Press release

2017 ANNUAL RESULTS AND UPDATE ON TANGO

- **Solid cash position of €16.3 million at December 31, 2017**
- **TANGO timing update: results postponed, full 12 month results expected in Q4 2018 per protocol**
- **Progression in the clinical developments of CER-209 in NASH and NAFLD**
- **Extension of the CERENIS HDL platform for immuno-oncology and chemotherapy**

Toulouse, FRANCE, Lakeland, UNITED-STATES, February 1st, 2018, 7.00 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 full-year 2017 financial results, as approved by the Board of Directors on February 1st, 2018. Audit procedures on statutory and consolidated accounts have been performed by the auditors and certification report is currently being issued.

Selected Financial Information (At December 31, 2017 / IFRS Consolidated accounts)

in € million	2017	2016
Revenue	0	0
R&D expenditure	-4.9	-17.0
Administrative, sales and marketing expenses	-1.7	-7.0
Operating income	**-6.6**	**-24.0**
Financial income	2.5	1.4
Financial expense	-0.8	-2.2
Net financial items	**1.7**	**-0.8**
Net income	**-5.0**	**-24.9**
Net income per share (€)	-0.27	-1.39
Net cash flows related to operating activities	-9.0	-19.2
Net cash flows related to financing activities	0.9	0.9
Cash position variation	**-8.4**	**-18.3**
Cash and cash equivalents at the end of the period	**16.3**	**24.7**

In line with expectations, CERENIS Therapeutics did not generate any revenue during 2017, the Company's products being at the Research and Development stage.

R&D expenditures totalled €4,899k in 2017, compared with €17,004k in 2016. This sharp decrease can be explained by the completion of the CARAT study and to the outcome of the action taken against the Montreal Heart Institute (Canada) "ICM" which generated a reduction in expenses of €1.6 million.

Financial income and charges correspond to the IFRS treatment of the BPI repayable advances and the effect of exchange rates variations when paying suppliers in foreign currencies (mainly the US and Australian dollars). As of December 31, 2017, due to CARAT's results and the continuation of the Phase 3 clinical study, TANGO, in the treatment of HDL deficiency, the repayment schedule of the BPI advances has been updated in accordance with the latest estimates. The rescheduling of repayments resulted in the recognition of net financial income of €1,601k in the interim consolidated financial statements as of December 31, 2017.

Cash and cash equivalents totaled €16.3 million at December 31, 2017.

Cyrille Tupin, **Chief Financial Officer** of **Cerenis**, comments: "The financial resources of CERENIS will allow us to complete all the clinical phases launched to date. Despite this satisfactory visibility in the medium term, we will maintain our prudent cash management and resource allocation optimization policy in order to optimize the value of our drug candidates' portfolio, which distinct high value-added action mechanisms are based on our expertise in HDL and lipid metabolism."

Key highlights of 2017: progression in the clinical developments of CER-001 and CER-009, respectively in genetic deficiency in HDL and in NASH and NAFLD

CER-001: Phase 3 TANGO study results postponed, full 12 month results expected in Q4 2018 per protocol

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. The planned 30 patients have been randomized, from several sites across Europe, Canada and the United States and will complete 12 months treatment in the fall of 2018 per protocol.
In the normal course of auditing the blinded study data, methodological information was received on January 31th, 2018. In light of that information, the Company decided that the analysis should occur on the full data set at end of the study at 12 months in order to assess the 0, 2, 6 and 12 months data together.

CER-209: positive results from Phase 1 Single Dose Tolerance Study for NAFLD and NASH

CER-209 is a selective P2Y13 receptor agonist that has shown the regression of atherosclerosis and liver steatosis in preclinical models.

The Phase 1 Single Dose Tolerance Study, completed last June, has reported an absence of safety and tolerance issues associated with CER-209, as well as pharmacokinetics observations supporting once-daily doses of this drug candidate.

Escalating doses of 1, 3, 10 and 30 mg were tested on 24 patients, treated in 4 cohorts of 6 subjects. In each cohort, 4 subjects were treated with active study medication and 2 subjects with a placebo.

Extension of the CERENIS HDL platform for immuno-oncology and chemotherapy

Acquisition of LYPRO Biosciences to build the first HDL-based targeted drug delivery platform, based on the use of HDL nanoparticles, 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), has the ability to target a specific human cell HDL receptor, SR-B1, in order to deliver anticancer agent directly to the diseased cells.

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.

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[1] classification. A total of 10 patients will undergo all study procedures.

Jean-Louis Dasseux, founder and **CEO** of **Cerenis**, commented: *"We are pleased with the clinical advances achieved in NASH and NAFLD as well as in HDL genetic deficiency. These two pathologies related to lipid metabolism represent major medical needs, a growing proportion of the world population developing liver diseases, while patients with the rare disease FPHA remain subject to*

[1] TNM classification: International classification that reports on the stage of cancer progression. The letter T is the tumor initial and corresponds to the size of the tumor; the letter N is the initial of "node" and indicates whether or not lymph nodes have been invaded; the letter M is the initial metastasis and indicates the presence or absence of metastases

serious complications due to the absence of HDL. Being fully focused on these promising projects, we look forward to the many milestones expected in 2018. It is therefore with enthusiasm that we are preparing for the launch of the second part of the Phase I study with CER-209 in the NASH and NAFLD, to study the safety and tolerance profile with multiple doses. Regarding the TANGO study, evaluating CER-001 in genetic HDL deficiency, the results should now be obtained in the fourth quarter of 2018, which does not change our goal of marketing the drug candidate in 2019. Major fact in 2017, CERENIS has extended its position to drug delivery in oncology and immuno-oncology following the acquisition of LYPRO Biosciences. This American biotech company, whose proprietary technology and associated pre-clinical data have been combined with our HDL particle mimetic, enables us today to offer the first HDL platform potentially suitable for the targeted drug delivery to cancer cells. The recent launch of the TARGET study must confirm the validity and safety of this highly innovative action mechanism based on biocompatibility, and the ability to transport active substance of apoA-I, which is the main constituent protein of HDL. "

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. 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:

Cash position and revenue for Q1 2018

April 19th, 2018

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