Press Release

2016 ANNUAL RESULTS

Solid cash position of €24.7 million and finalization of CARAT phase 2 clinical study

Toulouse, France, Ann Arbor, United States, February 17 2017 – 6 pm CET – 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 full-year 2016 financial results, as approved by the Board of Directors on February 17 2017. Audit procedures on statutory and consolidated accounts have been performed by the auditors and certification report is currently being issued.

SELECTED FINANCIAL INFORMATION AT DECEMBER 31 2016 (*IFRS Consolidated accounts*)

in € million	2016	2015
Revenue	0	0
R&D expenditure	-17.0	-12.6
Administrative, sales and marketing expenses	-7.0	-2.9
Operating income	**-24.0**	**-15.5**
Financial income	1.4	1.3
Financial expense	-2.2	-2.4
Net financial items	-0.8	-1.2
Net income	**-24.9**	**-16.6**
Net income per share (€)	-1.39	-1.00
Net cash flows related to operating activities	-19.2	-13.7
Net cash flows related to financing activities	1.0	49.0
Cash position variation	**-18.3**	**35.1**
Cash and cash equivalents at the end of the period	**24.7**	**43.0**

Cyrille Tupin, Chief Financial Officer of Cerenis, said: "The level of cash consumption, in line with our expectations, is directly linked to the clinical advances of our two main products, CER-001 and CER-209, potential therapeutic breakthroughs for indications which are major global public health issues: cardiovascular diseases and liver steatosis. The solid financial resources currently available to the Company enable us to comfortably consider the clinical developments expected in 2017, relating to the Phase 1 of CER-209 and TANGO, the Phase 3 of CER-001."

In line with expectations, Cerenis did not generate any revenue in 2016, the Company's products being at the Research and Development stage. Cerenis is currently pursuing the development of CER-001, a pre-beta HDL mimetic containing recombinant human apoA-I, after having completed CARAT, a phase 2 study, in post Acute Coronary Syndrome (post-ACS) patients, and through TANGO, a phase 3 study in patients with Familial Primary HypoAlphalipoproteinemia (FPHA: HDL deficiency due to defects of coding genes and including several orphan diseases). The results of the CARAT and TANGO studies are respectively expected in Q1 and Q3 2017. Cerenis Therapeutics is also developing CER-209, a P2Y13 receptor agonist for the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH). The first subject recruitment should occur in Q1 2017.

R&D expenditure increased from €12.6 million in 2015 to €17.0 million in 2016. This increase mainly reflects the pursuit of the CARAT and TANGO clinical trials. The expenses, for a large part, relate to wages induced by R&D, and subcontracting and consultancy fees regarding the studies and patent management. To a lesser extent, the increase of share-based payments, in line with IFRS 2 "Share-based Payment" accounting norm application, is also responsible for the rise of R&D expenditure.

Administrative, sales and marketing expenses, totalled €7.0 million at December 31 2016 compared to €2.9 million in 2015. This increase relates to the increase in share-based payments.

The evolution of the **operating loss**, from -€15.5 million in 2015 to -24.0 million 2016, is relating to the rise of R&D expenditure, as stated above.

After taking into account the **financial results** of -€0.8 million in 2016 versus -€1.2 million in 2015, Cerenis' **net loss** amounted to -€24.9 million at December 31 2016 compared to -€16.6 million at December 31 2015.

Cash and cash equivalents amount to 24.7 million at December 31 2016, as announced at the occasion of the 2016 revenue publication, compared to €43.0 million at December 31 2015.

2016 KEY EVENTS

Finalization of CARAT phase 2 study

Last patient recruitment occurred in August 2016, and the last patient received the tenth and final dose of CER-201 or placebo in Q4 2016. The results of the CARAT study are expected no later than the end of the first quarter of 2017.

CARAT is a phase 2 study intending to assess the impact of CER-001 on the regression of atherosclerotic plaque in post-ACS patients. The multicenter study included 301 patients across 4 countries: Australia, Hungary, The Netherlands and the United States.

The risk of recurrence of a heart attack for patients who have already experienced an acute coronary syndrome (ACS) event remains very high and represents a significant and unmet medical need. CER-001, by enabling the rapid regression of atherosclerotic plaques, could potentially provide a unique opportunity to reduce the risk of recurrent cardiovascular events during the first few months following an ACS event. CER-001, in addition to conventional treatments, such as long-term LDL-C lowering treatments, could produce further reductions in morbidity and mortality rates and become the new standard of care for treating patients following an ACS.

Development of TANGO phase 3 study

The active enrollment of patients in the TANGO phase 3 study is ongoing, with results that should be available in Q3 2017.

TANGO is a phase 3 study in the orphan disease FHPA, designed to evaluate the effects of a six months chronic treatment with CER-001 in 30 patients with HDL deficiency. The Company has engaged 18 sites worldwide to optimize the availability of patients with FPHA, a rare but clinically important orphan disease.

CER-001's POC and safety and tolerability data presented

The publication of the results of the LOCATION study in the renowned scientific journal of the European Society of Atherosclerosis (EAS) in June 2016, testifies the interest of the scientific community for CER-001 and therefore to the solidity of the POC.

The LOCATION study, whose positive results were announced in July 2015, allowed to assess the selectivity of CER-001, an HDL mimetic made of recombinant human apolipoprotein A-I (apoA-I) and phospholipids, for carotid plaques in patients with advanced atherosclerotic disease. LOCATION provided the first evidence of CER-001 selective targeting of atherosclerotic plaques in patients, and of the role of plaque permeability in plaque penetration by an HDL mimetic. The study evaluated 8 patients with >50% atherosclerotic stenosis of the carotid artery who received an infusion of CER-001 (3 mg/kg body weight) labeled with Zirconium-89, a tracer suited for PET/CT imaging, to determine the extent to which CER-001 targets and penetrates atherosclerotic plaques and the effect on cholesterol efflux, a marker which is inversely related to the incidence of adverse cardiovascular events.[1]

[1] *Rohatgi A, Khera A, Berry JD, Givens EG, Ayers CR, Wedin KE, Neeland IJ, Yuhanna IS, Rader DR, de Lemos JA, Shaul PW. HDL Cholesterol Efflux Capacity and Incident Cardiovascular Events. N Engl J Med. 2014;371(25):141118051511004*.

Clinical data showing the very satisfying safety and tolerability profile of CER-001 were presented at the 2016 European Society of Cardiology Congress (ESC), held in Rome in August 2016. This data supports the development of CER-001 as both a short (post-ACS population) and a long-term treatment (HDL-deficient patients). This poster which reports the clinical tolerability and safety findings seen with CER-001 across the clinical development program found a similar safety and tolerability profile to placebo.

CER-209's preclinical development completion

In December 2016, the U.S. Food and Drug Administration (FDA) informed Cerenis Therapeutics that clinical trials with CER-209 may proceed. The Investigational New Drug application (IND) for CER-209 includes plans for a Phase 1 clinical study of its P2Y13 receptor agonist drug candidate (CER-209) in healthy volunteers for the clinical investigation of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH). CER-209, a selective novel agonist of the P2Y13 receptor decreased both atherosclerosis and liver steatosis in preclinical models. Cerenis plans to begin subject enrollment in Q1 2017.

CER-009 preclinical results were presented at the Asian Pacific Association symposium (APASL) in February 2016, held in Tokyo. Two posters were presented at this occasion.

Financial agenda:
Revenue for the 1st quarter of 2017
April 20, 2017

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 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.

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 2 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 that is the target of successful drugs such as the anti-thrombotic agent Clopidogrel (Plavix®). 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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