Press release

Cash position and update on clinical developments for Q1 2017

Toulouse, FRANCE, Ann Arbor, UNITED-STATES, April 20, 2017, 6:30pm – **Cerenis Therapeutics (FR0012616852 – CEREN – PEA PME eligible)**, an international biopharmaceutical company dedicated to the discovery and development of innovative therapies based on lipid metabolism for treating cardiovascular and metabolic diseases, today announces its cash position at March 31, 2017.

Solid cash position of €19.0 million at March 31, 2017

Cash and cash equivalents totaled €19.0 million. In line with expectations, Cerenis Therapeutics did not generate any revenue during the first quarter of 2017, the Company's products being at the Research and Development stage.

Update on TANGO Phase 3 study in patients with HDL deficiency

Cerenis Therapeutics is currently conducting TANGO, a phase 3 study in patients with HDL deficiency, due to defects of coding genes for apoA-I and ABCA1, within the framework of the two orphan drug designations granted by the European Medicines Agency (EMA).

TANGO phase 3 is a clinical study designed to evaluate both the efficacy of CER-001 to regress atherosclerosis and its safety in patients with FPHA, who are characterized by an ABCA1 or an apoA-I genetic mutation and receiving background optimized lipid-lowering therapy.

Inherited defects in the apoA-I or ABCA1 genes can act to cause FPHA, a rare syndrome characterized by the absence or severe deficiency of HDL particles in the circulation. As a consequence the body's only natural mechanism for the elimination of cholesterol is compromised. These patients experience an accumulation of cholesterol, particularly in blood vessel walls, which often results in accelerated atherosclerosis and premature cardiovascular disease.

Launch of the Phase 1 clinical study with CER-209, a P2Y13 receptor, in NAFLD and NASH

The launch of this Phase 1 study follows the approval the IND (Investigational New Drug application) FDA approval, granted in December 2016, to initiate the clinical development of CER-209 in healthy volunteers for the future clinical investigation in patients with Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH).

The objective of this single-center, randomized, double blind and placebo controlled trial, is to evaluate efficacy, tolerance and the pharmacokinetic/pharmacodynamics following the infusion of

CER-209'increasing doses in healthy volunteers.

Incidence of NAFLD and NASH is increasing, now becoming common diseases of the liver in part related to the rise in obesity and diabetes rates. NAFLD, a precursor of NASH, is a disorder that is now considered as the most common liver disease in the western world, impacting 30% of the world's population, according to a publication in the World Journal of Hepatology.

CER-209 is well suited to the treatment of NAFLD and NASH

CER-209, a selective novel agonist of the P2Y13 receptor decreased both atherosclerosis and liver steatosis in preclinical models. CER-209 caused an increased uptake of high-density lipoprotein-cholesterol (HDL-c) in the liver that is associated with stimulation of bile acid secretion. Repeated dose administration stimulated the apoA-I synthesis and formation of small HDL particles, known to be atheroprotective. CER-209-treated plasma samples had high cholesterol efflux capacity for the mobilization of cellular cholesterol in vitro compared with the placebo group. CER-209 induced a decrease in atherosclerotic plaques in aorta and carotids as well as a remarkable decrease in steatosis in validated preclinical models.

In preclinical models, CER-209 resulted in a marked reduction in overall steatohepatitis as determined by reductions in cholesterol, triglycerides and fatty acids in the liver compared with placebo. Furthermore, CER-209 produced considerable decreases in liver enzymes (ALT and AST) in the plasma. These effects suggest the restoration of liver integrity and indicate a strong potential for CER-209 to treat liver disease such as Non-Alcoholic Steato-Hepatitis (NASH) and Non-Alcoholic Fatty Liver Disease (NAFLD) associated with cardiovascular disease.

Financial calendar:
Annual General Meeting
June 9, 2017

About Cerenis: www.cerenis.com
Cerenis Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative HDL and other 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 therapies, including HDL mimetics for patients with genetic HDL deficiency, as well as drugs which increase HDL for patients with a low number of HDL particles to treat atherosclerosis and associated metabolic diseases including Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH).

Cerenis is well positioned to become one of the leaders in this innovative lipid metabolism therapeutic market, with a broad portfolio of programs in development.

About TANGO clinical trial
TANGO is a Phase III, multicenter, randomized, 48-week, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of CER-001 on vessel wall area in thirty patients with genetically defined familial hypoalphalipoproteinemia (apoA-I and ABCA1 deficiencies) and receiving background optimized lipid therapy. Primary endpoint: to evaluate the effect of 24 weeks' treatment with CER-001 on carotid mean vessel wall area (MVWA) compared with placebo using 3TMRI. Secondary endpoints: to evaluate the effect of 8 and 48 weeks' treatment with CER-001 on carotid MVWA compared with placebo using 3TMRI.

About CER-209

CER-209 is the first drug candidate in the category of oral P2Y13 receptor agonists. The P2Y13 receptor is a member of the P2Y receptor family, a well-known receptor family including the P2Y12 receptor that is the target of successful drugs such as the anti-thrombotic agent Clopidogrel (Plavix®). CER-209 is a specific agonist of the P2Y13 receptor and does not interact with the P2Y12 receptor. In preclinical studies CER-209 promotes HDL recognition by the liver and increases Reverse Lipid Transport (RLT), thereby impacting atherosclerosis regression. Because of the favorable metabolic effects observed in the liver, CER 209 may also offer a new mechanism for the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH).

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. SAMBA, the clinical Phase 2 study in patients with hypoalphalipoproteinemia due to genetic defects, has provided important data demonstrating the efficacy of CER-001 in regressing atherosclerosis in several distinct vascular beds. 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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Contacts:

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

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

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