Press release

# Clinical progress, cash position and revenue for Q4 2016

**Toulouse, FRANCE, Ann Arbor, UNITED STATES, January 19, 2017 – 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 updates on its clinical advancements and announces its cash position at December 31, 2016 as well as its revenue for the fourth quarter 2016.

## Clinical study progress

Cerenis Therapeutics is finalizing a phase 2 study, in post-Acute Coronary Syndrome (post-ACS) patients. Cerenis Therapeutics is also pursuing TANGO, a phase 3 study for patients with HDL deficiency due to defects in genes coding for apolipoprotein A-I and ABCA1, for which Cerenis Therapeutics has been granted two orphan drug designations by the European Medicines Agency. Cerenis Therapeutics received FDA IND approval to begin studies with CER-209.

## Q4 2016 clinical advancements

### Cerenis therapeutics received FDA IND approval to begin studies with CER-209 in NAFLD and NASH

U.S. Food and Drug Administration (FDA) informed Cerenis Therapeutics that clinical trials with CER-209 may proceed. The Investigational New Drug application (IND) for CER-209 includes plans for a Phase 1 clinical study of its P2Y13 receptor agonist drug candidate (CER-209) in healthy volunteers for the clinical investigation of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH). CER-209, a selective novel agonist of the P2Y13 receptor, induced a decrease in atherosclerotic plaques in aorta and carotids as well as a remarkable decrease in steatosis in validated preclinical models. Cerenis plans to begin enrollment in Q1 2017.

### CER-001's last patient dosed in CARAT study

Enrollment was completed in August 2016 and the last patient received the tenth and final infusion of CER-001 or placebo in Q4 2016. The Company expects to report CARAT study results by the end of 2017 first quarter.

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

**Update regarding TANGO trial**

Active enrollment in the phase 3 TANGO trial continues. The Company has engaged 18 sites worldwide to optimize the availability of patients with Familial Primary Hypo-Alphalipoproteinemia (FPHA), a rare but clinically important orphan disease.

## Solid cash position of €24.7 million at December 31, 2016

Cash and cash equivalents totaled €24.7 million. In line with expectations, Cerenis Therapeutics did not generate any revenue during the fourth quarter of 2016 nor during the full year. Hence, the Company is aligned with its expected cash position in order to support its Research and Development activities.

Dr. Jean-Louis Dasseux, CEO of Cerenis, comments, *"The last quarter of 2016 has been marked by major clinical advancements for Cerenis, with the last patient dosed in CER-001's phase 2 CARAT study in post-ACS patients, and the successful filing of our IND and approval by the FDA to proceed with our first Phase 1 clinical trial for CER-209. This advancement reflects the potential of CER-209 for the treatment of NAFLD and NASH, through its ability to promote HDL recognition and fat elimination by the liver, and overall supports the potential of our therapeutic approaches. 2017 will be a milestone year for Cerenis with the results of the CARAT study, expected in the first quarter".*

**Financial agenda:**
Revenue for the 1st quarter of 2017
**April 20, 2017**

### 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 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 the HDL therapeutic market, with a broad portfolio of programs in development.

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.

## 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).

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## Contacts:


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

**LHA**
Investor relations (U.S.)
Kim Golodetz
kgolodetz@lhai.com
Tel: +1 212 838 3777

**RooneyPartners**
Media relations (U.S.)
Marion Janic
mjanic@rooneyco.com
Tel: +1 212 223 4017

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

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