



Press release

## Cash position and revenue for the 1<sup>st</sup> semester of 2016

**Toulouse, FRANCE, Ann Arbor, UNITED STATES, July 28, 2016** – (FR0012616852 - CEREN), an international biopharmaceutical company dedicated to the discovery and development of innovative HDL therapies (“good cholesterol”) for treating cardiovascular and metabolic diseases, today announces its cash position and revenue for the first semester of 2016.

- **A solid cash position of €32.9m at June 30, 2016**

Cash and cash equivalents totaled €32.9m\* including the gross earnings generated by the Company’s spectacular IPO that enabled it to successfully raise €53.4m in March 2015. In line with expectations, Cerenis Therapeutics did not generate any revenue during the first semester of 2016.

As announced at the time of its IPO, Cerenis Therapeutics is currently pursuing the clinical development of CER-001, an HDL mimetic, as part of the phase II study for the post Acute Coronary Syndrome (post-ACS) indication, CARAT, and the phase III study for the FPHA (Familial Primary Hypoalphalipoproteinemia, an orphan disease indication), TANGO. The first patients have been recruited, respectively during the third and the fourth quarter of 2015, and the studies are proceeding according to expectations. Cerenis is also pursuing the preclinical development of CER-209, a novel agonist of the P2Y13 receptor for the treatment of atherosclerosis and liver steatosis.

- **Several major publications marked the 1<sup>st</sup> semester of 2016**

**CER-001: publication of the LOCATION clinical study results in the renowned scientific journal ATHEROSCLEROSIS**

Last May, the publication of the LOCATION clinical study results in the world-renowned scientific journal of the European Atherosclerosis Society (EAS), ATHEROSCLEROSIS, offers a valuable validation of the functionality of CER-001, demonstrating the mimetic’s capacity to penetrate the vessel walls, to preferentially target atherosclerotic plaques and to increase cholesterol efflux capacity. The LOCATION study, whose positive results were announced in July 2015, are reassuring prior to the publication of the CARAT study results, planned for first quarter of 2017, as the targeting of atherosclerotic plaques was observed at the dose of 3 mg/kg, dose used in this phase II clinical study in post-ACS patients which intends to demonstrate plaque regression.

The press release on results of the LOCATION study is available on Cerenis' website in the section Media/Press releases. [Click here](#) to access.

### **CER-209: positive preclinical results demonstrate its active role to treat atherosclerosis and non-alcoholic steatohepatitis (NASH)**

At the 25<sup>th</sup> Conference of the Asian Pacific Association for the Study of the Liver (APASL), held in Tokyo in February 2016, Cerenis presented preclinical results of CER-209 ("P2Y13 receptor agonist CER-209 decreases both atherosclerosis and liver steatosis in vivo"<sup>1</sup>), a selective novel agonist of the P2Y13 receptor (P2Y13R) that caused an increased uptake of high-density lipoprotein-cholesterol (HDL-c) in the liver which is associated with stimulation of bile acid secretion. Repeated dose administration of CER-209 stimulated the apoA-I synthesis and formation of small HDL particles, known to be atheroprotective. CER-209-treated plasma samples had high cholesterol efflux capacity for the mobilization of cellular cholesterol in vitro compared with the placebo group. CER-209 induced a decrease in atherosclerotic plaques in aorta and carotids as well as a remarkable decrease in the steatosis in a validated preclinical model.

In a poster presentation, "P2Y13 receptor agonist CER-209, an anti-atherosclerotic compound, decreases liver steatosis in vivo"<sup>2</sup>, Cerenis presented results of CER-209, a selective novel agonist of the P2Y13 receptor (P2Y13R). In this preclinical model, CER-209 resulted in a marked reduction in overall steatohepatitis as determined by reductions in cholesterol, triglycerides and fatty acids compared with placebo. Furthermore, CER-209 produced considerable decreases in liver enzymes (ALT and AST) in the plasma. These effects suggest the restoration of liver integrity and indicate a strong potential for CER-209 to treat liver disease such as NASH and non-alcoholic fatty liver disease (NAFLD) associated with cardiovascular disease.

These are important findings given the current lack of treatment options for NASH and introduce P2Y13R as a new therapeutic target for this disorder. CER-209 exerts its beneficial effect on liver steatosis via a specific action on the cholesterol elimination pathways. Considering the fact that cardiovascular risk is further increased in patients with NASH and NAFLD diseases, CER-209 has a strong potential to become a reference treatment for atherosclerosis, NASH and NAFLD.

*\* Unaudited*

Reference

*1: P2Y13 receptor agonist CER-209 decreases both atherosclerosis and liver steatosis in vivo: Rudi Baron, Marine Goffinet, Nadia Boubekeur, Claudine Tardy, Guy Cholez, Daniela C. Oniciu, Narendra D. Lalwani, Jean-Louis H. Dasseux and Ronald Barbaras*

*2: P2Y13 receptor agonist CER-209, an antiatherosclerotic compound, decreases liver steatosis in vivo: François Briand, Thierry Sulpice, Jean-Louis H. Dasseux and Ronald Barbaras*

#### **Financial agenda:**

2016 half-year results  
**September 5, 2016**

Revenue for the 3<sup>rd</sup> quarter of 2016  
**November 7, 2016**

#### About Cerenis Therapeutics: [www.cerenis.com](http://www.cerenis.com)

Cerenis Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative HDL 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 cholesterol is removed from arteries and is transported to the liver for elimination from the body.

Cerenis is developing a portfolio of HDL therapies, including HDL mimetics for the rapid regression of atherosclerotic plaque in high-risk patients such as post-ACS patients and patients with HDL deficiency, and drugs which increase HDL for patients with low number of HDL particles to treat atherosclerosis and associated metabolic diseases.

Cerenis is well positioned to become one of the leaders in the HDL therapeutic market, with a broad portfolio of programs being developed.

Since its inception in 2005, the company has been funded by top tier investors: Sofinnova Partners, HealthCap, Alta Partners, EDF Ventures, Daiwa Corporate Investment, TVM Capital, Orbimed, IRDI/IXO Private Equity and Bpifrance (Fund for Strategic Investment) and last March successfully completed an IPO on Euronext raising €53.4m.

#### 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. Previous Phase II studies have provided important data demonstrating the efficacy of CER-001 in regressing atherosclerosis in several distinct vascular beds in patients representing the entire spectrum of cholesterol homeostasis. 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 in the market.

#### 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, a well-known receptor family including the P2Y12 receptor which is the target of successful drugs such as the anti-thrombotic agent Clopidogrel (Plavix®). 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. Because of the favorable metabolic effects observed in the liver, CER-209 may offer a new mechanism for the treatment of atherosclerosis and non-alcoholic steatohepatitis (NASH).



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