Press release

CERENIS announces the results of TANGO, a Phase III clinical study evaluating CER-001 in patients with HDL deficiency

- **Missed primary endpoint in the TANGO Phase III study, there was no statistically significant difference between the placebo and CER-001 treated groups for the primary outcome**
- **The safety and tolerability profile was favorable and consistent with previous CER-001 trials**
- **Results of the multiple ascending dose study with CER-209 in the NAFLD/NASH program are expected before the end of the year**
- **Further development of the targeted drug delivery HDL platform will continue**

Toulouse, FRANCE, Lakeland, USA, December 5, 2018, 8 am 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, metabolic diseases, and HDL platform technologies, today announces the results of TANGO, a Phase III clinical study evaluating CER-001 in patients with HDL deficiency.

Results of the Phase III clinical study, TANGO

This double-blind and placebo-controlled clinical study was carried out in the United-States, Canada, and Europe, involving 30 patients with Familial Hypoalphalipoproteinemia (FPHA), characterized by ABCA1 or apoA-I genetic mutations. The objective of the study was to assess the impact of 6 months of treatment with CER-001 on the mean vascular wall area (MVWA) of the carotid artery as determined by MRI.

In the first phase, patients received the placebo or CER-001 (at a dose of 8 mg/kg) once a week for 8 weeks (9 doses in total), followed by a second phase of 16 weeks with administration every two weeks (8 doses). In the final phase subjects received one administration every two weeks for an additional 24 weeks (12 doses). 3 Tesla Magnetic Resonance Imaging (3TMRI) was used to study changes in atherosclerotic plaque, using quantitative measurements in the carotid artery at 8, 24, and 48 weeks. The primary endpoint was pre-defined as the change in MVWA at 24 weeks.

However, no major treatment-related adverse events were observed, confirming the safety and good tolerance profile of CER-001. Analysis of the study data did not show a statistically significant reduction in atheroma plaque between the CER-001 and placebo groups.

Results of the multiple ascending dose study with CER-209 in the NAFLD/NASH program are expected by the end of the year

CER-209 is a drug candidate that increases the recognition by the liver of HDL loaded with lipids. The drug facilitates the elimination of liver fat and improves the vessel wall in models of NAFLD/NASH and atherosclerosis respectively. With the successful completion of the single-dose Phase I safety study, the multiple ascending dose study was authorized and the first patients were enrolled in April 2018. Results will be reported by the end of the year.

Further development of the targeted drug delivery HDL platform

The results for HDL mimetic and Cargomer® targeted drug delivery, were recently presented at the 30th EORTC/NCI/AACR[1] symposium. These data, combined with the preliminary positive results of Cerenis' TARGET Phase II clinical study announced on June 25th 2018, demonstrate the potential value of this unique platform, supporting its further development.

Jean-Louis Dasseux, founder and CEO of Cerenis, commented: "*The results of TANGO are disappointing and did not meet our expectations, particularly following the statistically significant efficacy results observed in the SAMBA Phase II trial. Our present efforts will continue to actively focus on the assessment of HDL as a targeted drug delivery platform. Recent evidence, including preliminary results from the Phase II TARGET study, have demonstrated the ability of HDL particles to act as universal carriers. Beyond tumor targeting in oncology and immuno-oncology, Cerenis is pursuing development for the treatment of NASH/NAFLD with its drug candidate CER-209. The results of the second Phase I study will be available before the end of this year. We therefore remain committed to further developing our portfolio of high-potential products, supported by our unique intellectual property and HDL industrial production capacity. We will also continue to explore new opportunities.*"

About CERENIS: www.cerenis.com

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-001

CER-001 is a bio-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. In animal models regression of atherosclerosis was demonstrated in several distinct vascular beds. SAMBA, the clinical Phase 2 study in patients with hypoalphalipoproteinemia due to genetic defects, has provided important pilot data demonstrating the potential of CER-001 leading to the TANGO study.

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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[1] European Organisation for Research and Treatment of Cancer (EORTC), the National Cancer Institute (NCI) and the American Association for Cancer Research (AACR), Dublin from November 13th to 16th, 2018