Press release
July 15, 2025

Cereno Scientific

Cereno Scientific announces positive topline results from Phase I trial of CS014 – a novel HDAC inhibitor – supporting advancement into Phase II

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 positive topline results from its Phase I trial of CS014, a novel HDAC inhibitor in development for idiopathic pulmonary fibrosis (IPF). The trial confirms a favorable safety and tolerability profile, and data support further clinical evaluation. Based on the findings, preparations are underway to initiate a Phase II trial.

“We are very pleased with the outcome of this study and the excellent collaboration with the CRO CTC. CS014 was well-tolerated and showed favorable safety in healthy volunteers. Notably, CS014 was safe and well tolerated at exposure levels that are expected to be sufficient to impact pathological pulmonary vascular remodeling and reduction of fibrosis — key drivers in several rare cardiovascular and pulmonary diseases. These findings position CS014 as a promising candidate in IPF and other rare diseases involving vascular remodeling and fibrosis,” said Rahul Agrawal, CMO and Head of R&D at Cereno Scientific.

The Phase I trial evaluated safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single and multiple ascending oral doses of CS014 in healthy volunteers. The trial was conducted in two parts: part one explored safety, tolerability and PK of single ascending oral doses (SAD) of CS014; part two explored safety, tolerability, PK, and PD following multiple ascending doses (MAD) of CS014, dosed for seven days. In total, 48 subjects were included in the trial, 30 in the SAD and 18 in the MAD part. The trial was conducted by CTC in Uppsala, Sweden.

Summary of the topline results from the Phase I trial:

- CS014 demonstrated favorable safety and tolerability in healthy volunteers.
- All 48 healthy volunteers completed the study; no early withdrawals or deaths were reported.
- No serious adverse events (SAEs) occurred.
- All treatment-related adverse events (AEs) reported were mild, transient, and fully recovered.
- CS014 achieved levels in the blood stream at and above those projected, based on non-clinical data, to be required for achieving maximal effects on reversal of pulmonary vascular remodeling and fibrosis.
- These findings, combined with non-clinical data demonstrating a favorable impact on plexiform lesions in the Sugen/Hypoxia rat model, offer insights that support dose selection and support advancement into Phase II development.

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"CS014 is a novel HDAC inhibitor with a unique mechanism of action through epigenetic modulation that could represent a differentiated treatment approach for IPF. These positive Phase I results, combined with strong non-clinical data, give us confidence as we advance into Phase II clinical development. CS014 is a cornerstone of our broader HDAC inhibitor portfolio, which we believe holds significant disease-modifying potential across a range of rare cardiovascular and pulmonary diseases. We are excited to continue pioneering treatments to improve the lives of patients in these diseases with high unmet medical needs," said Sten R. Sörensen, CEO at Cereno Scientific.

The company is advancing plans to prepare for a Phase II trial initiation in H1 2026. Full results from the Phase I trial will be submitted for publication in a peer-reviewed scientific journal.

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This information is information that Cereno Scientific AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 12:55 CET on July 15, 2025.

About CS014

CS014 is a proprietary new chemical entity and a HDAC inhibitor. Being an epigenetic modulator, with a multimodal mechanism of action, CS014 has the potential to target the underlying pathophysiology of several rare cardiovascular and pulmonary diseases with high unmet medical needs. The initial target is idiopathic pulmonary fibrosis (IPF). In non-clinical studies, CS014 has demonstrated strong effects on vascular remodeling and fibrosis, suggesting disease-modifying potential. The findings from the Phase I trial will inform the next steps in advancing CS014 as a potential new treatment for patients with severe, progressive diseases that currently lack effective therapies. Preparations and studies are underway to support the transition to a Phase II trial of CS014.

About Cereno Scientific AB

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

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 of reverse vascular remodeling and improvement of right heart function as observed in a Phase IIa trial in patients with PAH. An Expanded Access Program enables patients that have completed the Phase IIa trial to gain access to CS1. CS014, in Phase I development, is a new chemical entity with disease-modifying potential. CS014 is a HDAC inhibitor with a multimodal mechanism of action as an epigenetic modulator having the potential to address the underlying pathophysiology of rare cardiovascular and pulmonary diseases with high unmet needs such as idiopathic pulmonary fibrosis (IPF). Cereno Scientific is also pursuing a preclinical program with

CS585, an oral, highly potent and selective prostacyclin (IP) receptor agonist that has demonstrated the potential to significantly improve disease mechanisms relevant to cardiovascular diseases. While CS585 has not yet been assigned a specific indication for clinical development, preclinical data indicates that it could potentially be used in indications like Thrombosis prevention without increased risk of bleeding and Pulmonary Hypertension.

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.