Press release

Cerenis Therapeutics announces the initiation of the Phase 1 clinical study with CER-209 in NAFLD and NASH

Toulouse, FRANCE, Ann Arbor, UNITED-STATES, April 18, 2017, 8.00 AM – **Cerenis Therapeutics** (**FR0012616852 – CEREN – PEA PME eligible)**, an international biopharmaceutical company dedicated to the discovery and development of innovative lipid metabolism therapies ("good cholesterol") for treating cardiovascular and metabolic diseases, today announces that de Phase 1 clinical trial with CER-209, a P2Y13 receptor agonist, has been initiated.

Dr. Jean-Louis Dasseux, founder and CEO of Cerenis, declares: *« According to the American Liver Foundation, NASH is one of the leading causes of cirrhosis in adults in the United-States. 25% of adults having NASH will develop a cirrhosis, and there currently are no approved therapies for these diseases. 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]*.*
We believe that CER-209, new patented molecule coming from our research, has the potential to play an innovative part by both addressing hepatic steatosis and atherosclerosis. CER-209's major asset in NASH and NAFLD 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.

The entry of CER-209 into clinical development makes part of Cerenis' strategy which is based on a rich portfolio of several products at different development stages and operating through diversified mechanism of action, which constitutes as many growth drivers for the company".

Incidence of NAFLD and NASH is increasing, now becoming common diseases of the liver in part related to the rise in obesity and diabetes rates. NAFLD, a precursor of NASH, is a universal disorder that is now considered as the most common liver disease in the western world, impacting 30% of the world's population, according to a publication in the World Journal of Hepatology.

Launch of the Phase 1 clinical study with CER-209, within the framework of an IND

The launch follows the FDA IND (Investigational New Drug application) approval, granted in December 2016, to initiate the clinical development of CER-209 in healthy volunteers for the clinical investigation of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH).

1 Franque S. M. et al. Journal of Hepatology, 2016, vol. 65, 425-443

2 World J Gastroenterol 2015 June 14; 21(22): 6820-6834

The objective of this randomized, double blind and placebo controlled trial, is to evaluate efficacy and tolerance and also the pharmacokinetic/pharmacodynamics following the administration of CER-209' increasing doses in healthy volunteers.

CER-209, an agonist of the P2Y13 receptor, is well suited to the treatment of NAFLD and NASH

CER-209, a selective novel agonist of the P2Y13 receptor decreased both atherosclerosis and liver steatosis in preclinical models. CER-209 caused an increased uptake of high-density lipoprotein-cholesterol (HDL-c) in the liver that is associated with stimulation of bile acid secretion. Repeated dose administration stimulated the apoA-I synthesis and formation of small HDL particles, known to be atheroprotective. CER-209-treated plasma samples had high cholesterol efflux capacity for the mobilization of cellular cholesterol in vitro compared with the placebo group. CER-209 induced a decrease in atherosclerotic plaques in aorta and carotids as well as a remarkable decrease in steatosis in validated preclinical models.

In preclinical models, CER-209 resulted in a marked reduction in overall steatohepatitis as determined by reductions in cholesterol, triglycerides and fatty acids in the liver compared with placebo. Furthermore, CER-209 produced considerable decreases in liver enzymes (ALT and AST) in the plasma. These effects suggest the restoration of liver integrity and indicate a strong potential for CER-209 to treat liver disease such as Non-Alcoholic Steato-Hepatitis (NASH) and Non-Alcoholic Fatty Liver Disease (NAFLD) while reducing the risks associated with cardiovascular disease.

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 that is the target of successful drugs such as the anti-thrombotic agent Clopidogrel (Plavix®). 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 HDL and other 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 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 this innovative lipid metabolism therapeutic market, with a broad portfolio of programs in development.

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