Press Release

First patients enter phase II CARAT trial to assess reduction in atherosclerotic plaque using CER-001 in post Acute Coronary Syndrome (ACS) patients

- **CER-001 is a novel HDL-mimetic designed to mimic the beneficial properties of natural nascent HDL (HDL pre-β)**
- **A trial headed by Professor Stephen Nicholls, Director of the prestigious Heart Health Research team at SAHMRI (South Australian Health and Medical Research Institute, Adelaide, Australia) and world expert in HDL research via medical imaging**
- **The primary clinical endpoint of the CARAT trial is the percentage change in atheroma volume (PAV) compared with placebo in the trial population with a baseline PAV ≥30%**

Toulouse, FRANCE, and Ann Arbor, UNITED STATES, September 8th, 2015 – **Cerenis Therapeutics (FR0012616852-CEREN – PEA-PME eligible),** an international biopharmaceutical company dedicated to the discovery and development of innovative HDL therapies ("good cholesterol") for treating cardiovascular and metabolic diseases, today announces that the first patients have been enrolled into the phase II CARAT trial that is designed to maximize the therapeutic efficacy of CER-001 in post Acute Coronary Syndrome (ACS) patients.

The CARAT trial, which began in the 3rd quarter of 2015 as announced to investors at the time of the Company's IPO, is progressing in line with the defined schedule and its results are expected during the 1st quarter of 2017.
The CARAT trial will be followed by a phase III pivotal trial to register CER-001: CALMS.

- **CER-001 is a novel HDL-mimetic designed to mimic the beneficial properties of natural nascent HDL**

CER-001 is a novel, engineered HDL-mimetic comprised of recombinant human apoA-I and charged phospholipids that mimic the beneficial properties of natural nascent HDL, especially the ability to regress atherosclerotic plaque.

- **A trial headed by Professor Stephen Nicholls, Director of the prestigious Heart Health Research team at SAHMRI and world expert in HDL research through medical imaging**

The CARAT trial is a phase II, double-blind, placebo-controlled, multi-centre study in the USA, Hungary, The Netherlands and Australia and is being led by the South Australian Health and Medical Research Institute (SAHMRI). The novel HDL-mimetic CER-001 will be administered at the dose of 3 mg/kg once a week for 9 weeks for a total of 10 infusions. Patients arriving at hospital with ACS (heart attacks) will receive CER-001 infusions or placebo in addition to standard of care (including lipid lowering drugs such as statins).

The CARAT Steering Committee consists of world-renowned experts Professors Steve Nicholls (principal investigator, SAHMRI), Steven Nissen (Cleveland Clinic, USA), John Kastelein (Academic Medical Center, Amsterdam, Netherlands), Kausik Ray (Professor of Public Health, Department of Primary Care and Public Health, Imperial College London, UK), Gregory Schwartz (Professor of Medicine, University of Colorado, USA), Béla Merkely (Heart and Vascular Center, Semmelweis University, Budapest, Hungary) and Stephen Worthley (Royal Adelaide Hospital, Australia).

- **The primary clinical endpoint of the CARAT trial is the percentage change in atheroma volume (PAV) compared with placebo in the trial population with a baseline PAV ≥30%**

The primary clinical endpoint of the CARAT trial is the percentage change in atheroma volume (PAV) measured by the change in percentage atheroma volume (PAV) compared with placebo in the trial population with a baseline PAV ≥30% in the coronary artery examined by intravascular ultrasound (IVUS). It is known that even with the best LDL-cholesterol (LDL-C)-lowering drugs, patients often experience recurrent cardiovascular events within a few weeks to a few months after the initial event. CER-001 is being used to treat patients in the time period after ACS where the risk of another event is very high. LDL-C lowering drugs generally take far longer to affect mortality and morbidity.

Prof. Stephen Nicholls, the principal investigator for the CARAT trial, says "*We are very excited to have enrolled the first patients in this very important trial. The design of the CARAT study builds on the findings of the earlier phase II study, CHI SQUARE, which showed that CER-001 at the dose of 3 mg/kg induced atherosclerosis regression, in patients with a baseline PAV ≥30%, as illustrated by a statistically significant decrease in PAV, a marker directly linked to the risk of cardiovascular outcomes. We hope to convincingly demonstrate the key therapeutic potential of infused HDL as the results from CARAT will be critical to gaining more knowledge about how this exciting product can offer a positive treatment option for patients post-ACS*."

Dr. Renée Benghozi, Chief Medical Officer for Cerenis adds, "*The recruitment of the first patients into the CARAT trial is a significant milestone for Cerenis. We are committed to delivering our robust clinical trial programme, including the phase II trials CARAT and TANGO, which will investigate the potential for CER-001 to reduce the risk of future cardiac events in post-ACS patients and to correct deficiencies in apoA-I and HDL in patients with Familial Primary Hypoalphalipoproteinemia, thus resulting in plaque regression. With CER-001 we hope to be able to address the unmet medical need in these patients and bring this potential new medicine forward to help the fight against cardiovascular disease*."

Notes to editors

Atherosclerosis is a disease arising from formation of plaque, so-called atherosclerotic plaque, caused by deposits of lipids, especially cholesterol, in the vessel wall, which leads to the manifestation of cardiovascular diseases including myocardial infarction ("heart attack") and angina pectoris all designated by the term acute coronary syndrome (ACS). Atherosclerosis affects the entire vascular system and also leads to several other complications, including ischaemic stroke, renal failure and arteriopathy of the lower limbs.

The major carriers for cholesterol in the blood are lipoproteins, including the low-density lipoprotein (LDL) particles, and the high-density lipoprotein (HDL) particles. In a healthy human body, there is a balance between the delivery and removal of cholesterol. The LDL particles deliver cholesterol to organs, where it can be used to produce hormones, maintain healthy cells, and be transformed into natural products that assist in the digestion of lipids. The HDL particles remove cholesterol from arteries and tissues to transport it back to the liver for storage, recycling, and elimination through a pathway called "Reverse Lipid Transport (RLT)".

Epidemiological studies have historically demonstrated that the risk of developing cardiovascular disease appeared to be higher in patients with low HDL-cholesterol independent of the level of LDL-cholesterol, even when patients are treated with the best available standard of care. This observation can be explained by the role the HDL particle plays in the RLT pathway, the only natural mechanism capable of removing cholesterol from peripheral tissues and delivering it back to the liver for elimination. HDL particles mediate the flux of cholesterol through the RLT and therefore act to counterbalance the delivery of cholesterol to the vessel wall by the LDL particles. The RLT is a pathway that may protect against atherosclerosis and cardiovascular disease by clearing excess cholesterol from the arterial wall. The ATP-binding cassette transporter called ABCA1 is a protein that mediates the first step of RLT and acts as a gatekeeper for eliminating excess tissue cholesterol.

About Cerenis Therapeutics: www.cerenis.com

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 which increase HDL for patients with low number of HDL particles to treat atherosclerosis and associated metabolic diseases.

Cerenis is well-positioned to become one of the leaders in the HDL therapeutic market, with a broad portfolio of programs being developed.

Since its inception in 2005, the company has been funded by top tier investors: Sofinnova Partners, HealthCap, Alta Partners, EDF Ventures, Daiwa Corporate Investment, TVM Capital, Orbimed, IRDI/IXO Private Equity and Bpifrance (Fund for Strategic Investment) and last March successfully completed an IPO on Euronext raising €53.4m.

About CER-001:

CER-001 is an engineered complex of recombinant human apoA-I, the major structural protein of HDL, and phospholipids. It has been 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 in the market.

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