Press release
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Cereno Scientific

# Cereno Scientific reports first patient enrolled in Phase II study in PAH with drug candidate CS1 and update timeline for top-line results to Q1 2023

**Cereno Scientific (XSAT: CRNO B) today announced that the first patient has been enrolled in the Phase II study in pulmonary arterial hypertension (PAH) with drug candidate CS1. Based on the timing of enrollment and several factors mainly related to the activation of clinical sites, the study timeline has been adjusted by about a quarter and top-line results are now estimated for Q1 2023. The number of study sites has been increased to include about 10 clinics across the US with potential for further expansion in order to facilitate meeting the Q1 timeline.**

“It is great to have the first PAH patient enrolled in our Phase II study. We had originally expected about six months from IND acceptance to the first patient enrolled in the study. The lingering covid-19 pandemic in the US has affected our Phase II study start-up timeline through prolonged contracting due to staff shortages at the study’s clinical sites as well as extended processing time to obtain approvals from local boards and ethical committées. We are happy to see great interest from the study sites and excitement from the clinics having started active patient recruitment. Having the first patient enrolled signifies a significant milestone in our progress towards demonstrating that our drug candidate CS1, with its unique efficacy profile, has the potential to offer a safe, efficacious, and disease-modifying treatment option for patients suffering from the severe rare disease PAH,” says Sten R. Sörensen, CEO at Cereno Scientific.

Björn Dahlöf, Chief Medical Officer (CMO) at Cereno Scientific, comments “We are very pleased with the interest we have received from specialist clinics in the US to participate in our innovative Phase II study with our collaborative partner Abbott that provides the cutting-edge technology CardioMEMS to monitor cardiopulmonary hemodynamics. I am happy to see that patient enrollment has started and look forward to a good and timely recruitment process of all the 30 patients as we move forward.”

In March 2020, Cereno received the US FDA’s orphan drug designation (ODD) for the clinical development program for CS1 in PAH. Through the granted ODD, the FDA has indicated that they believe CS1 has the potential to provide significant benefit to patients suffering from PAH. In September 2021, an investigational drug application (IND) was accepted by the FDA to start a Phase II multi-center PAH study in the US. Since then, many activities and processes have been executed culminating in the activation of clinical sites participating in the study and the subsequent patient enrollment.

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**About the Phase II study with CS1 in PAH**

CS1 was granted an orphan drug designation (ODD) for the treatment of the rare disease PAH by the US FDA in March 2020 and in September 2021, Cereno obtained FDA acceptance of an investigational new drug (IND) application allowing initiation of the Phase II study. This study intends to evaluate drug candidate CS1's safety, tolerability, dose, and exploratory efficacy in patients with PAH. A collaboration agreement with global healthcare company Abbott allows Cereno to use Abbott's cutting-edge technology CardioMEMS HF System in the study. There will be a 12-week drug treatment period and a two-week follow-up period. The primary endpoint is safety and tolerability. All standard efficacy endpoints for this patient group will be explored as well as validated risk scores before and after treatment. The study includes at least ten different clinical sites in the US and aim to include 30 patients with PAH. Further information is available at https://www.clinicaltrials.gov/ (ClinicalTrials.gov identifier NCT05224531).

**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). CS1 is an HDAC (histone deacetylase) inhibitor that acts as an epigenetic modulator with pressure-reducing, reverse-remodeling, anti-inflammatory, anti-fibrotic and anti-thrombotic properties, all relevant for PAH. A clinical Phase II study is ongoing to evaluate CS1's safety, tolerability, and efficacy in patients with PAH. A collaboration agreement with global healthcare company Abbott allows Cereno to use their cutting-edge technology CardioMEMS HF System in the study. Cereno also has two promising preclinical drug candidates in development for cardiovascular disease through research collaborations with the University of Michigan. Drug candidate CS585 is a stable, selective, and potent prostacyclin receptor agonist. In preclinical studies CS585 has been documented to target the IP receptor for prevention of thrombosis without increased risk of bleeding. Drug candidate CS014 is a novel HDAC inhibitor with epigenetic effects. In preclinical studies CS014 has been documented to regulate platelet activity, fibrinolysis and clot stability for prevention of thrombosis without increased risk of bleeding. Cereno Scientific is headquartered in Gothenburg, 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.