Cereno Scientific

Cereno Scientific obtains IND acceptance from FDA to start Phase II study with drug candidate CS1 in PAH

Cereno Scientific (XSAT: CRNO B) today announced that the US Food and Drug Administration (FDA) has accepted Cereno's investigational new drug application (IND) for drug candidate CS1. This application was a collaborative effort with global partner Abbott for the IND opening study. The acceptance of the IND allows Cereno to start the planned Phase II study in patients with pulmonary arterial hypertension (PAH) at clinical sites in the US in accordance with the submitted study protocol.

"This is a great milestone for the team and the company. We are excited to see our rare disease strategy further realized by starting this Phase II study after the US FDA's clearance," says Sten R. Sörensen, CEO at Cereno Scientific. "CS1 as a HDACi (histone deacetylase inhibitor) with epigenetic properties has a unique potential and we believe the drug candidate can improve the lives of PAH patients with a safer and better treatment in the future."

"We have worked intensely together with our partners to prepare the necessary documentation and steps needed to start the clinical Phase II study. With this acceptance from the US FDA, we are glad to proceed with further studies to evaluate CS1's properties in patients with PAH," says Björn Dahlöf, Chief Medical Officer (CMO) at Cereno Scientific.

This Phase II study intends to evaluate drug candidate CS1's safety, tolerability, dose and exploratory efficacy in patients with the rare disease PAH. The primary endpoint is safety and tolerability. All standard efficacy endpoints for this patient group will be explored as well as a validated risk score. Cereno anticipates that dosing for later studies will be informed by the continuous pulmonary pressure readings derived from Abbott's CardioMEMS HF System. The CardioMEMS HF System has already been proven to significantly reduce heart failure hospital admissions and improve the quality of life for people living with severe heart failure.

Dr. Raymond Benza, a global thought-leader in PAH, part of Cereno's scientific advisory board, and the principal investigator (PI) of the Phase II study said "Ever since I started working with Cereno and CS1 during spring 2020, I have looked forward to new clinical trials in PAH. With this compound, due to its unique mechanisms of action, I feel CS1 has the potential to become a game-changer in the treatment of PAH patients."

CS1 was granted an orphan drug designation (ODD) by the US FDA in March 2020. The Phase II study will be executed at about six different US clinical sites and include about 30 patients.

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About Cereno Scientific AB
Cereno Scientific is a clinical stage biotech company within cardiovascular diseases. The lead drug candidate, CS1, is a Phase II candidate in development for the treatment of the rare disease pulmonary arterial hypertension (PAH) and thrombotic indications. CS1 is an HDAC (Histone DeACetylase) inhibitor that acts as an epigenetic modulator with anti-thrombotic, anti-inflammatory, anti-fibrotic and pressure-relieving properties, all relevant for PAH. In addition, Cereno has two promising preclinical development programs named CS014 and CS585 targeted at treating cardiovascular diseases. The company is headquartered in AstraZeneca's BioVenture Hub, Sweden, and has a US subsidiary Cereno Scientific Inc. based in Kendall Square in Boston, Massachusetts, US. Cereno is listed on the Swedish Spotlight Stock Market (CRNO B). More information on www.cerenoscientific.com.