

# Cerenis Therapeutics announces that CARAT Phase 2 Study data on CER-001 have been presented at ACC annual meeting 2017

- Primary endpoint, regression of coronary plaque in ACS, not met
- Safety profile of CER-001 is reinforced
- TANGO Phase 3 clinical study in patients with genetic HDL deficiencies is ongoing

## FOR IMMEDIATE RELEASE

**TOULOUSE, France and ANN ARBOR, Mich. (March 20, 2017 at 8.00 am CET) – Cerenis Therapeutics** (Euronext: CEREN — ISIN: FR0012616852), an international biopharmaceutical company dedicated to the discovery and development of innovative therapies for treating cardiovascular and metabolic diseases, announces that CARAT Phase 2 Study data on CER-001 in post-acute coronary syndrome (ACS) patients have been presented at the Annual American College of Cardiology (ACC) Scientific Sessions in Washington DC, USA.

As mentioned previously, details of CARAT have been presented by Dr. Stephen Nicholls at the ACC Scientific Sessions; they will be available for publication in the coming months.

The CARAT Phase 2 Study confirmed the safety profile of CER-001 but did not meet its primary efficacy endpoint of regression of atherosclerotic plaques in post-ACS patients. The negative results encountered with CER-001 were not consistent with the previously reported efficacy profile of CER-001 in the 3mg/kg subgroup of the CHI SQUARE clinical study.

Dr. Stephen Nicholls, Principal Investigator and Chairman of the Steering Committee for the Phase 2 clinical CARAT study of 3mg/kg CER-001 in post-Acute Coronary Syndrome (ACS) patients, stated: "Although we were convinced by the analyses of the Phase 2 CHI-SQUARE study highlighting the efficacy of the optimal 3mg/kg dose, we are surprised and disappointed by the results of the CARAT study. On the basis of further investigation of the CARAT data in its entirety, the inconsistency of results challenges our understanding of the mechanism of action of CER-001 previously observed in the past studies and compared to early efficacy signals. To date, the factors that could have negative impact on the efficacy endpoint in the CARAT study include: the type of patient population that was mainly composed of statin-naïve patients, the nature of the concomitant therapies, the dose or the duration of treatment. We are looking forward to further analyses in order to understand these results. We also look forward to the results of the TANGO Phase 3 clinical study in patients with genetic HDL deficiencies, reflecting a different patient population, with a different dose and administration schedule."

### About CER-001

CER-001 is an engineered complex of recombinant human apolipoprotein A-1 (apoA-I), the major structural protein of HDL, and phospholipids, designed to mimic the structure and function of natural, HDL. It is intended 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.

#### About Cerenis Therapeutics: www.cerenis.com

Cerenis Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative therapies for the treatment of cardiovascular and metabolic diseases. Cerenis is developing a portfolio of therapies, including HDL mimetics for patients with HDL deficiency. Since its inception in 2005, the company has been funded by top-tier investors including Sofinnova Partners, HealthCap, Alta Partners, EDF Ventures, Daiwa Corporate Investment, TVM Capital, Orbimed, IRDI/IXO Private Equity and Bpifrance. In March 2015 Cerenis completed an IPO on Euronext raising €53.4m.



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