

Cereno Scientific Confirms First Volunteer Dosed in CS014 PK-bridging Study Supporting Phase II Development 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 first healthy volunteer has been dosed in the Phase I pharmacokinetic (PK) bridging study of the company's novel HDAC inhibitor CS014. The FDA-aligned study is designed to support the continued clinical development of CS014 and a streamlined pathway toward a Phase IIb trial in pulmonary hypertension associated with interstitial lung disease (PH-ILD) starting in Q1 2027.

The "PK bridging" study is a clinical Phase I, open-label, randomized, two-period crossover pharmacokinetic (PK) trial in 14 healthy adult volunteers. The study is conducted in Sweden. The study will evaluate 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.

"The study is intended to provide important comparative pharmacokinetic data and aim to significantly shorten the clinical development timeline and reduce development costs for CS014," said Rahul Agrawal, CMO and Head of R&D at Cereno Scientific.

CS014 is a proprietary deuterated HDAC inhibitor and a new chemical entity designed to optimize pharmacokinetic properties and metabolic stability while targeting disease-driving mechanisms relevant in rare cardiopulmonary diseases such as vascular remodeling, fibrosis, inflammation and thrombosis.

The PK-bridging study is designed based on feedback received in a pre-IND meeting with FDA and is expected to remove the need for additional non-clinical safety studies and a Phase IIa trial. This supports a streamlined and capital-efficient development pathway toward a planned Phase IIb trial in pulmonary hypertension associated with interstitial lung disease (PH-ILD) starting in Q1 2027.

"This marks an important operational and regulatory milestone for CS014 as we continue advancing the program toward Phase IIb development," said Sten R. Sørensen, CEO of Cereno Scientific. "Dosing of the first volunteer demonstrates the strong execution capabilities of our team and partners and reflects our focused strategy to efficiently advance innovative therapies with disease-modifying potential for patients with rare cardiopulmonary diseases with high unmet medical needs."

Results from the Phase I pharmacokinetic study are expected in mid-2026.

To help investors better understand the Phase I pharmacokinetic trial of CS014, we published an explanatory article on our website in connection to the approval: [read here](#).

* 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).

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 treatment. 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, development focus for Phase II is 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.