Press release
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Cereno Scientific

Cereno Scientific Reports Favorable Safety and Tolerability After 12 Months of CS1 Treatment in PAH from the Expanded Access Program

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 initial learnings from the 12-month Expanded Access Program (EAP) with its lead drug candidate CS1 in pulmonary arterial hypertension (PAH). The data confirm a favorable safety and tolerability profile over long-term treatment, consistent with previous Phase IIa results, further strengthening the value proposition of CS1 as an oral, once-daily potentially disease-modifying therapy.

The Expanded Access Program (EAP) enrolled ten patients who had completed the Phase IIa trial, enabling continued treatment with CS1 under physician supervision. Initial learnings from the completed 12-month treatment period show that CS1 was well tolerated, with no unexpected safety concerns observed. No deaths were reported, and no discontinuations were reported to be related to CS1. Six out of ten patients completed the full 12 months of continuous treatment with CS1. Of the remaining patients, two discontinued CS1 treatment following atrial fibrillation events, which was assessed as not related to CS1; one withdrew consent, and one was lost to follow-up.

“These results provide important confirmation that the favorable safety and tolerability profile observed in the Phase IIa trial is maintained over longer-term use. In PAH, where existing therapies can be associated with safety and tolerability challenges, there remains a significant unmet need for safer, well-tolerated treatment options. These findings support the continued development of CS1 as a potential disease-modifying therapy,” said Rahul Agrawal, CMO and Head of R&D of Cereno Scientific.

The EAP was conducted under a formal FDA protocol and initiated following requests from patients and physicians. It enabled the generation of additional long-term data beyond the three-month Phase IIa trial, which had demonstrated that CS1 had favorable safety and tolerability and showed encouraging efficacy signals, including improvements in right heart function, functional class and patient quality of life, with signs consistent with reverse vascular remodeling. Together, the Phase IIa trial and the EAP provide up to 15 months of treatment experience in patients, further strengthening the overall clinical understanding of CS1 in PAH.

“The accumulated clinical Phase II data representing up to 15 months of treatment with CS1 in patients with PAH, provides us with further confidence in our goal to develop and deliver CS1 as a new treatment for patients with PAH. The results from the EAP study support the value proposition of CS1 as an oral, once-daily PAH therapy with a favorable safety and tolerability profile and potential disease-modifying effects,” said Sten R. Sörensen, CEO of Cereno Scientific.

The EAP was initiated following positive results of the Phase IIa trial, which evaluated the safety, tolerability, pharmacokinetics, and exploratory efficacy of CS1 on top of standard therapy in patients with PAH. The Phase IIa trial was conducted at 10 US clinics over 3 months with a total of 25 patients of which 21 were evaluated for efficacy parameters. The trial successfully met its primary endpoint of safety and tolerability, with no drug-related serious adverse events. Encouraging efficacy signals were observed in the trial, including improvements in right heart function, functional class and patient quality of life, with early signs consistent with reverse vascular remodeling. Preparations for a larger, placebo-controlled global Phase IIb study of CS1 in PAH are ongoing, with first patient enrollment anticipated in June 2026.

Further analyses from the EAP, including results from the exploratory imaging sub-study using Fluidda's technology, are planned to be communicated during Q2 2026.

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About PAH

PAH is a rare, progressive and life-threatening disease characterized by high blood pressure in the pulmonary arteries that leads to right heart failure and premature death. Current standard treatments mainly focus on managing symptoms, leaving a significant unmet need for disease-modifying therapies that can change the course of disease and improve long-term outcomes.

About CS1

CS1 is an orally administered histone deacetylase inhibitor (HDACi) in development as a well-tolerated, disease-modifying therapy for pulmonary arterial hypertension (PAH) with favorable safety profile. Acting through epigenetic modulation, CS1 targets key disease-driving mechanisms such as vascular remodeling, fibrosis and inflammation. CS1 has shown disease-modifying potential in early clinical evaluation and is being evaluated as an add-on (on top of standard-of-care) therapy with the potential to improve outcomes for patients with high unmet medical needs. It has been granted Orphan Drug Designation (ODD) in both the U.S. and the EU and received Fast Track designation from the U.S. FDA in August 2025, underscoring its potential to address a serious condition with high unmet medical need.

CS1 has first-in-class potential and is currently in preparation for a global Phase IIb trial.

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 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 yet been assigned a specific indication for clinical development, preclinical data indicates that it could potentially be used in rare thrombotic diseases.

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.