Press release

Completion of patient enrolment in the CARAT study – meeting the clinical schedule

Toulouse, FRANCE, Ann Arbor, UNITED STATES, August 30, 2016 – **Cerenis Therapeutics (FR0012616852 - CEREN),** an international biopharmaceutical company dedicated to the discovery and development of innovative HDL therapies ("good cholesterol") for treating cardiovascular and metabolic diseases, today announces the completion of recruitment for the CARAT clinical study, which is designed to test the therapeutic efficacy of CER-001 in patients following an Acute Coronary Syndrome (ACS).

- **CARAT is a phase II study in the post-ACS indication aiming to demonstrate CER-001's efficacy at reducing atherosclerotic plaque burden while maximising the number of administrations during the critical period following the first clinical event.**
- **CER-001 is a novel HDL-mimetic designed to mimic the beneficial properties of natural nascent HDL (HDL pre-β)**
- **The CARAT study is an academically led study involving a partnership between the several research organisations, South Australian Health and Medical Research Institute (SAHMRI) and the Cleveland Clinic, contract research organisations (InterEuropa and others) and the pharmaceutical sponsor (Cerenis)**
- **The primary clinical endpoint is the percentage change from baseline in percent atheroma volume (PAV) compared with placebo in a study population with a baseline PAV ≥30% in the index coronary artery.**

CARAT is a double blind, placebo-controlled, phase II study intending to assess the impact of CER-001 on the regression of atherosclerotic plaque in post-ACS patients by measuring PAV using intravascular ultrasound (IVUS) imaging of the coronary vascular wall.

To maximise the efficacy of CER-001 in post-ACS patients, the CARAT design involves administration of ten doses of the HDL-mimetic over a 9-week period, i.e. one dose per week, at the previously defined optimal dose of 3 mg/kg. The study, which includes 297 patients across 4 countries (Australia, Hungary, The Netherlands and the United States), is under the supervision of a prestigious steering committee, with Prof. Stephen Nicholls of the Heart Health Research team at SAHMRI (South Australian Health and Medical Research Institute, Adelaide, Australia) as the principal investigator.

The CARAT study draws on findings from prior studies in humans, particularly the positive data presented in November 2015 at the American Heart Association Scientific Congress, to establish whether CER-001 promotes plaque regression in patients following an ACS. The 3 mg/kg dose was selected based on the previous analysis performed by Stephen Nicholls and colleagues and also takes into account pre-clinical findings that confirm a larger number of CER-001 administrations at a low dose are more efficient at plaque regression than a smaller number of high-dose administrations.[1]

Enrolment in the CARAT study has completed on schedule and results are anticipated no later than the first quarter of 2017. Subject to the positive outcome of CARAT, a phase III pivotal study (CALMS) will then be launched.

No safety or tolerability issues have been identified in CARAT to prevent the study being completed as planned – periodic safety reviews have been performed during the on-treatment period by a data safety monitoring board (DSMB), which includes surveillance of laboratory testing and on-treatment safety events.

- **CER-001, a drug candidate showing critical therapeutic benefits for post-ACS patients**

Despite secondary prevention measures, the persistent risk of recurrence of a heart attack for patients who have already experienced an ACS event remains very high and represents a significant and unmet medical need.

Given this substantial unmet medical need, CER-001, by enabling the rapid regression of atherosclerotic plaques, could potentially provide a unique 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 mortality and morbidity rates and become the new standard of care for treating patients following an ACS.

Prof. Stephen Nicholls, Principal Investigator, says: *"We are excited to have completed enrolment of patients in this very important study and that there have been no safety or tolerability issues reported. The design of the CARAT study builds on the findings of the earlier phase II study, CHI SQUARE, which showed that CER-001 at a dose of 3 mg/kg produced a statistically significant decrease in PAV, a marker directly linked to the risk of cardiovascular outcomes, in patients with a baseline PAV ≥30%. We hope that the findings of the CARAT study will convincingly demonstrate the key therapeutic potential of infused HDL and provide more knowledge and insight about how this exciting product can offer a positive treatment option for patients post-ACS and reduce atherosclerotic plaque burden."*

Dr. Jean-Louis Dasseux, founder and CEO of Cerenis, comments: *"The enrolment of the final patient in the CARAT clinical study is in line with the clinical development schedule announced at the time of Cerenis' IPO. We are now eager to obtain the definitive results, expected no later than the first quarter of 2017, that should confirm our drug candidate's potential for efficiently treating patients with Acute Coronary Syndrome and thus significantly improve their living standards. We remain confident in CARAT's success, the study's optimal design enabling CER-001's effect to be maximised".*

[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.

Financial agenda:

Revenue for 3rd quarter of 2016 : **November 7, 2016**

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) 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.

About Post-Acute Coronary Syndrome patients

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

In total, the target population of post-ACS prevention patients for CER-001 is estimated at approximately 2.8 million patients per year for North America and Europe.

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Contacts:

Cerenis
Jean-Louis Dasseux
CEO
info@cerenis.com
Tel: +33 (0)5 62 24 09 49

NewCap
Investors relations
Emmanuel Huynh/Louis-Victor Delouvrier
cerenis@newcap.eu
Tel: +33 (0)1 44 71 98 53

NewCap
Media relations
Nicolas Merigeau
cerenis@newcap.eu
Tel: +33 (0)1 44 71 94 98

[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.