Press release

Positive safety and tolerability profile of CER-001 presented at the European Society of Cardiology (ESC) Congress 2016

Professor Alberto Corsini, Department of Pharmacology and Biomolecular Sciences, University of Milan, Italy, presented CER-001 data at ESC

Toulouse, FRANCE, Ann Arbor, UNITED STATES, September 1 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 the presentation of a poster on the positive tolerability and safety findings of its drug candidate CER-001, at the occasion of the European Society of Cardiology congress, which will be held from the 24tth to 31st August 2016 in Rome.

- **The positive safety and tolerability profile of CER-001 observed in the clinical trial program to date supports its continued development as both a short- (post-ACS population) and a long-term treatment (HDL-deficient patients).**

Clinical trials in patients with familial hypercholesterolaemia or hypoalphalipoproteinaemia have shown that CER-001 reduces carotid wall thickness and enhances cholesterol excretion, thus reducing atherosclerotic burden[1]. Furthermore, encouraging efficacy results have also been reported with CER-001 in patients with acute coronary syndrome (ACS)[2].

This poster reports the clinical tolerability and safety findings seen with CER-001 across the clinical development programme, to date, and determines whether any specific treatment-related adverse events (AEs) emerge as clinical experience with the product grows.

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[1] Hovingh GK, et al. The effect of an apolipoprotein A-I-containing high-density lipoprotein-mimetic particle (CER-001) on carotid artery wall thickness in patients with homozygous familial hypercholesterolemia: The Modifying Orphan Disease Evaluation (MODE) study. Am Heart J 2015; 169: 736-42.e1.
Kootte RS, et al. Effect of open-label infusion of an apolipoprotein A-I-containing particle (CER-001) on reverse cholesterol transport and artery wall thickness in patients with familial hypo-alphalipoproteinemia. J Lipid Res 2015; 56: 703–12.

[2] Tardif JC, et al. Infusions Significantly QUicken Atherosclerosis REgression (CHI-SQUARE) Investigators. Effects of the high-density lipoprotein mimetic agent CER-001 on coronary atherosclerosis in patients with acute coronary syndromes: a randomized trial. Eur Heart J 2014; 35: 3277–86.
Kataoka Y, et al. Greater regression of coronary atherosclerosis with the pre-beta high-density lipoprotein mimetic CER-001 in patients with more extensive plaque burden. Circulation 2015; 132: A12156.

The results of the Phase I placebo-controlled study, which involved 32 subjects, showed CER-001, across a wide dose range of 0.25 to 45 mg/kg, to have a tolerability profile similar to that of placebo. Moreover, this study showed that CER-001 significantly mobilises cholesterol in the HDL fraction without causing significant elevation of liver enzymes, even at the higher doses. Additionally, no adverse effects of CER-001 on ECGs were observed and no antibodies to ApoA-I, the natural protein in HDL contained in the CER-001 complex, were detected following single dose administration.

Pooling safety and tolerability data from 530 patients involved in the completed Phase II studies that evaluated multiple doses of CER-001 across the range 3–12 mg/kg found a safety profile that is comparable with placebo. No unusual or concerning AEs have been reported to date and after six administrations, one each week, in post-ACS patients, no antibodies against ApoA-I were detected at 6 months. CER-001 is not associated with any adverse impact on hepatic safety as no clinically relevant differences in elevations of liver enzyme levels between CER-001 and placebo have been observed.

Professor Alberto Corsini of the Department of Pharmacology and Biomolecular Sciences, University of Milan, commented, "*While the evaluation of efficacy data is important, the collection and collation of safety data on CER-001 that is gathered during the Phase I and II clinical development programme is of critical importance in the further development of this candidate drug. Following multiple doses over a 6-month period, CER-001 appears to have a clinical safety profile similar to that of placebo and the candidate drug was not associated with any hepatic safety concerns. These reassuring safety results support the continued clinical development of CER-001 for both short- and long-term treatment.*"

The detailed poster, presented by Dr Nicola Ferri to the ESC congress on 30 August 2016, is available on the website of Cerenis in the tab "Our therapies / Scientific Presentations". Click here to access it. [Click to access]

Doctor Jean-Louis Dasseux, founder and CEO of Cerenis, comments: *"The presentation of these positive findings, which confirms the good tolerability and safety of CER-001, demonstrates the scientific community's interest in our drug candidate. The quality of the findings for CER-001's clinical program obtained thus far, is notably linked to the differentiating feature of our technology, based on the reproduction through bioengineering of natural HDL particles which imitate the structure and positive attributes of the natural nascent particle. More generally, the analysis of the tolerability and safety findings strengthens our confidence in the capacity of CER-001 to become, amongst HDL-mimetics, the best therapeutic solution on the market."*

Financial agenda:

Half Year Results 2016
September 5, 2016

Revenue for the 3rd quarter of 2016
November 7, 2016

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 HDL deficiency, and drugs which increase HDL for patients with low number of HDL particles to treat atherosclerosis and associated metabolic diseases.

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

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.

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. Previous Phase II studies have provided important data demonstrating the efficacy of CER-001 in regressing atherosclerosis in several distinct vascular beds in patients representing the entire spectrum of cholesterol homeostasis. 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 in the market.

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