Press release
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Cereno Scientific

Cereno Scientific Highlights Strategic Value of Meeting Primary Endpoint of Safety and Tolerability of 12-month CS1 Data in PAH

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 provides additional context on the safety and tolerability data from up to 12 months of treatment from the Expanded Access Program (EAP) with CS1 in pulmonary arterial hypertension (PAH). Safety and tolerability were the primary endpoint of the EAP. Further analysis of the EAP including results from the Fluidda imaging sub-study will be communicated during the second quarter of 2026. Together, the accumulative 15-month safety and tolerability data strengthens the overall documentation of CS1 and support continued development toward the planned Phase IIb study, regulatory pathway and ongoing partnering discussions.

The Expanded Access Program, conducted following the Phase IIa study, provides up to 12 months of additional treatment data. The EAP data confirm that CS1 maintains a favorable safety and tolerability profile over 12 months of treatment, consistent with previous Phase IIa results. Together, the Phase IIa trial and the EAP provide up to 15 months of treatment data, representing an important addition to the clinical dataset strengthening the overall understanding of CS1. No safety signals related to CS1 were observed in the EAP, and reported events are consistent with the underlying disease.

“In PAH, a progressive and life-threatening disease, safety and tolerability are critical as patients often require long-term treatment. Existing therapies are often associated with safety and tolerability challenges, which means that there is a significant unmet medical need in the treatment of PAH. These results strengthen our confidence in CS1’s properties with observations consistent with the underlying disease and not related to treatment, and support continued development as planned,” said Rahul Agrawal, CMO and Head of R&D of Cereno Scientific.

PAH is a serious and progressive disease with significant unmet medical need. The use of many currently available therapies is limited due to safety and tolerability issues,[1,2] highlighting the importance and need of well-tolerated treatment options suitable for long-term use. The EAP was conducted under an FDA-approved protocol and initiated following requests from patients and physicians after the completed Phase IIa trial. The EAP plays an important role in strengthening the clinical package for CS1 by providing additional long-term data beyond the Phase IIa trial.

Of the ten patients enrolled in the EAP, six completed 12 months of treatment. No discontinuations were reported as related to CS1. Two patients discontinued treatment due to atrial fibrillation requiring anticoagulation therapy, which is not permitted under the EAP study protocol. Atrial fibrillation is a known and relatively common condition in PAH, reported in up to one third of patients, particularly in later stages of disease and is not considered

related to CS1 treatment. One patient withdrew consent, and one patient was lost to follow-up. Importantly, no discontinuations were assessed as related to CS1.

Dr. Jason Guichard, Prisma Health-Upstate, investigator in the EAP and Phase IIa trial of CS1 in PAH commented: “These are encouraging results and consistent with what I have observed in my patients treated with CS1. The favorable safety and tolerability profile over longer-term use is particularly important in PAH, where patients require lifelong therapy. I look forward to following the continued development of CS1 as a potential new treatment option for patients living with this serious disease.”

“The 12-month EAP data confirm the safety and tolerability profile we observed in Phase IIa, now extended to 15 months of cumulative treatment experience. This strengthens the clinical package for CS1 as we advance toward Phase IIb. We are very pleased with the results and how it supports the value proposition of CS1 as an oral, once-daily well-tolerated PAH therapy with a favorable safety profile and disease-modifying effects, said Sten R. Sörensen, CEO of Cereno Scientific. “We look forward to presenting the further analyses from the EAP and Fluidda imaging sub-study evaluating changes in the pulmonary vessels in Q2. The Phase IIb trial remains on track for first patient enrollment in June 2026”.

To help investors better understand what the EAP data means and the strategic value, we have also published an explanatory article on our website: https://cerenoscientific.com/stories/.

References: 1. Steinberg, D., Management of Pulmonary Arterial Hypertension: Secondary prevention and intervention, 2020. 2. Sotatercept (Winrevair): Therapeutic area: Pulmonary arterial hypertension (WHO group 1): Reimbursement Review [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2025 Feb. Clinical Review.

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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. 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. CS1 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 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 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.