

Cereno Scientific Receives FDA Orphan Drug Designation for the Treatment of Pulmonary Arterial Hypertension

Cereno Scientific today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the company's lead compound CS1, for the treatment of Pulmonary Arterial Hypertension (PAH). PAH is a form of high blood pressure in the lungs where the increased pressure is primarily caused by changes in the lung vessels.

CS1 is a reformulation of valproic acid (VPA), an HDAC (Histone DeAcetylase) inhibitor that acts as an epigenetic modulator with anti-thrombotic, anti-inflammatory, anti-fibrotic and pressure-relieving properties. These characteristics are a good match with the mechanisms of the disease involved in PAH.

In December 2019, Cereno Scientific submitted an application for Orphan Drug Designation (ODD) for the development of CS1 in PAH with the U.S. Food and Drug Administration (FDA) and today, the Company received the FDA approval.

"We are very pleased that the FDA has granted orphan drug designation to our HDAC inhibitor CS1, which allows us to implement a clinical development program on the rare and serious disease PAH aiming to help a broader group of patients, that now includes patients with rare diseases, with our lead compound CS1. Our focus to develop drug candidates that effects epigenetic modulation, stems from our commitment at Cereno Scientific to help patients with cardiovascular related diseases." said Sten R. Sørensen, Chief Executive Officer of Cereno Scientific.

The FDA, through its Office of Orphan Products Development (OOPD), grants ODD to drugs and biologic products that are intended for treatment of rare diseases or disorders that affect fewer than 200,000 people in the United States. The ODD status is intended to facilitate drug development for rare diseases and may provide certain benefits and incentives to drug developers, including seven years of market exclusivity if the drug is approved, FDA assistance in clinical trial design, and tax credits for qualified clinical trial costs.

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About Cereno Scientific AB

Cereno Scientific is developing a pipeline of preventive therapeutics to treat cardiovascular and rare diseases by epigenetic modulation through histone deacetylase inhibition (HDACi). The company's lead program, CS1, is a phase II dual-acting antithrombotic drug aimed at venous thrombosis and stroke prevention for atrial fibrillation. Cereno Scientific also evaluates the potential of epigenetic modulation for rare diseases related to pulmonary fibrosis, thrombosis, inflammation and high blood pressure in the pulmonary circulation system. Cereno Scientific also has two preclinical HDAC inhibitors, CS014 and CS036. The company is located in AstraZeneca's BioVenture Hub. Cereno Scientific's B share has been listed on Spotlight Stock market since June 2016 with the ticker CRNO B, ISIN SE0008241558.