Press release

2017 Half-Year Results

Solid cash position of €20 million and significant scientific progress

Toulouse, FRANCE, Lakeland, UNITED STATES, September 12, 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 results for the first half of 2017.

Jean-Louis Dasseux, **founder and CEO of Cerenis**, comments: *"The latest clinical outcomes of CER-209, currently being evaluated in a Phase 1 study, have provided an important initial validation of the safety and tolerability profile of our potential drug candidate dedicated to the treatment of common liver diseases, NAFLD and NASH, two indications that represent major global health challenges. Henceforth we are looking forward to finalizing Phase 1 in order to assess the efficacy of CER-209, whose pre-clinical results highlighted the potential of Cerenis's innovative approach, based on the stimulation of a natural metabolic pathway that increases the elimination of lipids by the liver. Lastly, we are actively continuing the TANGO Phase 3 study in HDL genetic deficiency, the results of which are expected in early 2018."*

Cyrille Tupin, Chief Financial Officer of Cerenis, adds: "*The high level of financial resources available to Cerenis, coupled with a solid balance sheet, will ensure that current clinical phases will be completed, in HDL genetic deficiency with CER-001 as well as in NAFLD and NASH with CER-209, while continuing to study the therapeutic potential of our other drug candidates characterized by clearly distinct mechanisms of action."*

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

€ millions	H1 2017	H1 2016
Revenue	0	0
R&D expenditure	-2.13	-10.21
Administrative, sales and marketing expenses	-0.76	-3.83
Operating income	**-2.89**	**-14.04**
Financial income	*2.69*	*0.55*
Financial charges	*-0.51*	*-1.18*
Net financial items	**2.19**	**-0.63**
Net income	**-0.71**	**-14.66**
Net income per share (€)	**-0.04**	**-0.82**
Net cash flow related to operating activities	-5.23	-11.02
Net cash flow related to financing activities	0.90	0.94
(Decrease) / Increase in cash position	**-4.33**	**-10.08**
Cash and cash equivalents at end of period	**20.34**	**32.87**

In line with expectations, Cerenis Therapeutics did not generate any revenue during the first half of 2017; the Company's products being at the Research and Development stage. Cerenis Therapeutics is currently conducting TANGO, a Phase 3 clinical study in patients suffering from HDL deficiency due to defects in genes coding for apoA-I and ABCA1, within the framework of two orphan drug designations granted by the European Medicines Agency (EMA). The results of this study are expected in early 2018. Cerenis is also pursuing the preclinical development of the CER-209 drug candidate for the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH).

Research and Development costs totaled €2,133k over the period, compared with €10,213k over the first half of 2016. This substantial decrease in expenses was due to:

- The completion of the CARAT study, whose results were announced in a press release on March 1st, 2017;
- The settlement of the claim brought against the Montreal Heart Institute, Canada ("ICM"), which generated a €1.6 million reduction in expenses.

Financial income and charges correspond to the IFRS treatment of the BPI repayable advances and the effect of exchange rates variations when paying suppliers in foreign currencies (mainly the US and Australian dollars). As of June 30, 2017, due to CARAT's results and the continuation of the Phase 3 clinical study in the treatment of HDL deficiency, the results of which should be available in early 2018, the repayment schedule has been updated in accordance with the latest estimates. The rescheduling of repayments resulted in the recognition of financial income of €2,113k in the interim consolidated financial statements as of June 30, 2017.

Cash and cash equivalents totaled €20.3 million at June 30, 2017

H1 2017 scientific outcomes

CER-209: positive results from Phase 1 Single Dose Tolerance Study for NAFLD and NASH

The Phase 1 Single Dose Tolerance Study, completed in June, has reported an absence of safety and tolerance issues associated with CER-209, as well as pharmacokinetics observations supporting once-daily doses of this drug candidate.

The objective of the Single Dose Tolerance study carried out in the US was to assess the safety, tolerability and pharmacokinetics of CER-209 when taken orally as a single dose. Escalating doses of 1, 3, 10 and 30 mg were tested on 24 patients, treated in 4 cohorts of 6 subjects. In each cohort, 4 subjects were treated with active study medication and 2 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 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".

CER-001: update on TANGO, a Phase 3 study in patients with HDL deficiency

Cerenis Therapeutics is currently conducting TANGO, a Phase 3 study in patients with HDL deficiency due to defects of genes coding for apoA-I and ABCA1, within the framework of two orphan drug designations granted by the European Medicines Agency (EMA). The results of this study are expected in early 2018.

TANGO is a Phase 3 clinical study designed to evaluate both the efficacy of CER-001 to regress atherosclerosis and its safety in patients with FPHA caused by an ABCA1 or an apoA-I genetic mutation and who are receiving optimized background lipid-lowering therapy.

Inherited defects in the apoA-I or ABCA1 genes can cause FPHA, a rare syndrome characterized by the absence or severe deficiency of HDL particles in the blood. This means that the body's only natural mechanism for eliminating cholesterol is compromised. These patients thus experience an increased accumulation of cholesterol, particularly in blood vessel walls, which often results in accelerated atherosclerosis and premature cardiovascular disease.

Financial agenda:
Revenue for the 3rd quarter of 2017
October 26, 2017

About Cerenis: 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-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).

About TANGO clinical trial

TANGO is a Phase 3, multicenter, randomized, 48-week, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of CER-001 on vessel wall area in thirty patients with genetically defined familial hypoalphalipoproteinemia (apoA-I and ABCA1 deficiencies) and receiving background optimized lipid therapy. Primary endpoint: to evaluate the effect of 24 weeks' treatment with CER-001 on carotid mean vessel wall area (MVWA) compared with placebo using 3TMRI. Secondary endpoints: to evaluate the effect of 8 and 48 weeks' treatment with CER-001 on carotid MVWA compared with placebo using 3TMRI.

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 2 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.

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