed to the delay: a patient scheduled for randomization experienced a fall and was hospitalized the day before the scheduled visit. The event occurred before any study treatment had been administered.

In parallel, activation of additional sites continues to expand the EPIMODE trial's recruitment capacity. Based on the current site activation and recruitment plan, Cereno Scientific continues to target completion of recruitment during 2027 and topline results in Q4 2028.

While the first patient randomization, also referred to as First Patient In (FPI), is an important operational milestone for EPIMODE, the timing of the trial's topline results is driven by recruitment performance across all participating sites and when the last patient is randomized.

"The expansion of the number of sites activated in the EPIMODE trial marks an important period of execution for our lead CS1 program. With up to 15 sites expected to be activated by the end of 2026, and more site activations planned globally thereafter, our focus is on translating site activation into patient identification, screening, and randomization. EPIMODE is designed to build on the encouraging signals observed with CS1 to date and further define CS1's clinical potential in a global, randomized, placebo-controlled Phase IIb trial. Based on the current plan, we continue to target completion of recruitment during 2027 and anticipate topline results in Q4 2028," said Sten R. Sørensen, CEO of Cereno Scientific.

Key milestones of the global EPIMODE trial

- Up to 15 clinical sites are expected to be activated by year-end 2026.
- More than 50% of the planned global clinical sites are expected to be activated by the end of Q1 2027.
- Patient recruitment is planned to be completed during 2027.
- Topline results continue to be anticipated in Q4 2028.

Why the expanding site network matters

As additional specialist PAH centers become operational, the global site network available to identify, screen and randomize eligible patients will increasingly broaden. This planned expansion supports Cereno Scientific's objective of completing patient recruitment during 2027 and reporting topline results in Q4 2028.

EPIMODE is a global, randomized and placebo-controlled Phase IIb trial 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. Progress in building the global recruitment network is therefore directly relevant to advancing CS1 toward its next major clinical data readout.

Global site activations progressing across three regions

Regulatory and site-level preparations are progressing across North America, Europe and South America. In Europe, site activations are anticipated to begin in Q4 2026, subject to regulatory approval. In South America, where clinical trial authorization is conducted through national regulatory processes, the first country is expected to begin site activation in Q4 2026, subject to regulatory approval. These activities are progressing alongside ongoing trial execution in North America.

Cereno Scientific is conducting the EPIMODE trial together with an experienced global contract research organization (CRO), investigators and specialist PAH centers.

EPIMODE is led by Professor Marc Humbert, Principal Investigator and Chair of the Clinical Steering Committee, together with Professor Sandeep Sahay, University of Houston, as Committee Co-Chair.

"Our focus is on ensuring that each participating center is positioned to effectively identify, screen and randomize eligible patients once activated. As the number of operational specialist PAH centers increases, so does the network available to support recruitment performance in the EPIMODE trial," said Rahul Agrawal, CMO and Head of R&D at Cereno Scientific.

What EPIMODE is designed to evaluate

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 primary endpoint is change in pulmonary vascular resistance (PVR) after the first treatment period of nine months. PVR measures the resistance to blood flow through the pulmonary circulation and the strain placed on the right side of the heart.

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

In addition to PVR, the study will evaluate right-heart function, functional capacity, risk evaluation, biomarker changes, clinical worsening, patient-reported outcomes and pharmacokinetics. The total study period is 56 weeks.

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 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](https://clinicaltrials.gov/ct2/show/study/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.