Press release

Cerenis Therapeutics Receives FDA IND Approval to Begin Studies with CER-209 in NAFLD and NASH

Toulouse, FRANCE, Ann Arbor, MICH. (December 15, 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 that the U.S. Food and Drug Administration (FDA) has informed Cerenis Therapeutics that clinical trials with CER-209 may proceed. The Investigational New Drug application (IND) for CER-209 includes plans for a Phase I clinical study of its P2Y13 receptor agonist drug candidate (CER-209) in healthy volunteers for the clinical investigation of Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steato-Hepatitis (NASH). Cerenis plans to begin enrollment in Q1 2017.

Dr. Jean-Louis Dasseux, CEO of Cerenis, comments, *"The successful filing of our IND and approval by the FDA to proceed with our first Phase 1 clinical trial for CER-209 is a major strategic milestone for Cerenis. Our team has demonstrated how efficiently it can advance our drug candidates into the clinic, supported by its in-depth expertise of lipid metabolism, specifically regarding the reverse lipid transport mediated by the HDL particle. We believe CER-209 will be a compelling drug candidate for the treatment of NAFLD and NASH, through its ability to promote HDL recognition and lipid elimination by the liver, and overall reaffirmed the potential of our therapy approaches."*

"Incidences of NAFLD and NASH are increasing, becoming common diseases of the liver with the rise in obesity rates. NAFLD 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. In addition, the American Liver Foundation says that NASH is one of the leading causes of cirrhosis in adults in the United States, with up to 25% of adults with NASH having cirrhosis. There currently are no approved therapies for these diseases and we are hopeful that CER-209 will be able to play a role in treatment," Dr. Dasseux added.

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) 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 Therapeutics: 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 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.

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.

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