



Press release

## **Cash position and activity update for H1 2018 and key perspectives for the end of 2018**

- **Solid cash position of €13.5 million at June 30, 2018**
- **Key highlights of H1 2018: primary objective met in the first results of TARGET PHASE II study and with the strategic partnership with the University of North Texas Health Science Center**
- **Key perspectives by the end of 2018: results of TANGO PHASE III study with CER-001 with HDL deficiency patients and PHASE I study of repeated and increasing doses to assess CER-209 in NASH/NAFLD NAFLD/NASH**

**Toulouse, FRANCE, Lakeland, UNITED-STATES, July 18, 2018, 6.00 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, metabolic diseases, and HDL platform technologies today recapitulates the major events previously communicated and announced its cash position at June 30, 2018 and perspectives for the end of 2018.

### **Solid cash position of €13.5 million at June 30, 2018**

Cash and cash equivalents totaled €13.5 million at June 30, 2018. In June, the Company was granted €1.3 million in research tax credit for R&D expenses. In line with expectations, Cerenis Therapeutics did not generate any revenue during the first half of 2018, the Company's products being at the Research and Development stage.

### **Key highlights in the first half-year of 2018: Primary objective met in the first results of TARGET PHASE II study and strategic partnership with the University of North Texas Health Science Center**

The first results of TARGET PHASE II study published on June 25<sup>th</sup>, 2018, demonstrate the ability of CER-001, an HDL mimetic, to target tumor in patients with esophageal cancer. The primary objective is met with clinically meaningful targeting of esophageal tumor tissue by radiolabeled CER-001. The sustained tumor labeling supports future use of HDL mimetics to improve effective delivery of therapeutic agents. Results are consistent with preclinical studies using HDL mimetics. These encouraging results were observed in patients with esophageal cancer, often refractory to standard therapy. No safety or tolerability issues were observed.

In the first half-year of 2018 CERENIS Therapeutics announced the signing of a strategic partnership with the University of North Texas Health Science Center to develop new HDL technologies for drug delivery. The joint program will focus on the development of new HDL drug delivery products and technologies in collaboration with Andras Lacko, PhD, a prominent pioneering scientist in the

development of HDL delivery systems for cancer drugs. This initiative is another marker of Cerenis' strategic evolution into a company with novel HDL platforms for drug delivery in immunotherapy.

## **Key perspectives by the end of 2018: results of TANGO PHASE III study with CER-001 with HDL deficiency patients and PHASE I study of repeated and increasing doses to assess CER-209 in NASH/NAFLD NAFLD/NASH**

**Following the first results of TARGET PHASE II study, two other outstanding results are expected by the end of 2018:**

**CER-001:** results of TANGO PHASE III study with CER-001 with HDL deficiency patients. The Phase III TANGO trial is designed to assess both the efficacy of CER-001 to regress atherosclerosis and its safety in patients with FPHA. 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 of CER-001 in the end of 2019.**

**CER-209** in NAFLD/NASH and atherosclerosis with a validated mechanism of action: PHASE I of repeated and increasing doses. CER-209, by activating the natural metabolic pathways mediated by the P2Y13 receptor, promotes HDL recognition and lipid elimination by the liver. The Phase 1 Single Dose Tolerance Study was completed with success. **First patients were included last April and no tolerability issues were observed in the safety study. After approval to launch the Phase I Study with escalating doses the results of the study are expected in the second half year of 2018.**

**About CERENIS:** [www.cerenis.com](http://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, metabolic diseases, and HDL platform technologies. HDL is the primary mediator of the reverse lipid transport, or RLT, the only natural pathway by which excess lipids are removed from arteries and transported to the liver for elimination from the body.

In addition to advancing HDL technologies for drug delivery, 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). CERENIS is well positioned to become one of the leaders in the HDL therapeutic market, with a broad portfolio of programs in development.

### **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.

Cargomer™, apo-AI multimeric nanoparticles, and HDL particles such as CER-001 have the future potential to serve as carriers of multiple anti-cancer drugs, antigens, interfering RNA (siRNA's), and anti-sense oligonucleotides (ASOs) opening the path for the Cerenis platform.

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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