

#### **Press Release**

## STATEMENT FOLLOWING THE EVOLUTION OF THE CERENIS SHARE PRICE

- Management confirms no new information related to the clinical developments of the TANGO Phase III study with CER-001 has occurred
- Reminder of the clinical schedule for the end of 2018: results of the TANGO Phase III study with CER-001 in patients with HDL deficiency due to genetic mutations and results of the Phase I study with CER-209
- Solid cash position of €12.9 million at 30 September 2018

Toulouse, FRANCE, Lakeland, UNITED-STATES, November 21, 2018, 8:00am 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 reminds its clinical development schedule and informs investors that no new information, regarding the clinical results of TANGO with CER-001 in HDL deficiency, is currently available.

Cerenis Therapeutics is pursuing its development strategy as anticipated. As a reminder, the Company has a solid cash position which stood at €12.9 million at 30 September 2018.

Reminder of the clinical schedule for the end of 2018: results of the TANGO Phase III study with CER-001 in patients with HDL deficiency and results of Phase I study with CER-209 in NAFLD/NASH after administration of repeated and increasing doses

# CER-001: HDL therapy for patients with FPHA - Phase III (TANGO)

CER-001 is an HDL mimetic for the treatment of patients with HDL deficiency (FPHA: Familial Primary HypoAlphalipoproteinemia) due to genetic mutations in the gene coding for the ABCA-1 and the apoA-I. Cerenis Therapeutics has received two Orphan Drug Designations from the European Medicines Agency (EMA) for the use of CER-001 in the treatment of HDL deficiency patients. CER-001 reconstituted the reverse lipid transport (RLT) pathway in individuals who have defects in the natural HDL pathway, facilitating elimination of cholesterol from the body. The results of the PHASE III study are expected by the end of 2018. Positive TANGO results could lead to market authorization filing of CER-001 by the end of 2019.

CER-209 to address NAFLD/NASH and associated atherosclerosis through a validated mechanism of action - *Phase I multiple doses* 

CER-209 is a drug candidate that increases the recognition of HDL loaded with lipids by the liver and facilitates their elimination in patients with NAFLD/NASH and atherosclerosis. With the successful completion of the single-dose Phase I safety study, the repeated and escalating dose study was authorized and the first patients were included last April. Results are expected by end of Q4 2018.

#### 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. 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 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.

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