



Press release

## 2018 Half-Year Results

### Solid cash position of €13.5 million and significant scientific advances

- **Key highlights in the first half-year of 2018: primary objective met in the first results of TARGET PHASE II study, strategic partnership with the University of North Texas Health Science Center and launch of PHASE I study of repeated and increasing doses with CER-209**
- **Results of TANGO PHASE III study with CER-001 with HDL deficiency patients, and results of PHASE I with CER 209, by the end of 2018.**

**Toulouse, FRANCE, Lakeland, UNITED-STATES, September 10, 2018, 7.00 am cest – CERENIS Therapeutics (FR0012616852 – CEREN – PEA PME eligible)**, an international biopharmaceutical company dedicated to the discovery and development of HDL-based innovative therapies for treating cardiovascular and metabolic diseases, as well as new HDL-based vectors for targeted drug delivery in the field of oncology, today announces its first half-year 2018 financial results, and takes stock of its clinical advances.

**Jean-Louis Dasseux, founder and CEO of Cerenis**, commented: *"We are pleased with the clinical progress made over the period concerning CER-001 and CER-209 as well as the HDL platform for drug delivery in immuno-oncology. Given the clinical milestones planned for the second half of 2018 - the results of the TANGO PHASE III study with CER-001 and those of the PHASE I study of increasing doses with CER-209 - an inflection point could be crossed by the end of the year. In order to better prepare for further developments, CERENIS has made a major effort in terms of structuring its governance and overseeing its technology. The Scientific Advisory Board dedicated to oncology has thus welcomed some of the world's most renowned specialists in their field, while the Board of Directors has strengthened its expertise in terms of business partnership following the arrival of Barbara Yanni. CERENIS therefore has the resources adapted to its ambitious objectives, with unmatched technological expertise in the field of HDL and sufficient financial visibility to ensure its next clinical developments in the short and medium term. These assets should allow us to rapidly cross new milestones to offer patients new solutions addressing HDL deficiency, an indication without treatment, as well as NAFLD/NASH and targeted drug delivery in oncology, major health issues."*

## Financial Information *(at June 30 / IFRS Consolidated Financial Statements)*

| M€  | H1 2018      | H1 2017      |
|---|--------------|--------------|
| Sales   | 0            | 0            |
| R&D expenses                                      | -1.67        | -2.13        |
| Administrative and commercial expenses            | -1.32        | -0.76        |
| <b>Operating income</b>                           | <b>-2.98</b> | <b>-2.89</b> |
| <i>Financial products</i>                         | 0.28         | 2.69         |
| <i>Financial expenses</i>                         | -0.70        | -0.51        |
| <b>Financial Result</b>                           | <b>-0.43</b> | <b>2.19</b>  |
| <b>Net income</b>                                 | <b>-3.41</b> | <b>-0.71</b> |
| <b>Net income per share (€)</b>                   | <b>-0.19</b> | <b>-0.04</b> |
| <b>Net cash flow from operating activities</b>    | <b>-2.73</b> | <b>-5.23</b> |
| <b>Net cash flow from financing activities</b>    | <b>-0.01</b> | <b>0.90</b>  |
| <b>(Decrease) / Increase in cash position</b>     | <b>-2.76</b> | <b>-4.33</b> |
| <b>Cash and cash equivalents at end of period</b> | <b>13.51</b> | <b>20.34</b> |

In line with expectations, Cerenis Therapeutics did not generate any revenue during the first half of 2018, the Company's products being at the Research and Development stage. Cerenis Therapeutics is currently conducting TANGO, a PHASE III clinical study in patients suffering from HDL deficiency due to defects in genes coding for apoA-I and ABCA1 within the framework of two orphan drug designations granted by the European Medicines Agency (EMA). CERENIS is also continuing the development of the CER-209 drug candidate, dedicated to the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatitis (NASH), as part of a PHASE I clinical trial, and has initiated activities within the framework of the HDL platform, including CER-320 and CER-350 programs in immuno-oncology.

**Research and development expenses**, which amounted to €1,669 thousand over the period, compared to €2,133 thousand in the first half of 2017, mainly correspond to the clinical developments mentioned above.

**Financial income and expenses** correspond to the IFRS treatment of BPI repayable advances and the effect of exchange rates variations when paying suppliers in foreign currencies (mainly the US and Australian dollars). The change is attributable to the recognition of an exceptional income at June 30, 2017 for one of the BPI repayable advances. In the first half of 2017, following the results of the CARAT study and the continuation of the TANGO PHASE III study for the treatment of HDL deficiency, which results are expected at the end of the 2018 fiscal year, the repayment schedule of the BPI advances had been updated in accordance with the latest estimates. The rescheduling of repayments had thus resulted in the recognition of a financial income of €2,113 thousand in the interim consolidated financial statements at June 30, 2017.

**Cash and cash equivalents** totaled € 13.51 million at June 30, 2018.

## Significant clinical advances in the first half of 2018:

- Achievement of the primary endpoint for the first results of the TARGET PHASE II study
- Strategic initiative to develop new HDL-based pharmaceuticals with the North Texas Health Science Center
- Launch of PHASE I study of increasing doses with CER-209 in NASH/NAFLD

The first results of TARGET PHASE II study, published on June 25, 2018, demonstrate CER-001's ability to target tumors in patients with esophageal cancer. The primary objective is achieved with the clinically meaningful targeting of esophageal tumor tissue by radiolabeled CER-001. The sustained tumor labeling supports future use of HDL mimetics to improve effective delivery of therapeutic agents. These encouraging results have been observed in patients with esophageal cancer, an indication often refractory to standard therapy. No safety and tolerability issues were observed.

In the first half-year of 2018 CERENIS Therapeutics announced the signing of a strategic partnership with the University of North Texas Health Science Center to develop new HDL technologies for drug delivery. The joint program will focus on the development of new HDL drug delivery products and technologies in collaboration with Andras Lacko, PhD, a prominent scientist, in the development of HDL delivery systems for cancer drugs. This initiative is another marker of Cerenis' strategic evolution into a company with novel HDL platforms for drug delivery in immuno-oncology.

Finally, the second step of the PHASE I study, assessing the daily administration over a 28-day period of increasing doses of CER-209 in patients with a high risk of developing NASH/NAFLD, was launched during the first half of the year. The primary endpoints concern safety and tolerance following the administration of multiple doses of CER-209. In particular, pharmacokinetic endpoints will also be studied in order to define the optimal dose for the next studies.

### About CERENIS: [www.cerenis.com](http://www.cerenis.com)

CERENIS Therapeutics is an international biopharmaceutical company dedicated to the discovery and development of innovative lipid metabolism therapies for the treatment of cardiovascular, metabolic diseases, and HDL platform technologies. HDL is the primary mediator of the reverse lipid transport, or RLT, the only natural pathway by which excess lipids are removed from arteries and transported to the liver for elimination from the body. In addition to advancing HDL technologies for drug delivery, CERENIS is developing a portfolio of lipid metabolism therapies, including HDL mimetics for 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). Leveraging its expertise, Cerenis is developing the first platform for the targeted drug delivery by HDL dedicated to the field of oncology (immuno-oncology and chemotherapy).

CERENIS is well positioned to become one of the leaders in the HDL therapeutic market, with a broad portfolio of programs in development.

### About Targeted HDL Drug Delivery

HDL particles, loaded with an active agent, hold the promise to target and selectively kill malignant cells while sparing healthy ones. A wide variety of drugs can be embedded in these particles targeting markers specific to cancer cells and bring these potent drugs to their intended site of action, with lowered systemic toxicity. Cerenis intends to develop the first HDL-based targeting drug delivery platform dedicated to the oncology market, including immuno-oncology and chemotherapy.

### Financial Agenda:

Cash position and revenue for Q3 2018  
October 25, 2018



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