Press release

Cash position and revenue for Q3 2016

Toulouse, FRANCE, Ann Arbor, UNITED STATES, November 7, 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 September 30, 2016 and its revenue for the third quarter 2016.

Solid cash position of €28.7 million at September 30, 2016

Cash and cash equivalents totaled €28.7 million. In line with expectations, Cerenis Therapeutics did not generate any revenue during the third quarter of 2016, the Company's products being at the Research and Development stage.

Cerenis Therapeutics is currently finalizing a phase II study in post Acute Coronary Syndrome (post-ACS), whose patients' enrolment was recently completed. Cerenis Therapeutics is also pursuing TANGO, a phase III study for patients with HDL deficiency due to defects in genes coding for apolipoprotein A-I and ABCA1, within the framework of the two orphan drug designations granted by the European Medicines Agency.

Publications and clinical progress recorded during Q3 2016

End of patients' enrolment in CARAT study, in line with the clinical schedule

CARAT is a double blind, placebo-controlled, phase II study intending to assess the impact of CER-001 on the regression of atherosclerotic plaque in post-ACS patients by measuring the percent atheroma volume (PAV) using intravascular ultrasound (IVUS) imaging of the coronary vascular wall, before and after the treatment.

To maximize the efficacy of CER-001 in post-ACS patients, the CARAT design involves administration of ten doses of the HDL-mimetic over a 9-week period, i.e. one dose per week, at the previously defined optimal dose of 3 mg/kg. The CARAT study, which includes 301 patients across 4 countries (Australia, Hungary, The Netherlands and the United States), is under the supervision of a prestigious steering committee, with Prof. Stephen Nicholls of the Heart Health Research team at SAHMRI (South Australian Health and Medical Research Institute, Adelaide, Australia) as the principal investigator.

The CARAT study draws on findings from prior studies in humans, particularly the positive data presented in November 2015 at the American Heart Association Scientific Congress by the Prof. Stephen Nicholls to establish whether CER-001 promotes plaque regression in patients following an ACS. The 3 mg/kg dose was selected taking into account clinical and pre-clinical findings that confirm

a larger number of CER-001 administrations at a low dose are more efficient at plaque regression than a smaller number of high-dose administrations[1].

Enrolment in the CARAT study has completed on schedule and results are anticipated no later than the first quarter of 2017. Subject to the positive outcome of CARAT, a phase III pivotal study (CALMS) will then be launched.

No safety or tolerability issues have been identified in CARAT to prevent the study being completed as planned – periodic safety reviews have been performed during the on-treatment period by a data safety monitoring board (DSMB), which includes surveillance of laboratory testing and on-treatment safety events.

Preclinical data showing favorable safety and tolerability profile of CER-001 were presented at the 2016 European Society of Cardiology Congress (ESC)

This poster reports the clinical tolerability and safety findings seen with CER-001 across the clinical development program, to date, and determines whether any specific treatment-related adverse events (AEs) emerge as clinical experience with the product grows.

The results of the Phase I placebo-controlled study, which involved 32 subjects, showed CER-001, across a wide dose range of 0.25 to 45 mg/kg, to have a tolerability profile similar to that of placebo. Moreover, this study showed that CER-001 significantly mobilises cholesterol in the HDL fraction without causing significant elevation of liver enzymes, even at the higher doses. Additionally, no adverse effects of CER-001 on ECGs were observed and no antibodies to apoA-I, the protein present in natural HDL and in the CER-001 complex, were detected following single dose administration.

Pooling safety and tolerability data from 530 patients involved in the completed Phase II studies that evaluated multiple doses of CER-001 across the range 3-12 mg/kg found a safety profile that is comparable with placebo. No unusual or concerning AEs have been reported to date and after six administrations, one each week, in post-ACS patients, no antibodies against apoA-I were detected at 6 months. CER-001 is not associated with any adverse impact on hepatic safety as no clinically relevant differences in elevations of liver enzyme levels between CER-001 and placebo have been observed.

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.

[1] Kataoka Y, et al. Greater regression of coronary atherosclerosis with the pre-beta high-density lipoprotein mimetic CER-001 in patients with more extensive plaque burden. Circulation 2015; 132: A12156.

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.

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