Press release
January 14, 2020

Cereno Scientific
Epigenetic Modulation for Cardiovascular Disease

Cereno Scientific signs CRO for Phase II study with drug candidate CS1 in rare disease PAH

Cereno Scientific today announced that the company has signed a letter of intent with the global contract research organization (CRO) Worldwide Clinical Trials. Worldwide will provide support and guidance in the final preparatory steps as well as conduct the clinical Phase II study with drug candidate CS1 in pulmonary arterial hypertension (PAH). The clinical trial application process for the study has been initiated and the study start is expected to be initiated in mid-2021.

"We are confident that we have found a competent partner for our Phase II study in the CRO Worldwide Clinical Trials. They have extensive experience in conducting studies in cardiovascular disease in general and PAH in particular. They also have the right network of clinicians and study sites to set us up for success," said Sten R. Sörensen, CEO at Cereno Scientific. "It is beneficial to now get their input in finalizing the study protocol and regulatory study documentation to facilitate the process in the best way possible and, ultimately, start the study. We are excited to kick-off the new year and look forward to the study milestones ahead."

The clinical development program for drug candidate CS1 in PAH is anchored in the orphan drug designation (ODD) that was granted by the American regulatory agency FDA in March 2020. A first Phase II study is planned to evaluate CS1's therapeutic effect in patients with the rare disease PAH and to find the right dose to use in future studies. The process to obtain an investigational new drug (IND) acceptance from the FDA for permission to start the study in the US has been initiated. Recent interactions have successfully been held with the FDA through a pre-IND meeting, an advisory meeting with the goal to receive confirmation that the drug development plan and future clinical trials are acceptable to the FDA. The Phase II study with CS1 in PAH is expected to be initiated in mid-2021.

A letter of intent (LOI) between the parties has been signed for the collaboration to start immediately.

For further information, please contact:
For Cereno Scientific
Daniel Brodén, CFO
Tel: +46 768 66 77 87
Email: info@cerenoscientific.com
www.cerenoscientific.com

For Worldwide Clinical Trials
Sherri Stuart, Vice President Marketing and Communications
Email: Sherri.Stuart@worldwide.com
www.worldwide.com

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About Worldwide Clinical Trials
Worldwide Clinical Trials employs more than 2,000 professionals around the world, with offices in North and South America, Eastern and Western Europe, Russia, and Asia. Founded by physicians committed to advancing medical science, Worldwide is out to change how the world experiences CROs – in the best possible way. From early phase and bioanalytical sciences through late phase, post-approval and real-world evidence, we provide world-class, full-service drug development services.

With infrastructure and talent spanning 60 countries, we execute predictable, successful studies with operational excellence across a range of therapeutic areas, including central nervous system, cardiovascular, metabolic, general medicine, oncology and rare diseases. We never compromise on science or safety. We're never satisfied with the status quo. We're the Cure for the Common CRO. For more information, visit www.worldwide.com/.

About Cereno Scientific AB
Cereno Scientific is a leading clinical stage biotech company within cardiovascular epigenetic modulation. 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. A clinical phase II study program for CS1 in PAH is planned to start mid-2021 under its US FDA granted orphan drug designation (ODD) status. In addition, Cereno has a preclinical HDAC inhibitor development program targeted at treating cardiovascular diseases. The company is headquartered in AstraZeneca's BioVenture Hub, Sweden, and has an office in Kendall Square in Boston, Massachusetts, US. Cereno is listed on the Swedish Spotlight Stock Market (CRNO B). More information on www.cerenoscientific.com.