



Press release

## Cash position and activity update for Q3 2017

- **Solid cash position of €18.3 million at September 30, 2017**
- **CER-001: completion of patient enrollment in the Phase III study, TANGO, in HDL genetic deficiency**
- **CER-209: positive results from Phase I Single Dose Tolerance study for NAFLD and NASH**

**Toulouse, FRANCE, Lakeland, UNITED STATES, October 26, 2017** — **Cerenis Therapeutics (FR0012616852 – CEREN – PEA PME eligible)** an international biopharmaceutical company dedicated to the discovery and development of innovative therapies based on lipid metabolism for treating cardiovascular and metabolic diseases, today announces its cash position at September 30, 2017 and key highlights of the 3<sup>rd</sup> quarter of 2017.

### **Solid cash position of €18.3 million at September 30, 2017**

Cash and cash equivalents totaled €18.3 million at September 30, 2017. In line with expectations, Cerenis Therapeutics did not generate any revenue during the 3<sup>rd</sup> quarter of 2017, the Company's products being at the Research and Development stage.

### **Reminder of the latest clinical advances**

#### **CER-001: completion of patient enrollment in the Phase III study, TANGO, in HDL genetic deficiency**

The Phase III TANGO trial is designed to assess both the efficacy of CER-001, a pre-beta HDL particle containing human recombinant apolipoprotein A-I, to regress atherosclerosis, measured by 3T-MRI imaging, and its safety in patients with Familial Primary HypoAlphalipoproteinemia (FPHA), who are characterized by ABCA1 or apoA-I genetic mutations and are already receiving optimized background lipid therapy.

The TANGO trial is a multicenter, randomized, double-blind, parallel-group and placebo-controlled study. It involves 30 patients from several sites across Europe, Canada and the United States. The difficulties encountered in the identification of patients with FPHA, a rare disease, explain the past delay in the study schedule. Enrollment is now complete and results are expected late Q1 2018.

Existing data, obtained from the SAMBA Phase II trial of CER-001 in patients with FPHA, have supported the two orphan designation approvals granted by the European Medicines Agency (EMA). Data showed that CER-001 reconstitutes the reverse lipid transport (RLT) metabolic pathway in individuals who have

defects in the natural HDL pathway, facilitating elimination of cholesterol from the body. Importantly, one month of treatment with 9 doses of CER-001, given in addition to optimized standard of care for LDL-cholesterol-lowering therapy, resulted in a statistically significant reduction of atherosclerosis (reduction in carotid artery mean vessel wall area), as measured by magnetic resonance imaging (3T-MRI).

### **CER-209: positive results from Phase I Single Dose Tolerance study for Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH)**

CER-209 is a specific agonist of the P2Y<sub>13</sub> receptor which has demonstrated atherosclerosis and liver steatosis regression in preclinical models.

The Phase I Single Dose Tolerance Study, completed in June, has reported an absence of safety and tolerance issues associated with CER-209, as well as pharmacokinetic observations supporting once-daily doses of this drug candidate. Escalating doses of 1, 3, 10 and 30 mg were tested in 4 cohorts of 6 subjects. In each cohort, four subjects were treated with active study medication and two subjects with a placebo.

The increasing incidence of NAFLD and NASH, now becoming common diseases of the liver, is related to the rise in obesity and diabetes in the population. NAFLD, a precursor of NASH, is a disorder that is now considered to be the most common liver disease in the western world, affecting 30% of the world's population, according to a publication in the World Journal of Hepatology.

### **Financial calendar**

Cash position and revenue update for Q4 2017

**January 25, 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 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).

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 II 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. 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. CER-209 is a specific agonist of the P2Y13 receptor and does not interact with the P2Y12 receptor. In preclinical studies CER-209 promotes HDL recognition by the liver and increases Reverse Lipid Transport (RLT), thereby impacting atherosclerosis regression. Because of the favorable metabolic effects observed in the liver, CER 209 may also offer a new mechanism for the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH).



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