Press Release

Cash position and revenue for the 1st quarter of 2016

Toulouse, FRANCE, Ann Arbor, UNITED STATES, May 3, 2016 – **Cerenis Therapeutics** (**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 at March 31, 2016 and its revenue for the 1st quarter of 2016.

- **A solid cash position of €38.4m at March 31, 2016**

At March 31, 2016, cash and cash equivalents totaled €38.4m[1] 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 quarter of 2016.

Cerenis Therapeutics is currently pursuing the development 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, as announced at the time of its IPO.

- **Major clinical breakthroughs for CER-001 in 2015**

In accordance with the development plan, during the third quarter of 2015 the Company announced the enrollment of the first patients into the phase II CARAT trial, which assesses reduction in atherosclerotic plaque using CER-001 in post-ACS patients. The first patient in the TANGO trial for the treatment of HDL genetic deficiency (FPHA) was enrolled during the final quarter of 2015, in line with the clinical development plan.

Prior to the launch of TANGO, new data for CER-001 was presented by Professor Stephen Nicholls at the 2015 American Heart Association (AHA) scientific sessions. The data, which demonstrates atherosclerosis plaque regression at the 3 mg/kg dose in patients with a baseline percentage of atheroma volume (PAV[2]) higher or equal to 30%, makes it possible to reassert Cerenis Therapeutics' strong belief in CER-001's efficiency and to confirm the optimal design of both the CARAT and TANGO studies currently being developed.

In summary, to date all the preclinical and clinical results demonstrate that CER-001 behaves as a natural HDL particle by emulating the reverse transport of cholesterol, the metabolic pathway responsible for the mobilization of cholesterol from extra-hepatic tissue, and in particular vessel walls, the esterification and the transport of cholesterol to the liver for elimination in the feces. This results in a clinical benefit, as illustrated by the regression of atherosclerotic plaque.

- **Positive preclinical results demonstrating that CER-209 plays an active role in the treatment of atherosclerosis and non-alcoholic steatohepatitis (NASH)**

At the 25th Conference of the Asian Pacific Association for the Study of the Liver (APASL), held in Tokyo in February 2016, Cerenis presented CER-209 preclinical results ("P2Y13 receptor agonist CER-209 decreases both atherosclerosis and liver steatosis in vivo"[3]), a selective novel agonist of the P2Y13 receptor (P2Y13R), that caused an increased uptake of high-density lipoprotein-cholesterol (HDL-c) by 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 show high cellular cholesterol efflux capacity 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.

HDL is known to protect against atherosclerosis by promoting the reverse lipid transport resulting in the elimination of lipids, and notably cholesterol, in the feces. This new pathway for the regulation of HDL-c recognition by the liver involving F1-ATPase and P2Y13 receptor (P2Y13R) has been described in vitro and, more recently, observed in a preclinical model. An increase in the expression of liver mRNA coding for apoA-I as well as an increase in plasma apoA-I concentration were observed in a preclinical model treated by CER-209. The uptake of large, mature HDL particles loaded with cholesterol by the liver also stimulates de novo synthesis of nascent HDL particles, thereby enhancing the cholesterol efflux capacity of the serum. The overall implication of this increase is not only to allow the removal of cholesterol from atherosclerotic plaques, but also to assure lipid homeostasis in the liver.

In another poster presentation ("P2Y13 receptor agonist CER-209, an anti-atherosclerotic compound, decreases liver steatosis in vivo"[4]), Cerenis presented further results with the selective novel agonist of the P2Y13R, CER-209. 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 of liver enzymes (ALT and AST) in the plasma. These effects suggest the restoration of liver integrity and indicate a substantial potential for CER-209 to treat liver diseases 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.
Given that patients with NASH and NAFLD are at a higher cardiovascular risk, CER-209 has substantial potential to establish itself as a benchmark treatment for atherosclerosis, NASH and NAFLD.

1: unaudited
2: marker directly linked to the risk of cardiovascular events

3: 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
4: P2Y13 receptor agonist CER-209, an antiatherosclerotic compound, decreases liver steatosis in vivo: François Briand, Thierry Sulpice, Jean-Louis H. Dasseux and Ronald Barbaras

Upcoming events

Investor and scientific forum:

Gilbert Dupont 14th Annual Healthcare Conference
May 10, 2016

BioEquity Europe 2016 Copenhagen
May 10-11, 2016

Jefferies Global Healthcare Conference
June 7-10, 2016

Kepler Cheuvreux Biotech Days
June 15-16, 2016

Financial agenda:

Shareholders' meeting
June 10, 2016

Revenue for the 1st half of 2016
July 28, 2016

2016 half-year results
September 5, 2016

About Cerenis Therapeutics: 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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