Press release

Cash position and activity update for Q4 2017

- **Solid cash position of €16.3 million at December 31, 2017**
- **Acquisition of LYPRO Biosciences to build the first HDL-based targeted drug delivery platform, dedicated to the immune-oncology and chemotherapy market**
- **First patients enter TARGET study, recently initiated to evaluate the tumor targeting by HDL nanoparticles in patients with esophageal cancer**
- **Completion of patient enrollment in the Phase 3 study, TANGO, evaluating CER-001 in HDL genetic deficiency**

Toulouse, FRANCE, Lakeland, UNITED-STATES, January 25, 2018, 6.00 pm CET – CERENIS Therapeutics (FR0012616852 – CEREN – PEA PME eligible), an international biopharmaceutical company dedicated to the discovery and development of HDL-based innovative therapies for treating cardiovascular and metabolic diseases, as well as new HDL-based vectors for targeted drug delivery in the field of oncology, today announces its cash position at December 31, 2017 and key highlights for the 4th quarter of 2017.

Solid cash position of €16.3 million at December 31, 2017

Cash and cash equivalents totaled €16.3 million at December 31, 2017. In line with expectations, CERENIS Therapeutics did not generate any revenue during the 4th quarter of 2017, the Company's products being at the Research and Development stage.

Key highlights and clinical advances of the 4th quarter 2017

Completion of patient enrollment in the Phase 3 study, TANGO, evaluating CER-001 in HDL genetic deficiency

TANGO is being conducted in patients with HDL deficiency due to defects of genes coding for apoA-I and ABCA1, within the framework of the two orphan drug designations granted by the European Medicines Agency (EMA) for the use of CER-001.

The Phase 3 TANGO trial is designed to assess both the efficacy of CER-001 to regress atherosclerosis, and its safety in patients with FPHA, who are characterized by ABCA1 or apoA-I genetic mutations and are already receiving optimized background lipid therapy.

The TANGO trial is a multicenter, randomized, double-blind, parallel-group and placebo-controlled study. It involved 30 patients from several sites across Europe, Canada and the United States. The difficulties encountered in the identification of patients with FPHA, a rare disease, explain the delay in the study schedule, results being expected late Q1 2018.

Acquisition of LYPRO Biosciences to build the first HDL-based targeted drug delivery platform dedicated to the immune-oncology and chemotherapy markets

LYPRO's technology, NanoDisk, is based on nanometer-scale bioparticles capable of incorporating active drugs to stable and water-soluble particles in order to target a cellular cell. NanoDisk, LYPRO's most advanced technology, combined with the CERENIS' mimetic HDL (such as CER-001 and CER-522), targets a specific human cell HDL receptor, SR-B1, in order to deliver anticancer agent directly to the diseased cells. The SR-B1 and other HDL receptors (ABCA1) are receptors allowing the cell lipid supply by HDL, which plays a key role in cell homeostasis, proliferation and growth, parameters that are up-regulated in cancer cells. Therefore, these receptors serve as a potential gateway for the delivery of therapeutic agents transported by HDL nanoparticles to cancer cells and tumors.

The combination of NanoDisk technology with CERENIS' natural recombinant human apoA-I used with its HDL mimetics will result in the next generation of drug delivery platforms in the fields of oncology, immune-oncology and chemotherapy. This should allow for increased efficacy in these fields, with reduced side effects while needing lower doses compared to current drug delivery technologies.

Acquiring the LYPRO Biosciences pre-clinical data supporting the proof of concept, CERENIS Therapeutics could launch, by the end of 2019, the first Phase I study to evaluate an HDL particle as a nano transporter of active drug for an oncologic indication. In the short term, CERENIS will set up a clear clinical strategy to select the most appropriate initial indication in oncology in order to demonstrate safety and efficacy of its new product candidate.

First patients enter TARGET study, recently initiated by CERENIS Therapeutics and the Amsterdam Medical Center to evaluate HDL nanoparticles in patients with esophageal cancer

TARGET is the first ever performed clinical study testing the potential of labelled HDL to visualize tumors in cancer patients. A number of preclinical studies have already validated the concept. However, this study will support the opportunity to treat cancer patients using HDL nanoparticles as a specific drug delivery platform targeting tumors.

The aim of the TARGET study is to assess the concentrations of Zirconium 89 (89Zr) labeled CER-001 in tumor tissue. Recent pre-clinical studies have demonstrated that reconstituted radio-labeled HDL nanoparticles may be used to label tumors, with specificity for tumor associated macrophages. Furthermore, in cancer patients, 89Zr-labeled HDL mimetic CER-001 will allow for non-invasive evaluation of the potential of drug delivery strategies in selected cancers. Success will pave the way for loading of HDL nanoparticles with immune-oncology and chemotherapeutic agents.

The secondary objective of the TARGET study is to evaluate the biodistribution of 89Zr labeled CER-001, the correlation between 89Zr-labeled CER-001 and tumor microcirculation as assessed with Dynamic Contrast Enhanced-MRI (CE-MRI), as well as Diffusion Weighted Imaging/Intravoxel Incoherent Motion (DWI/IVIM) MRI. This information could provide proof of concept for the tumor selectivity of this strategy. The study will also evaluate the relationship between histological markers from the tumor biopsy and the 89Zr-PET signal and MRI parameters.

The TARGET study is a single-center observational trial directed by Drs. Erik Stroes and Hanneke Van Laarhoven from the Amsterdam Medical Center enrolling adult subjects with a pathologically proven diagnosis of primary esophageal carcinoma *in situ*. Patients are all T2 staged according to the TNM classification. A total of 10 patients will undergo all study procedures. The study is expected to be completed by the end of Q2 2018.

About CERENIS: www.cerenis.com

CERENIS Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative lipid metabolism 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 lipids is removed from arteries and is transported to the liver for elimination from the body.

CERENIS is developing a portfolio of lipid metabolism 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). Capitalizing on its expertise, Cerenis is developing the first HDL-based targeting drug delivery platform dedicated to the oncology field (immuno-oncology and chemotherapy).

CERENIS is well positioned to become one of the leaders in the HDL therapeutic market, with a broad portfolio of programs in development.

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, and leading to the TANGO study with results expected at the end of Q1, '18. 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.

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 which is the target of successful drugs such as the anti-thrombotic agent Clopidogrel (Plavix®). CER-209 is a specific agonist of P2Y13 receptor and is not interacting with the P2Y12 receptor. In preclinical studies CER-209 promotes HDL recognition by the liver and increase the activity of Reverse Lipid Transport (RLT), and thus has an impact on 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 HDL targeting Drug Delivery

HDL particles, charged with active substance, hold the promise to target and selectively kill malignant cells while sparing healthy ones. A wide variety of drugs can be embedded in these particles which will target markers specific to cancer cells and bring these potent drugs to their intended site of action, with lowered systemic toxicity. Cerenis intends to develop the first HDL-based targeting drug delivery platform dedicated to the oncology market, including immuno-oncology and chemotherapy.

Financial Agenda:
2017 Annual Results
February 1st, 2018

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