Press release

Cash position and activity update for Q1 2018

Progress of CER-209's clinical development in NASH/NAFLD

- **Solid cash position of €14.1 million at March 31, 2018**
- **Progress of CER-209's clinical development in NASH/NAFLD: enrollment of the first patients in the Phase 1 Study assessing repeated and increasing doses**

Toulouse, FRANCE, Lakeland, UNITED STATES, April 19, 2018, 6:30 pm CEST – **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 March 31, 2018, as well as the enrollment of the first patients in the Phase I Study to assess CER-209 in Non-Alcoholic Steato-Hepatitis (NASH) and/or Non-Alcoholic Fatty Liver Disease (NAFLD) following the administration of repeated and increasing doses of this drug candidate.

Solid cash position of €14.1 million at March 31, 2018

Cash and cash equivalents totaled €14.1 million at March 31, 2018. In line with expectations, CERENIS Therapeutics did not generate any revenue during the 1st quarter of 2018, the Company's products being at the Research and Development stage.

Progress of CER-209's clinical development in NASH/NAFLD: enrollment of the first patients in the Phase I Study assessing repeated and increasing doses

On April 19, 2018, the first patients in the Phase I study of repeated and increasing doses to assess CER-209 in NASH/NAFLD received the first doses. This progress follows the granting of regulatory authority approval to begin the study, as announced at the 2nd annual H.C. Wainwright NASH Investor Conference, held on March 19, 2018 in New York.

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

In June 2017, the first part of this phase I study assessing a single dose of CER-209 has shown no safety and tolerance issues as well as pharmacokinetics observations supporting once-daily doses of this drug candidate.

Daily administration of repeated and increasing doses of CER-209 over a 28-day period in patients with a high risk of NAFLD/NASH

The primary endpoints concern safety and tolerance following the administration of multiple doses of CER-209. Pharmacokinetic and pharmacodynamic endpoints will also be studied in order to define the optimal dose for the next studies.

The subjects included in the study have large waist circumferences and high triglyceride levels, parameters associated with a high risk of subsequently developing metabolic diseases such as NAFLD and NASH.

The protocol for this randomized, double blind and placebo controlled trial foresees the enrollment of 6 cohorts of subjects. Multiple doses of CER-209 will be administered in 6 cohorts of 5 subjects each. Daily doses of 10, 30, and 60 mg of CER-209 will be given for 28 days. In all cohorts 4 subjects will receive active drug.

First clinical assessment of the mechanism of action associated with the P2Y13 receptor

The profile of the study's subjects will enable assessment of two parameters associated with the mechanism of action of CER-209:

- Changes in the level of lipids in the liver, measured using magnetic resonance imaging (MRI-PDFF);
- The rate of fecal elimination of cholesterol and bile acids.

Positive efficacy signals, demonstrating improvement in these parameters, would enable validation of previous findings, and would strengthen CER-209's therapeutic potential, already highlighted in preclinical studies.

The mechanism of action of CER-209, an agonist of the P2Y13 receptor

In preclinical models, CER-209 results in a marked reduction in steatohepatitis as determined by a reduction in the levels of cholesterol, triglycerides and fatty acids in the liver compared with the placebo, as well as a reduction in atherosclerosis. Furthermore, CER-209 produces significant decreases in liver enzymes (ALT and AST) in the plasma. These effects suggest the restoration of liver integrity and indicate CER-209’s strong potential for treating NAFLD and NASH while reducing the risks associated with cardiovascular disease.

About CERENIS: www.cerenis.com

CERENIS Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative 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, well-known receptors including the P2Y12 receptor which is the target of successful drugs such as the anti-platelet agent Clopidogrel (Plavix®). CER-209 is a specific agonist of P2Y13 receptor and does not interact 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 as well as liver fat. Thus the favorable metabolic effects of CER-209 in the liver offers a new mechanism for the treatment of non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steato-hepatitis (NASH).

About Targeted HDL Drug Delivery

HDL particles, loaded with an active agent, 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 targeting 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 Q2 2018: July 26, 2018

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