PRESS RELEASE
07 July 2026 11:00:00 CEST

Cereno Scientific

Cereno Scientific Completes All Dosing and Participant Visits in CS014's FDA-Aligned PK-Bridging Study, Advancing Capital-Efficient Path Toward Phase IIb in PH-ILD

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 announced that the active treatment period of the Phase I pharmacokinetic (PK) bridging study of the Company's novel HDAC inhibitor CS014 has been completed. The last healthy volunteer has completed their last visit in the study. The study will now proceed through data management, database lock and analysis, with topline results anticipated in Q3 2026 providing an important value inflection point for the CS014 program.

The completion of all dosing and participant visits marks an important operational and strategic milestone for CS014. The FDA-aligned study is designed to support a direct, time-saving and capital-efficient development path toward a Phase IIb trial in pulmonary hypertension associated with interstitial lung disease (PH-ILD). With positive topline results from this study supporting the intended bridging strategy, Cereno Scientific believes CS014 may advance to Phase IIb without the need for additional non-clinical safety studies and a Phase IIa trial, which would reduce development time, cost and complexity.

"Completing the last participant visit is an important operational milestone for the CS014 program," said Rahul Agrawal, CMO and Head of R&D at Cereno Scientific. "The study is designed to characterize CS014's pharmacokinetic profile and provide data that supports the intended bridging regulatory strategy. These results are expected to provide an important regulatory and clinical foundation for advancing CS014 directly toward Phase IIb in PH-ILD while reducing development time, cost and risk."

The PK-bridging study evaluates how CS014 behaves in the body and whether its exposure profile can be compared with an established reference compound. In this study, CS014 is compared with valproic acid (VPA), a well-established HDAC inhibitor with extensive clinical use. The relevance for Cereno Scientific is that supportive study results may allow the company to leverage existing scientific and clinical knowledge around VPA and HDAC inhibition while advancing CS014 as a proprietary, next-generation, precision deuterated new chemical entity. This is what may enable the program to efficiently progress toward Phase IIb without additional non-clinical safety studies and Phase IIa study that is traditionally needed.

"For shareholders, the significance of this milestone lies in what the study is designed to enable: a potentially shorter, less expensive and more direct route toward efficacy evaluation in PH-ILD. The potential value is concentrated in four areas: a near-term Q3 2026 readout, a more capital-efficient route toward Phase IIb, a strengthened second clinical HDAC inhibitor program alongside CS1, and exposure to a substantial PH-ILD opportunity with an estimated market size of over USD 6 billion by 2032, and revenue potential at more than USD 3 billion," said Sten R. Sörensen, CEO at Cereno Scientific. "We are pleased to progress the CS014 program on the back of the recently completed directed share issue of SEK 60 million at a premium to the latest closing price, strengthening our financial flexibility ahead of the next value-driving phase.

CS014 is a proprietary precision deuterated HDAC inhibitor and a new chemical entity designed to optimize pharmacokinetic properties and metabolic stability. The drug candidate targets disease-driving mechanisms, including vascular remodeling, fibrosis, inflammation and thrombosis, central in a range of rare cardiopulmonary diseases such as IPF/PPF, PH-COPD, PH-LHD, PH-HFpEF and MASH. This supports a broader “pipeline-in-a-drug” opportunity beyond the initial PH-ILD focus.

Cereno Scientific is building a differentiated clinical-stage HDAC inhibitor platform with disease-modifying potential in rare cardiopulmonary diseases with drug candidates CS1 advancing in Phase IIb development in PAH and CS014 moving toward Phase IIb in PH-ILD. The strategic value of having two Phase IIb-oriented HDAC inhibitor programs is significant. It provides pipeline depth, reduces dependency on a single asset and creates multiple opportunities to generate clinical data in diseases with high unmet medical need. Importantly, it further positions Cereno Scientific as more than a single-asset biotech; it strengthens the company’s profile as a clinical-stage company with several potential paths to value creation.

This is precisely the type of profile that potential partners, including Big Pharma business development teams and specialist life science investors, actively look for: clinical maturity, a differentiated mechanism, strong IP, platform scalability, clear value inflection points and multiple shots on goal. The anticipated results from the PK-bridging study in Q3 2026 could strengthen CS014 as a strategic pipeline asset, and further enhance the attractiveness and perceived strategic value of Cereno’s broader HDAC inhibitor platform in partnering, business development and investor activities.

The “PK bridging” study is a clinical Phase I, open-label, randomized, two-period crossover pharmacokinetic (PK) trial in 14 healthy volunteers. The study is conducted in Sweden. The study evaluates steady-state pharmacokinetics following seven days of repeat oral dosing of CS014 compared to valproic acid (VPA), a well-established HDAC inhibitor. The primary objective is to characterize total and unbound plasma concentrations of CS014 at steady state compared to VPA.

Following supportive results from the PK-bridging study, Cereno Scientific will progress with the preparations for regulatory activities during H2 2026, including the submission of an IND (Investigational New Drug) application to the FDA ahead of a planned Phase IIb study in 2027.

** Formal clinical trial name: A phase 1, open label, randomised, 2-period, 2 sequence, 7-days repeat-dosing, crossover oral pharmacokinetic trial comparing multiple dosing of CS014 to valproic acid in healthy adults.*

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About CS014

CS014 is a new chemical entity, being developed as a next-generation (precision deuterated) histone deacetylase (HDAC) inhibitor and novel chemical entity designed to modulate epigenetic pathways that target the root mechanisms of several cardiovascular and pulmonary diseases. Non-clinical studies have demonstrated potent effects on pathways involved in vascular remodeling, fibrosis and thrombosis, which are key drivers of disease progression in several cardiovascular and pulmonary conditions and suggests disease-modifying potential (**Stanger, L. et al (2025**). The recently completed Phase I study confirmed that CS014 has a favorable safety profile and is well tolerated at and above exposure levels that, based on non-clinical data, are predicted to support maximal effects on the reversal of pulmonary vascular remodeling and fibrosis. These findings support advancement of CS014 into Phase II with an initial development focus of pulmonary hypertension associated with interstitial lung disease (PH-ILD). The company's HDACi portfolio is protected until 2045/46, excluding potential patent term extensions.

CS014 is strategically important both as an individual drug candidate, and as part of Cereno Scientific's broader HDAC inhibitor platform. The candidate's proprietary and precision deuterated design is intended to combine the biological relevance of HDAC/VPA-based mechanisms with optimized pharmacokinetic properties and metabolic stability.

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 root mechanisms of the 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 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 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. based in Kendall Square, Boston, Massachusetts, US. 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**.