



Press Release

## Publication of the LOCATION clinical study results in the renowned scientific journal of the European Atherosclerosis Society (EAS)

Results of the LOCATION study demonstrate the functionality of CER-001 and are reassuring prior to the publication of the study CARAT, planned for first quarter of 2017

Toulouse, FRANCE, Ann Arbor, UNITED STATES, June 2, 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 the publication of the LOCATION clinical study results in the internationally peer-reviewed journal *ATHEROSCLEROSIS* ([Click here to access the abstract](#)), the reference publication of the European Atherosclerosis Society (EAS).

**Dr. Jean-Louis Dasseux, Founder and CEO of Cerenis Therapeutics declared:** *"Results of the LOCATION study offer a valuable 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. Indeed, these outcomes are of major scientific importance, as proved by their publication in the world-renowned scientific journal *ATHEROSCLEROSIS*. Additionally, they are particularly reassuring prior to the publication 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, dose used in this phase II clinical study in post-ACS patients which intends to demonstrate plaque regression".*

**Professor Erik Stroes, Principal Investigator of the LOCATION study commented:** *"The LOCATION study confirms for the first time the targeting of atherosclerotic plaques by apoA-I containing HDL mimetics in humans, an effect only previously observed in experimental models of atherosclerotic disease. Our results are also consistent with the observed reduction in atherosclerosis shown in patients with HDL deficiencies, in patients with homozygous familial hypercholesterolaemia, and in post-ACS patients. Our data support the concept that CER-001 targets plaque regions in patients, which correlates with plaque contrast enhancement. These clinical findings are supportive of the ongoing CARAT and TANGO studies and may also guide future nanomedicine development using HDL particles for drug delivery in atherosclerosis".*

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<sup>1</sup>.

The results of the LOCATION study are consistent with the findings of the CER-001 pre-clinical and clinical programs to date, which have shown that CER-001 effectively mobilises cholesterol and regress atherosclerosis. The findings of this study validate plaques targeting with CER-001 at the dose being investigated in the planned CARAT study (NCT02484378), a double-blind, placebo-controlled, phase II study assessing the effect of CER-001 on atherosclerosis regression in patients with acute coronary syndrome (ACS). The press release on results of the LOCATION study is available on Cerenis' website in the section Media/Press releases. [Click here](#) to access.

#### Reference

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.

#### Upcoming events

##### Investor and scientific forum:

Jefferies Global Healthcare  
Conference  
**June 7-10, 2016**

Outstanding conference on HDL  
therapy in Toulouse, France  
**June 10, 2016**

Kepler Cheuvreux Biotech Days  
**June 15-16, 2016**

##### Financial agenda:

Shareholders' meeting  
**June 10, 2016**

Revenue for the 1<sup>st</sup> half of 2016  
**July 28, 2016**

2016 half-year results  
**September 5, 2016**

#### About Cerenis Therapeutics: [www.cerenis.com](http://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.



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