Press release

Completion of patient enrollment in the Phase 3 study, TANGO, evaluating CER-001 in HDL genetic deficiency

Toulouse, FRANCE, Lakeland, UNITED STATES, October 18, 2017 —- Cerenis Therapeutics (FR0012616852 – CEREN – PEA PME eligible) an international biopharmaceutical company dedicated to the discovery and development of innovative therapies based on lipid metabolism for treating cardiovascular and metabolic diseases, today announces the completion of patient enrollment in TANGO, evaluating CER-001 in patients with Familial Primary HypoAlphalipoproteinemia (FPHA).

Jean-Louis Dasseux, founder and **CEO** of **Cerenis,** comments: *"Positive TANGO results could lead to market authorization of CER-001. The drug could then be commercialized in Europe by targeting two of the different orphan diseases leading to FPHA. Subsequently, other pathologies linked to the HDL genetic deficiency could later be considered. SAMBA, the study after which two orphan drug designations were granted for CER-001, had already shown a significant decrease in atherosclerotic plaque in these populations. We are thus confident regarding the study conclusions, as SAMBA has demonstrated that CER-001 acts as a natural HDL in patients deprived of this essential particle to carry out the four steps of reverse lipid transport. If these results are positive, we would then open discussions with other regulatory agencies including the US FDA."*

Patients with HDL deficiency are exposed to a high cardiovascular risk and represent an unmet medical need

TANGO is being conducted in patients with HDL deficiency due to defects of genes coding for apoA-I and ABCA1, within the framework of the two orphan drug designations granted by the European Medicines Agency (EMA) for the use of CER-001.

Inherited defects in the apoA-I or ABCA1 genes can cause FPHA, a rare syndrome characterized by the absence or severe deficiency of these gene products that leads to a deficiency of HDL particles in the blood. This means that the body's only natural mechanism for eliminating cholesterol is compromised. These patients thus experience an increased accumulation of cholesterol, particularly in blood vessel walls, which often results in accelerated atherosclerosis and premature cardiovascular and cerebrovascular diseases.

Patients grouped under the generic term FPHA represent a population of a rare disease estimated at approximately 100,000-150,000 subjects in the United States and Europe. Current management of FPHA patients is therefore very limited and focused on diet control and aggressive pharmacotherapy intended

to decrease LDL cholesterol. There is no treatment currently available which can directly restore normal and functioning HDL particles.

The primary endpoint of the TANGO trial is to evaluate the effect of 24 weeks treatment with CER-001 on carotid vessel wall area as compared to placebo using magnetic resonance imaging (MRI)

The Phase 3 TANGO trial is designed to assess both the efficacy of CER-001 to regress atherosclerosis, and its safety in patients with FPHA, who are characterized by ABCA1 or apoA-I genetic mutations and are already receiving optimized background lipid therapy.

The TANGO trial is a multicenter, randomized, double-blind, parallel-group and placebo-controlled study. It involves 30 patients from several sites across Europe, Canada and the United States. The difficulties encountered in the identification of patients with FPHA, a rare disease, explain the delay in the study schedule, results being expected late Q1 2018.

Prior data supporting the orphan designation applications were obtained from the SAMBA Phase 2 trial of CER-001 in patients with FPHA. Data showed that CER-001 reconstitutes the reverse lipid transport (RLT) metabolic pathway in individuals who have defects in the natural HDL pathway, facilitating elimination of cholesterol from the body. Importantly, one month of treatment with 9 doses of CER-001, given in addition to optimized standard of care for LDL-cholesterol-lowering therapy, resulted in a statistically significant reduction in carotid artery mean vessel wall area, as measured by magnetic resonance imaging.

A steering committee comprised of world-renowned experts

The TANGO Steering Committee include recognized experts such as Prof. Erik Stroes, MD, PhD (Vascular Medicine, Academic Medical Center, Amsterdam, The Netherlands); Prof Gouni-Berthold (Center for Endocrinology, Diabetes and Preventive Medicine, University of Cologne, Cologne, Germany, Fellow Royal Society of Public Health); Prof. Jacques Genest, MD (Cardiology, Faculty of Medicine, McGill University, Montreal, Canada); Prof. Henry Ginsberg, MD (Columbia University College of Physicians and Surgeons, New-York, USA); Prof. Eran Leitersdorf, Director (Center for Research, Prevention and Treatment of Atherosclerosis, Dorothy & Maurice Bucksbaum Chair in Molecular Genetics and Dean of the Hebrew University of Hadassah School of Medicine, Israel); Prof. Arnold von Eckardstein (Chair of the Institute of Clinical Chemistry, University of Zurich, Switzerland, European Lipoprotein Club, Executive Committee of the Swiss Working Group on Lipids and Atherosclerosis) and Prof. Paolo Raggi (University of Alberta, Edmonton, Canada, Mazankowski Alberta Heart Institute, Alberta Health Services, Cardiology, 2012, Chair of Cardiac Research).

Financial calendar:
Revenue for the 3rd quarter of 2017
October 26, 2017

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.

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. SAMBA, the clinical Phase 2 study in patients with hypoalphalipoproteinemia due to genetic defects, has provided important data demonstrating the efficacy of CER-001 in regressing atherosclerosis in several distinct vascular beds. 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 on the market.

About TANGO clinical trial

TANGO is a Phase 3, multicenter, randomized, 48-week, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of CER-001 on vessel wall area in thirty patients with genetically defined familial hypoalphalipoproteinemia (apoA-I and ABCA1 deficiencies) and receiving background optimized lipid therapy. Primary endpoint: to evaluate the effect of 24 weeks' treatment with CER-001 on carotid mean vessel wall area (MVWA) compared with placebo using 3TMRI. Secondary endpoints: to evaluate the effect of 8 and 48 weeks' treatment with CER-001 on carotid MVWA compared with placebo using 3TMRI.

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