PRESS RELEASE
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Cereno Scientific

Cereno Scientific Reports Positive Topline Results from CS014 Phase I PK-bridging Study, Strengthening Intended Direct 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 positive topline results from the Phase I pharmacokinetic (PK) bridging study of its HDAC inhibitor CS014. The results met the Company's predefined expectations and strengthen the intended regulatory strategy to advance CS014 directly toward Phase IIb without a Phase IIa trial or further non-clinical safety studies, subject to FDA review of the complete IND package. Cereno Scientific plans to submit an IND application to the FDA in Q4 2026, with a Phase IIb trial in PH-ILD anticipated to start in Q3 2027, subject to regulatory approval.

Positive topline results strengthen the intended bridging strategy
The Phase I PK-bridging study design was informed by feedback received from the FDA and conducted to characterize the pharmacokinetic relationship between CS014 and VPA, a well-established HDAC inhibitor with long history of clinical use in neurological conditions.

A pharmacokinetic, or PK, study examines what happens to a drug in the body, including the level of drug exposure over time. The PK-bridging study was an open-label, randomized, two-period crossover trial in 14 healthy volunteers conducted in Sweden. In a crossover study, each participant receives both treatments during separate treatment periods, allowing the pharmacokinetic profiles of CS014 and VPA to be compared within the same participants. The study evaluated steady-state pharmacokinetics following seven days of repeat oral dosing of CS014 and VPA, respectively. Steady state means that drug exposure has reached stable levels across several dosing intervals.

The primary objective was to characterize and compare plasma concentration profiles of CS014 and VPA at steady state. The topline analysis compared the plasma concentration profiles of CS014 and VPA across 14 sampling points.

The observed relationship between the plasma concentration profiles of CS014 and VPA was consistent across the assessed sampling period and aligned with the assumptions underlying Cereno's intended bridging strategy. The results met the Company's predefined expectations and strengthen the Company's plan to include the PK data as part of the Investigational New Drug (IND) package supporting the intended direct progression of CS014 toward a Phase IIb trial.

All 14 participants completed the study. All reported adverse events were mild, none led to study withdrawal, and no serious adverse events occurred. These findings were consistent with the favorable safety and tolerability profile previously observed for CS014 in the first-in-human Phase I study.

More comprehensive results from the study are intended for publication in a peer-reviewed scientific journal in 2027.

“The study achieved its objective of characterizing the steady-state pharmacokinetic relationship between CS014 and VPA, and the observed profiles were consistent with the assumptions underlying our intended bridging strategy,” said Rahul Agrawal, CMO and Head of R&D at Cereno Scientific. “CS014 was also generally well tolerated, with all participants completing the study. These positive results address an important pharmacokinetic question and will form part of the total data package for our planned IND submission and discussions with the FDA regarding progression to Phase IIb.”

What the results mean for CS014’s development path
The significance of the PK-bridging study lies not only in its positive outcome, but in what the results may enable for continued development of CS014.

CS014 is a proprietary, precision-deuterated new chemical entity, while VPA is a well-characterized HDAC inhibitor with a long history of safe clinical use in neurological conditions such as epilepsy. VPA with its extensive human pharmacokinetic and safety data provides a useful, well-characterized benchmark for CS014. The bridging strategy is designed to enable Cereno to leverage existing knowledge and data relating to VPA, potentially avoiding the need to repeat parts of an otherwise more extensive development program.

The bridging strategy is assessed based on the overall pharmacokinetic relationship between CS014 and VPA, rather than whether the study achieves a single predefined PK value. The similarity in plasma concentration profiles observed throughout the assessed sampling period supports the assumptions behind Cereno’s intended development strategy.

The results therefore do more than complete another Phase I development step. It addresses an important pharmacokinetic question, reduces a key area of development uncertainty and strengthens the basis for a more streamlined route into patient-based development.

Based on the results generated to date, Cereno remains confident in its intended strategy to advance CS014 directly into a Phase IIb trial in pulmonary hypertension associated with interstitial lung disease (PH-ILD) without conducting a Phase IIa trial or further non-clinical safety studies. This pathway could allow Cereno to focus time and resources on executing the first controlled patient study, designed to evaluate whether the differentiated profile demonstrated by CS014 in non-clinical and Phase I studies can translate into clinical benefit.

“These positive results reduce an important area of development uncertainty for CS014 and strengthen our intended direct path to Phase IIb. Subject to FDA approval, this pathway could allow us to avoid a Phase IIa trial and further non-clinical safety studies, potentially reducing development time, cost and complexity. We are now moving forward with our planned IND submission and preparations for CS014’s next major clinical milestone,” said Sten R. Sörensen, CEO at Cereno Scientific.

Advancing toward IND submission and Phase IIb

With the important pharmacokinetic question addressed, Cereno Scientific is progressing the regulatory, manufacturing and clinical preparations required for the next stage of CS014's development.

Submission of an IND application to the FDA is planned in Q4 2026. The application will bring together the PK-bridging results with the existing clinical, non-clinical and chemistry, manufacturing and controls (CMC) documentation supporting the proposed Phase IIb program. In parallel, CMC and manufacturing activities are progressing to ensure clinical supply readiness for the planned Phase IIb trial.

The placebo-controlled Phase IIb trial in PH-ILD is planned to be initiated in Q3 2027, subject to necessary regulatory approvals.

The planned study represents the next major clinical milestone for CS014 and will be the first trial designed to evaluate whether the candidate's differentiated profile can translate into clinical benefit for patients with PH-ILD.

The positive PK-bridging outcome therefore establishes a clear sequence of upcoming development milestones: submission and clearance of the IND package, continued CMC and manufacturing readiness and planned initiation of Phase IIb.

Advancing CS014 in a disease with significant unmet medical need

PH-ILD is a serious and progressive condition in which pulmonary hypertension develops in patients with interstitial lung disease, placing additional strain on the heart and contributing to poor outcomes.

Despite the severity of the disease, treatment options remain very limited with only one treatment currently approved for PH-ILD in the US and none in Europe. This highlights a significant unmet need for new therapeutic options.

Cereno believes CS014's multimodal mechanism of action may be particularly relevant in pulmonary hypertension associated with interstitial lung disease (PH-ILD).

As a precision-deuterated HDAC inhibitor and epigenetic modulator, CS014 is designed to target several interconnected mechanisms involved in cardiopulmonary disease progression, including fibrosis (tissue scarring), pathological vascular remodeling (harmful changes to the blood vessels in the lungs), inflammation and thrombosis (blood clot formation).

Rather than focusing solely on symptom management, CS014 is designed to target several underlying biological processes associated with disease progression.

In the completed first-in-human Phase I study, CS014 demonstrated a favorable safety and tolerability profile in healthy volunteers. All participants completed the study, no serious adverse events occurred, and all treatment-related adverse events were mild, transient and fully resolved.

The Phase I study also showed that CS014 achieved blood concentrations at and above levels projected from non-clinical data to support maximal effects on the reversal of pulmonary vascular remodeling and fibrosis. Together with non-clinical findings demonstrating effects across several disease-driving mechanisms, these results provide the scientific and clinical rationale for advancing CS014 into patient-based development.

The planned Phase IIb trial in PH-ILD will be the first study designed to evaluate translation of CS014's differentiated profile into clinical benefit for patients.

Beyond PH-ILD, the multimodal mechanism of CS014 provides a scientific rationale for its potential application across other cardiovascular and pulmonary diseases in which fibrosis, vascular remodeling, inflammation and thrombosis contribute to disease progression.

Strengthening Cereno’s clinical HDAC inhibitor portfolio
Advancing CS014 toward Phase IIb will further strengthen Cereno Scientific's position as a multi-asset clinical-stage company.

CS014 complements lead candidate CS1, which is currently being evaluated in the global Phase IIb EPIMODE trial in pulmonary arterial hypertension (PAH).

CS1 and CS014 are distinct drug candidates with different formulations, indications and development paths, but share a scientific foundation in HDAC inhibition and epigenetic modulation. Both candidates are designed to address underlying biological mechanisms associated with disease progression rather than focusing solely on symptom management. Cereno's HDAC inhibitor portfolio is protected until 2045/46, excluding potential patent term extensions.

The progression of CS014 will give Cereno two differentiated clinical HDAC inhibitor programs advancing in separate rare cardiopulmonary indications. This provides greater pipeline depth, broadens the Company’s clinical opportunity and creates multiple opportunities to generate clinical data. It also enables the Company to evaluate the potential of epigenetic modulation across different diseases.

For further information, please contact:
Tove Bergenholt, Head of IR & Communications
Email: **tove.bergenholt@cerenoscientific.com**
Phone: +46 73- 236 62 46

This information is information that Cereno Scientific is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-09-25 10:14 CEST.

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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.

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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**.