

Cereno Scientific Receives Approval to Initiate FDA-aligned Phase I Pharmacokinetic Study of CS014 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 Swedish Medical Products Agency has approved the initiation of a Phase I pharmacokinetic study of CS014. The study is designed based on feedback received in a pre-IND meeting with the U.S. Food and Drug Administration (FDA) and is expected to remove the need for additional safety studies and a Phase IIa trial. This supports a streamlined and capital-efficient development pathway toward the planned Phase II trial in pulmonary hypertension associated with interstitial lung disease (PH-ILD) in Q1 2027.

The approved study is a Phase I, open-label, randomized, two-period crossover pharmacokinetic (PK) trial in 14 healthy adult volunteers. 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.

Following a constructive pre-IND meeting, the FDA indicated that comparative bioavailability data would be acceptable to support the initiation of a Phase IIb trial with CS014. The pharmacokinetic comparison allows Cereno Scientific to leverage the extensive clinical experience with VPA to strengthen the CS014's safety package. A successful trial is expected to remove the need for additional nonclinical safety studies and a clinical Phase IIa trial, allowing Cereno Scientific to progress directly toward Phase IIb preparations.

"This study represents a regulatory aligned and strategically important step in the continued development of CS014," said Sten R. Sørensen, CEO of Cereno Scientific. "By incorporating FDA feedback early, we have designed a focused pharmacokinetic program that supports efficient progression toward our planned Phase IIb study in PH-ILD and enables a more streamlined development pathway toward potential marketing approval. This reflects our capital-efficient and disciplined approach to development and our ambition to bring pioneering treatments to patients faster and with greater probability of success."

CS014 is a precision deuterated HDAC inhibitor and proprietary new chemical entity within Cereno Scientific's differentiated HDAC inhibitor platform. Designed as a multi-modal epigenetic modulator, CS014 aims to optimize pharmacokinetics and metabolic stability while targeting underlying disease mechanisms such as fibrosis, vascular remodeling, inflammation and thrombosis, which are central drivers in several cardiopulmonary diseases.

“CS014 builds on our strong expertise in HDAC inhibition and epigenetic modulation,” said Rahul Agrawal, CMO and Head of R&D at Cereno Scientific. “By generating comparative pharmacokinetic data with VPA, this study allows us to leverage the extensive clinical experience of this HDAC inhibitor class while advancing CS014 toward Phase II development in PH-ILD, a serious condition with limited treatment options.”

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

** 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.*

For further information, please contact:

Tove Bergeholt, Head of IR & Communications
Email: tove.bergeholt@cerenoscientific.com
Phone: +46 73- 236 62 46

About CS014

CS014 is 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 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 and patient quality of life, consistent with reverse vascular remodeling. An Expanded Access Program enables patients that have completed the Phase IIa trial to gain access to CS1. 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 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

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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.

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.