Press Release

Positive results from the CER-209 Phase I Single Dose Tolerance study for NAFLD and NASH

- The completion of the Single Dose Tolerance study (SDT) for CER-209
- No drug related safety nor tolerance issues identified
- The pharmacokinetics observations support CER-209 once daily oral dosing
- Multiple Dose Tolerance study (MDT) now ready to proceed

Toulouse, FRANCE, Ann Arbor, UNITED-STATES, June 7, 2017, 07:00 pm cet – **Cerenis Therapeutics (FR0012616852 – CEREN – PEA PME eligible)**, an international biopharmaceutical company dedicated to the discovery and development of innovative lipid metabolism therapies for treating cardiovascular and metabolic diseases announces today positive results in the SDT Phase I development of CER-209 for the treatment of liver diseases NAFLD (Non-Alcoholic Fatty Liver Disease) and NASH (Non-Alcoholic Steato-Hepatitis).

The objective of the Single Dose Tolerance study carried out in the USA was to assess the safety, tolerability and pharmacokinetics of CER-209 when taken orally as a single dose. Escalating doses of 1, 3, 10, 30 mg were tested on 24 subjects who were treated in four cohorts of 6 subjects. In each cohort, four subjects were treated with active study medication and two subjects with placebo.

"The positive results from the Single Dose Tolerance study allows us to proceed to the next stage of the Phase I clinical development with a Multiple Dose Safety and Tolerance study. Given the current lack of treatment options for NAFLD and NASH, CER-209 has the potential to play an important role in treating hepatic steatosis and atherosclerosis. CER-209's major asset in NAFLD and NASH treatment lies in its ability to promote HDL recognition and lipid elimination by the liver, through the activation of natural metabolic pathways mediated by the P2Y13 receptor. In addition, the study's confirmation that the pharmacokinetics of CER-209 permit once daily oral dosing is excellent news for patient treatment", said Dr. Jean-Louis Dasseux, CEO of Cerenis.

CER-209, an agonist of the P2Y13 receptor, is well suited to the treatment of NAFLD and NASH. NAFLD, a precursor of NASH, is a disorder that is now considered as the most common liver disease in the Western world, impacting 30% of the world's population[1]. In addition, epidemiological studies demonstrate that the cardiovascular risk is increased in patients with hepatic steatosis and that the cardiovascular diseases associated are the leading causes of death in patients with liver steatosis[1,2].

In preclinical models, CER-209 resulted in a marked reduction in steatohepatitis as determined by reductions in cholesterol, triglycerides and fatty acids in the liver compared with placebo. CER-209 exerts its beneficial effect on liver steatosis via a specific action on the lipid elimination pathways. Furthermore, CER-209 produced considerable decreases in liver enzymes (ALT and AST) in the plasma.

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[1] *Source: World Journal of Hepatology*
Franque S. M. et al. Journal of Hepatology, 2016, vol. 65, 425-443
[2] *World J Gastroenterol 2015 June 14; 21(22): 6820-6834*

These effects suggest the restoration of liver integrity and indicate a strong potential for CER-209 to treat NAFLD/NASH and to lower the risk of associated cardiovascular disease. CER-209 exerts its beneficial effect on liver steatosis via a specific action on the cholesterol elimination pathways and has robust potential as a treatment for NASH and NAFLD.

About P2Y13 receptor

The P2Y13 receptor is a member of the P2Y receptor family, a well-known "druggable" receptor family including the P2Y12 receptor that is the target of successful drugs such as the anti-thrombotic agent Clopidogrel (Plavix®). P2Y13 deficiency in preclinical models reduces biliary lipid secretions and fecal loss of cholesterol and bile acids.

Deficiency leads to impaired Reverse Lipid Transport from macrophages to feces. P2Y13 receptor activation by small molecule ligands stimulates plasma HDL clearance and HDL endocytosis by the liver so increasing biliary lipid secretion and stimulating overall RLT[3].

[3] *Goffinet M. et al., PLoS ONE 2014;9:e95807*

About CER-209

CER-209 is the first drug candidate in the category of oral P2Y13 receptor agonists. CER-209 is a specific agonist of the P2Y13 receptor and does not interact with the P2Y12 receptor. In preclinical studies CER-209 promotes HDL recognition by the liver and increases Reverse Lipid Transport (RLT), thereby impacting 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 Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH).

About Cerenis: 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 and metabolic diseases. HDL is the primary mediator of the reverse lipid transport, or RLT, the only natural pathway by which excess lipids is removed from arteries and is transported to the liver for elimination from the body.

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).

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

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Contacts:

Cerenis
Jean-Louis Dasseux
CEO
info@cerenis.com
+33 (0)5 62 24 09 49

NewCap
Investors relations
Emmanuel Huynh / Louis-Victor Delouvrier
cerenis@newcap.eu
+33 (0)1 44 71 98 53

NewCap
Media relations
Nicolas Merigeau
cerenis@newcap.eu
+33 (0)1 44 71 94 98