Cerenis Therapeutics Announces Last Patient Dosed in CARAT Phase II Study with CER-001 in Post-Acute Coronary Syndrome Patients

Topline data to be announced no later than the first quarter of 2017

TOULOUSE, France and ANN ARBOR, United States, November 8, 2016 - Cerenis Therapeutics (Euronext: CEREN- ISIN: FR0012616852), an international biopharmaceutical company dedicated to the discovery and development of innovative HDL (good cholesterol) therapies for treating cardiovascular and metabolic diseases, announces the dosing of the last patient in the global Phase II CARAT study. CARAT is designed to assess the therapeutic efficacy of CER-001, a pre-beta HDL mimetic, in post-acute coronary syndrome (ACS) patients.

Enrollment in CARAT was completed in August 2016 and the last patient has now received the final infusion of CER-001 or placebo. The last patients will undergo intravascular ultrasound (IVUS) imaging of the coronary arteries in the coming weeks and the final follow-up safety visit is expected to occur at the end of the month. Data analysis will commence thereafter and the Company expects to report topline results no later than the first quarter of 2017.

Dr. Jean-Louis Dasseux, founder and CEO of Cerenis, commented: "We are delighted to have completed patient dosing and to be nearing the end of the clinical portion of CARAT. Of note, we have reached this stage of the study ahead of schedule. Data collection and analysis will involve imaging of 301 patients who were randomized to either CER-001 or placebo over nine weeks, followed by 30 days of observation, including a follow-up IVUS conducted two weeks after dosing. The design of the CARAT trial and the selection of the optimal dose were based on multiple successful previous studies, and we look forward to announcing topline results no later than the first quarter of 2017".

Despite secondary prevention measures, the persistent risk of recurrence of a heart attack for patients who have experienced an ACS event remains very high and represents a significant and unmet medical need. By enabling the rapid regression of atherosclerotic plaque, CER-001 could potentially provide an opportunity to reduce the risk of recurrent cardiovascular events during the first few months following an ACS event. Hence CER-001, in addition to long-term LDL-C lowering treatments, could produce further reductions in morbidity and mortality and become the new standard of care for treating patients following an ACS.

About the CARAT Study

CARAT is a double-blind, placebo-controlled Phase II study designed to assess the impact of CER-001 on the regression of atherosclerotic plaque in post-ACS patients by measuring the percent atheroma volume (PAV) using IVUS imaging of the coronary arteries. The primary endpoint is the percentage change from baseline in PAV compared with placebo in a study population with an estimated baseline PAV ≥30% in the target coronary artery.

A total of 301 patients were randomized to either 3 mg/kg of CER-001 or placebo in a 1:1 ratio on Day 1 and weekly thereafter for a total of 10 infusions, followed by a 30-day observation period, including a follow-up IVUS two weeks post-dose. The study was conducted at 35 sites in Australia, Hungary, the Netherlands and the United States under the supervision of a prestigious steering

committee. Prof. Stephen Nicholls of the Heart Health Research team at SAHMRI (South Australian Health and Medical Research Institute, Adelaide, Australia) is the principal investigator.

The CARAT study draws on findings from prior clinical trials, particularly the positive data presented in November 2015 at the American Heart Association Scientific Congress by the Prof. Stephen Nicholls, to establish whether CER-001 promotes plaque regression in patients following an ACS. The 3 mg/kg dose was selected as optimal taking into account clinical and preclinical findings that confirm a larger number of CER-001 administrations at a low dose are more effective at plaque regression than a smaller number of high-dose administrations.[1]

Periodic safety reviews were performed during the treatment period by a data safety monitoring board (DSMB), which included surveillance of laboratory testing and on-treatment safety events. To date no safety or tolerability issues have been identified in patients enrolled in the CARAT trial.

About CER-001

CER-001 is an engineered complex of recombinant human apolipoprotein A-1 (apoA-I), the major structural protein of HDL, and phospholipids. It is designed to mimic the structure and function of natural, nascent HDL, also known as pre-beta HDL. Its mechanism of action is to increase apoA-I and the number of HDL particles transiently, to stimulate the removal of excess cholesterol and other lipids from tissues including the arterial wall and to transport them to the liver for elimination through a process called Reverse Lipid Transport. Previous Phase II studies have provided important data demonstrating the efficacy of CER-001 in regressing atherosclerosis in several distinct vascular beds in patients representing the entire spectrum of cholesterol homeostasis. The totality of the data to date indicates that CER-001 performs all of the functions of natural pre-beta HDL particles and has the potential to be the best-in-class HDL mimetic.

About Post-Acute Coronary Syndrome

Approximately 12% of ACS patients experience a recurrent cardiovascular event within one year of the initial event.[2] The risk of recurrence is especially high during the first two months, during which time over half of the deaths and major cardiac events occur.

The target post-ACS population for CER-001 is estimated to be approximately 2.8 million patients per year for North America and Europe.

About Cerenis Therapeutics

Cerenis Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative HDL therapies for the treatment of cardiovascular and metabolic diseases. HDL is the primary mediator of the reverse lipid transport, or RLT, the only natural pathway by which excess cholesterol is removed from arteries and is transported to the liver for elimination from the body. Cerenis is developing a portfolio of HDL therapies, including HDL mimetics for the rapid regression of atherosclerotic plaque in high-risk patients such as post-ACS patients and patients with HDL deficiency, and drugs that increase HDL for patients with a low number of HDL particles to treat atherosclerosis and associated metabolic diseases. Cerenis is well positioned to become a leader in HDL therapeutics, with a broad portfolio of programs being developed. Since its inception in 2005, the company has been funded by top-tier investors including Sofinnova Partners, HealthCap, Alta Partners, EDF Ventures, Daiwa Corporate Investment, TVM Capital, Orbimed, IRDI/IXO Private Equity and Bpifrance. In March 2015 Cerenis completed an IPO on Euronext raising €53.4m. Please visit www.cerenis.com.

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[1] Kataoka Y, et al. Greater regression of coronary atherosclerosis with the pre-beta high-density lipoprotein mimetic CER-001 in patients with more extensive plaque burden. Circulation 2015; 132: A12156.

[2] Cornel, J. et al., for the PLATO study group. Prior smoking status, clinical outcomes, and the comparison of ticagrelor with clopidogrel in acute coronary syndromes-insights from the PLATelet inhibition and patient Outcomes (PLATO) trial. Am Heart J 2012, 164, 3, 334–342.e1.

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