

Phase 2b Trial Shows Unique Lipid Efficacy Profile of Novel Compound to Reduce Elevated Triglyceride Levels

The Associated Press

Essentialis, Inc., today announced Phase 2b trial results for its investigational compound DCCR demonstrating a reduction in triglyceride (TG) levels by 30 to 40 percent in patients whose TG levels exceeded 500 mg/dL (Very High Triglycerides VHTG). The study included an arm combining DCCR with fenofibrate treatment (Abbott Laboratories' Trilipix® (fenofibric acid)); in the combination arm, DCCR was shown to be additive to fenofibrate for all lipid fractions except LDL-C. In contrast, a 2009 study of VHTG patients using prescription omega-3 fatty acid in combination with fenofibrate revealed no clinically important change compared to fenofibrate alone(1).

More than five million people in the United States have very high TG levels. This population is at elevated risk for a number of diseases, including acute pancreatitis, diabetes and cardiovascular events (e.g., sudden death, myocardial infarction, acute coronary syndrome, revascularization, stroke and atrial fibrillation).

"The results of this study contribute to the growing body of knowledge on the potential of DCCR as a triglyceride-lowering treatment," said Richard C. Pasternak, M.D., Essentialis board member and head of the Company's scientific advisory board. "These data clearly motivate us to advance DCCR into larger trials that may demonstrate benefit to patients with multiple disease risk factors." In this Phase 2b double-blind, placebo-controlled study, subjects were included in one of two subgroups. About half of the subjects were included in the atorvastatin combination subgroup, where they were randomized to receive either DCCR 290 mg or placebo in combination with atorvastatin (Pfizer Inc.'s Lipitor®) 20 mg for 18 weeks. The remaining subjects in the study were included in the monotherapy/fenofibrate combination subgroup, where they were randomized to receive either DCCR 290 mg or placebo for 12 weeks, followed by co-administration of fenofibrate (Trilipix) 135 mg for another six weeks.

In combination with statin, DCCR 290 mg resulted in placebo-adjusted median reductions in TG of 28%, in VLDL-C of 51%, in non-HDL-C of 16%, and an increase in HDL-C of 11% after 18 weeks of treatment. In statin treated subjects, there was no change in mean LDL-C; however, all statin-treated subjects with LDL-C > 100 mg/dL at baseline who received DCCR showed improvements in LDL-C.

In combination with fenofibrate, treatment with DCCR resulted in median reductions in TG of 78%, in non-HDL-C of 34%, and an increase in HDL-C of 38%. DCCR was additive to fenofibrate for all lipid fractions except LDL-C. The increase in LDL-C was lower in fenofibrate + DCCR (42%) than in fenofibrate + placebo (57%).

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Through 18 weeks, treatment with DCCR resulted in nearly a 40% improvement in HOMA-IR, a measure of insulin resistance, and a reduction in median weight of more than 3 kilograms, compared to a worsening of HOMA-IR (+13 and no change in median weight in the placebo-treated subjects. The incidence, severity and nature of adverse events in the DCCR arm were comparable to placebo.

"There is a significant unmet need within the patient community for a compound like DCCR," said Aaron D. Berg, President and Chief Executive Officer, Essentialis, Inc. "Patients with very high triglyceride levels often do not reach accepted targets with current agents. Our plans to pursue next steps with DCCR are clear - we want to help patients reduce medical risks associated with very high triglyceride levels."

(1) Roth, et al, "Prescription Omega-3 Fatty Acid as an Adjunct to Fenofibrate Therapy in Hypertriglyceridemic Subjects", J Cardiovascular Pharmacol (2009)

54:196-203 About DCCR DCCR is a proprietary crystalline salt of diazoxide in a controlled-release, once-a-day tablet formulation. It is in development for patients with very high triglyceride (TG) levels.

Essentialis has completed an End-of-Phase 2 meeting with the FDA and has obtained an SPA covering a pivotal study. Essentialis expects to initiate Phase 3 clinical trials in 2012. DCCR is covered by multiple issued US and granted EU patents, which provide composition of matter protection until 2028. Essentialis has evaluated DCCR in several double-blind, placebo-controlled studies which demonstrated that the drug was well tolerated and that statistical significance for various endpoints was achieved in patients with elevated triglycerides. More than 100,000 patient-years of treatment with diazoxide help support the acceptable safety of DCCR.

About Essentialis, Inc.

Essentialis is a San Diego-headquartered pharmaceutical company focused on the development of breakthrough medicines targeted to the ATP-sensitive potassium channel, a metabolically regulated membrane protein whose modulation has potential to treat and prevent a wide range of cardiovascular and metabolic diseases. For more information visit <http://essentialistherapeutics.com/>.

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