Press release

Results of the Phase I study of repeated and increasing doses to assess CER-209 in NASH/NAFLD

- **Absence of any major adverse events, confirming CER-209's favorable safety and tolerance profile**
- **Daily administration of increasing doses of CER-209 over a 28-day period in patients with a high risk of NAFLD/NASH demonstrated proportional increase in CER-209 blood levels**
- **The mechanism of action via the P2Y13 receptor supported by changes in HDL cholesterol**

Toulouse, FRANCE, Lakeland, UNITED STATES, December 20, 2018, 7:30 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 the favorable results of the Phase I study of repeated and increasing doses to assess CER-209 in NASH/NAFLD.

Jean-Louis Dasseux, **Founder** of **Cerenis**, commented: "*Beyond the validation of the standard tolerance, safety and determination of the pharmacokinetic parameters, this Phase IB study supports the therapeutic potential of the CER-209 drug candidate as a dose related fall in fasted HDL cholesterol levels was observed at 28 days. These effects were consistent with CER-209 innovative mechanism of action observed in preclinical models to promote HDL recognition and lipid elimination by the liver by stimulating the P2Y13 receptor. The next step consists of developing a formulation and assessing CER-209's NASH efficacy endpoints within the framework of a Phase II study of longer duration.*"

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

CER-209 was safe and well tolerated following the administration of multiple doses in patients at high risk for NAFLD/NASH based on the presence of visceral obesity and/or dyslipidemia. Pharmacokinetic and pharmacodynamic endpoints were also studied in order to define the optimal dose for future studies. The protocol for this randomized, double-blind and placebo controlled trial involved the enrollment of six cohorts of patients, each receiving doses of 10, 30, and 60 mg of CER-209 or placebo given daily for 28 days.

The mechanism of action via the P2Y13 receptor supported by changes in HDL cholesterol

The observed absorption of CER-209 was fast (within thirty minutes) and proportional to the administered dose.

Although the duration of the administration of CER-209 in this study was too short to observe any metabolic changes, there were dose dependent decreases in fasted HDL-C on Day 28 compared to Day 1 which is consistent with the innovative mechanism of action of CER-209. This activation by CER-209 of the P2Y13 receptor promotes HDL recognition and lipid elimination by the liver.

The next steps will include the development of a formulation with optimal bioavailability in preparation for a Phase II clinical study in patients with NASH over a longer period of time.

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

Founded in 2005, Cerenis Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of HDL-based innovative therapies. CERENIS' expertise has translated into a rich portfolio of programs for the treatment of cardiovascular disease and associated metabolic diseases such as NAFLD and NASH as well as a HDL targeted drug delivery platform in oncology, more specifically in 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 and several products in clinical phases.

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 an HDL-based targeted drug delivery platform dedicated to the oncology market, including immuno-oncology and chemotherapy.

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