



Press release

## Cash position and revenue for 2015

### Significant clinical achievements in 2015 Strengthening of the patent strategy

**Toulouse, FRANCE, Ann Arbor, UNITED STATES, February 16, 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 December 31, 2015, and its revenue for the 2015 financial year.

- **A solid cash position of €43.0m at December 31, 2015**

Cash and cash equivalents totaled €43.0m<sup>1</sup> including the gross product generated by the spectacular IPO that enabled the company to successfully raise €53.4m in March. In line with expectations, Cerenis Therapeutics did not record any revenue over the 2015 financial year.

As announced at the time of the company’s IPO, efforts are currently focused on the development of the phase II study for the post Acute Coronary Syndrome indication (CARAT) and the phase III study for the treatment of patients affected by Familial Hypoalphalipoproteinemia (FPHA) orphan disease, in particular with apoA-I and ABCA1 deficiencies (TANGO).

- **Significant clinical achievements in 2015**

In accordance with the development plan, during the third quarter the company announced the enrollment of the first patients into the phase II CARAT trial, which assesses reduction in atherosclerotic plaque using CER-001 in post Acute Coronary Syndrome (post-ACS) patients. The first patient in the TANGO trial for the treatment of HDL genetic deficiency (FPHA) was enrolled during the final quarter of 2015, also in line with the clinical development plan.

Prior to the launch of the TANGO trial, new data for CER-001 was presented by Professor Stephen Nicholls at the 2015 American Heart Association (AHA) scientific sessions. The data, which demonstrates atherosclerosis plaque regression at the 3 mg/kg dose in patients with a baseline percentage of atheroma volume (PAV<sup>2</sup>) higher or equal to 30%, makes it possible to reassert Cerenis Therapeutics’ strong belief in CER-001’s efficiency and to confirm the optimal design of both the CARAT and TANGO studies. In September 2015, the company announced the publication of positive preclinical data in the world-renowned scientific journal PLOS ONE. This data also demonstrates the ability of natural HDL and their mimetic, CER-001, to inhibit the formation of atherosclerotic plaque with better efficacy at lower doses.

- **Strengthening of the patent strategy**

Currently, nine granted patent families protect Cerenis Therapeutics’ products portfolio, covering the targeted indications and the production process in the various countries. Since the IPO, the Company has successfully expanded the coverage of the main families to strategic markets such as the United States, other countries members of the European Patent Office (EPO), Mexico and Hong Kong. This strengthening of the international IP strategy specifically concerns CER-001 and CER-209.

**CER-001** is covered by several granted patent families, one related to the charged lipoprotein complex that includes a negatively-charged phospholipid, and another associated with the manufacturing process of the negatively-charged complexes. New patents have been successfully recently granted in Mexico, Hong Kong and the United States.

**CER-209** has patents related to P2Y13 receptor agonists and their use, notably, as part of the treatment of metabolic disorders. P2Y13 receptor stimulation facilitates the elimination of mature HDL particles charged with lipids such as cholesterol, through an increased bile acid secretion associated with an improved uptake of HDL-c in the liver. A new patent, relating to this product and these mechanisms of action, has been granted in the United States and contributes to reinforce CER-209 protection, a promising product dedicated to the treatment of atherosclerosis and associated metabolic diseases, specifically NASH (Non Nonalcoholic Steatohepatitis).

Jean-Louis Dasseux, founder and CEO of Cerenis, comments: “Fully confident in the potential of CER-001, we are satisfied with the 2015 clinical improvements, achieved in accordance with the announced schedule and promising in terms of results. Both studies currently under development benefit from an optimal design, as emphasized by the scientific data presented at the 2015 American Heart Association scientific sessions and highlighted by the positive preclinical results published in the PLOS ONE journal. Furthermore, we are reaffirming our confidence in our prospects for 2016. Indeed, Cerenis has sufficient financial resources to calmly pursue the enrollment of patients and to complete the phase II CARAT study, whose results are expected in Q1 2017, and the phase III TANGO study, whose results are expected in Q3 2017 before potential market approval in Q3 2018. Lastly, we are continuing our efforts to efficiently increase the value of our HDL therapy portfolio that aims to address major health challenges on a global level”.

1. *unaudited*
2. *marker directly linked to the risk of cardiovascular events*

#### 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.

#### 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 which is the target of successful drugs such as the anti-thrombotic agent Clopidogrel (Plavix®). In preclinical studies CER-209 promotes HDL recognition by the liver and increase the activity of Reverse Lipid Transport (RLT), and thus has an impact on 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 steato-hepatitis (NASH).



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