Press release

2016 Half-Year Results

Solid cash position of €33 million and major scientific results

Toulouse, FRANCE, Ann Arbor, UNITED STATES, September 5, 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 results for the first half of 2016.

Jean-Louis Dasseux, **founder and CEO of Cerenis**, comments: "*The progress made in our clinical programs is entirely in line with the schedule announced at the time of Cerenis' IPO. We remain confident in the success of our clinical programs with our drug candidate CER-001, an HDL mimetic, for efficiently treating patients with acute coronary syndrome (ACS) or suffering from an HDL genetic deficiency. This is reinforced by the scientific community's interest in the positive results obtained for CER-001 by the SAHMRI (South Australian Heart Health Research Institute) team in reduction of plaque burden, the results of the LOCATION study showing targeted delivery to plaque and the recently presented safety data at the European Society of Cardiology annual congress. Lastly, following the positive scientific results presented during the conference of the APASL (Asian Pacific Association for the Study of the Liver) in February 2016, we will announce CER-209's clinical development plan during the second half of 2016, this product intending to help NASH patients with a very high cardiovascular risk, which is a major global health problem".*

Cyrille Turpin, Chief Financial Officer of Cerenis, adds: "*Our Research & Development costs, mainly associated with the progress of the CARAT and TANGO trials, are perfectly consistent with our financing plan and provides us with a clear path forward. We have a solid treasury position, linked to good scientific results, in perfect accordance with our future plans".*

Financial information *(at June 30 / IFRS consolidated accounts)*

in million €	H1 2016	H1 2015
Revenue	0	0
R&D expenditure	-10.21	-5.24
Administrative, sales and marketing expenses	-3.83	-1.06
Operating income	**-14.04**	**-6.30**
Financial income	0.55	0.44
Financial expenses	-1.18	-1.20
Net financial items	**-0.63**	**-0.76**
Net income	**-14.66**	**-7.06**
Net income per share (€)	**-0.82**	**-0.46**
Net cash flow related to operating activities	-11.02	-6.08
Net cash flow related to financing activities	0.94	48.92
(Decrease) / Increase in cash position	**10.08**	**42.82**
Cash and cash equivalents at end of period	**32.87**	**50.66**

In line with expectations, Cerenis Therapeutics did not generate any revenue during the first half of 2016; the Company's products are at the Research and Development stage. Cerenis Therapeutics is currently pursuing the clinical development of CER-001, an HDL mimetic, as part of a phase II study in post Acute Coronary Syndrome (post-ACS) patients, CARAT, and a phase III study for FPHA (Familial Primary Hypoalphalipoproteinemia, an HDL deficiency due to a genetic defect which is an orphan disease), TANGO. 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.

Research and Development costs totaled €10,213k over the period, compared with €5,239k at June 30, 2015. The substantial increase in these expenses was due to the significant progress made by the CARAT and TANGO clinical studies, initiated in the third and fourth quarters of 2015, respectively. These expenses mainly include the conduct of the phase II CARAT trial by SAHMRI (South Australian Health and Medical Research Institute) and the enrolment of patients for the TANGO study. They also include the expenses associated with the production of CER-001 batches by Cerenis Therapeutics' manufacturing partner.

The financial charges result from the application of IFRS to BPI repayable advances, and to the impact of exchange rate fluctuations when paying service providers in their local currency (mainly American and Australian dollars).

Cash and cash equivalents totaled €32.9m* including the gross earnings generated by the Company's IPO that raised €53.4m in March 2015.

H1 2016 publications and scientific results

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

May's publication of the LOCATION clinical study results in the world-renowned scientific journal of the European Atherosclerosis Society (EAS), ATHEROSCLEROSIS, further supports the 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 positive results of the LOCATION study are reassuring in advance 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, the same dose used in CARAT, a phase II clinical study in post-ACS patients intended to demonstrate plaque regression.

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

CER-209: positive preclinical results demonstrate its active role to treat 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 preclinical results of CER-209 ("P2Y13 receptor agonist CER-209 decreases both atherosclerosis and liver steatosis in vivo"[1]), a selective novel agonist of the P2Y13 receptor (P2Y13R) that caused an increased uptake of high-density lipoprotein-cholesterol (HDL-c) in the liver and stimulation of bile acid secretion. Repeated dose administration of CER-209 stimulated 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 another poster presentation, "P2Y13 receptor agonist CER-209, an anti-atherosclerotic compound, decreases liver steatosis in vivo"[2], Cerenis presented additional results for CER-209. In a preclinical model, CER-209 resulted in a marked reduction in overall steatohepatitis as demonstrated 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 fatty 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 cardiovascular risk is further increased in patients with NASH and NAFLD, CER-209 has substantial potential to become a reference treatment for atherosclerosis, NASH and NAFLD.

** Unaudited*

References

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:
Revenue for the 3rd quarter of 2016
November 7, 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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