Press Release

New Data for CER-001 presented in key Oral Session at AMERICAN HEART ASSOCIATION (AHA) CONFERENCE 2015

Data show that CER-001 at 3 mg/kg dose induced atherosclerosis regression as illustrated by a statistically significant decrease in plaque burden, a marker directly linked to the risk of cardiovascular outcomes

Professor Stephen Nicholls, Director of the prestigious Heart Health Research team at SAHMRI (South Australian Health and Medical Research Institute) presented CER-001 data at AHA

Toulouse, FRANCE, November 10 2015 – **Cerenis Therapeutics (FR0012616852-CEREN)** today announced that new data for CER-001 were presented at a top symposium on atherosclerosis within the American Heart Association (AHA) Scientific Sessions 2015, held in Orlando, Florida, from November 7-11, 2015.

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

Cerenis Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative HDL therapies ("good cholesterol") for treating cardiovascular and metabolic diseases.

The new data showed that CER-001 at the dose of 3 mg/kg induced atherosclerosis regression as measured by coronary IVUS, in patients with a baseline PAV ≥30%. Investigators reported a statistically significant decrease in PAV vs. placebo. PAV is a marker directly linked to the risk of cardiovascular outcomes.

The data were presented at an AHA oral session by Professor Stephen Nicholls, Director of the prestigious Heart Health Research team at the South Australian Health and Medical Research Institute (SAHMRI) in Adelaide, Australia, and world expert in HDL research through medical imaging. Pr. Nicholls noted that, "*these findings identify Acute Coronary Syndrome (ACS) patients with high-risk plaque features are the most likely to benefit from HDL mimetic therapy with CER-001. It also supports the design of the phase II CARAT trial which SAHMRI is leading*".The full publication of these data is now being prepared.

Cerenis recently announced that the first patients had entered the phase II CARAT trial, which uses IVUS to assess reduction in atherosclerotic plaque using CER-001 in post-ACS patients. The CARAT trial is progressing in line with the defined schedule and the results are expected during the 1st quarter of 2017. If CARAT is successful, Cerenis plans to proceed with a pivotal Phase III study.

Dr. Jean-Louis Dasseux, Founder and CEO of Cerenis comments: *"These results are key to further understanding the benefits of CER-001 at slowing or reversing the progression of the atherosclerotic plaque as well as identifying in which patients CER-001 would be the most effective. These data also illustrate that it is in line with the preclinical data showing the U-shape dose response and that it is better to have more administrations at a low dose than fewer administrations at a high dose."*

- **Data presented on Monday, November 9, 2015, 6:15 pm**
- **Abstract Oral Session, Lipoprotein Modifying Therapies**
- **Title "Greater Regression of Coronary Atherosclerosis with the Pre-beta High-density Lipoprotein Mimetic CER-001 in Patients with More Extensive Plaque Burden"**

- ENDS -

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 functions 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. 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 on the market.

CEREN LISTED EURONEXT

ELIGIBLE PEA PME

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.fr
Tel: +33 (0)1 44 71 98 53

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