Press release
August 26, 2025

Cereno Scientific

Cereno Scientific Granted FDA Fast Track Designation for CS1 in Rare Disease Pulmonary Arterial Hypertension (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 announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its lead program, CS1, for the treatment of pulmonary arterial hypertension (PAH). Fast Track designation is designed to accelerate the development and regulatory review of new therapies for serious conditions with high unmet medical need. The designation highlights CS1's potential as a differentiated treatment approach for PAH, a rare and progressive disease where safer, disease-modifying therapies are urgently needed.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs intended to treat serious conditions with the potential to address unmet medical needs. Fast Track designation enables closer and more frequent interaction with the FDA, eligibility for rolling review, and potential priority review, with the goal of bringing promising treatments to patients more quickly.

"The Fast Track designation for CS1 underscores the FDA's recognition of its potential to address the significant unmet need in PAH," said Rahul Agrawal, MD, CMO & Head of R&D at Cereno Scientific. "Fast Track designation will enable closer interaction with the FDA, enabling timely feedback on our development plans as we advance CS1 into its Phase IIb trial and beyond. This designation marks an important step in the development journey for CS1 and supports our goal of making innovative treatment options available to PAH patients as efficiently as possible."

"We are very pleased to have achieved Fast Track designation for CS1, which both validates the strength of our CS1 program and supports our mission to bring pioneering treatments to patients with devastating rare diseases like PAH," said Sten R. Sörensen, CEO of Cereno Scientific. "For patients, Fast Track can accelerate the pathway to new therapies. For Cereno, it is a significant milestone that enhances the value of CS1, reinforces our competitive position, and creates further opportunities for strategic collaborations."

Drug candidate CS1 is an oral HDAC inhibitor (HDACi) with a unique mechanism of action through epigenetic modulation. In a Phase IIa trial in PAH, CS1 met its primary endpoint of safety and tolerability while showing encouraging efficacy signals in a Phase IIa trial in PAH, including improvement of REVEAL risk score, functional class, quality of life, and early signs of reverse vascular remodeling and improvement of right heart function. A global Phase IIb trial is being prepared to further evaluate CS1 as a potential disease-modifying treatment for PAH.

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This information is information that Cereno Scientific AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 11:40 CET on August 26, 2025.

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 full.

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 of reverse vascular remodeling and improvement of right heart function as observed in a Phase IIa trial in patients with PAH. An Expanded Access Program enables patients that have completed the Phase IIa trial to gain access to CS1 CS014, a new chemical entity with disease-modifying potential, showed favorable safety and tolerability profile in a Phase I trial. CS014 is a HDAC inhibitor with a multimodal mechanism of action as an epigenetic modulator having the potential to address the underlying pathophysiology of rare cardiovascular and pulmonary diseases with high unmet needs such as idiopathic pulmonary fibrosis (IPF). 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 indications like Thrombosis prevention without increased risk of bleeding and Pulmonary Hypertension.

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.