

## ESSENTIALIS MEETS PRIMARY ENDPOINT IN PHASE 2B TRIAL OF DCCR FOR TREATMENT OF HYPERTRIGLYCERIDEMIA AND IS GRANTED EXTENSIVE PATENT COVERAGE IN THE US

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Carlsbad, California – (PR Newswire) - Essentialis Inc, a clinical stage pharmaceutical company, announced today that it met its primary endpoint of statistically significant triglyceride reduction in a 90-patient Phase 2b trial of DCCR in dyslipidemic patients. The study encompassed both patients with very high triglycerides and mixed dyslipidemia and included normal weight, overweight and obese patients presenting with or without hypertension.

The randomized, double-blind study, which was powered as if it were pivotal, assessed the drug's effect on dyslipidemia and evaluated three different doses of DCCR given over an 8-week period compared to placebo. The study included 90 subjects with high and very high triglycerides as well as subjects on stable doses of statins. At the end of 8 weeks, treatment with DCCR resulted in a 30% placebo-adjusted median reduction in triglycerides. The reduction was clinically relevant, highly significant and competitive with existing approved drugs. In subjects with very high baseline triglycerides, DCCR treatment resulted in a substantially greater reduction in triglycerides. In contrast to the effects of Lovaza and fenofibrate - the current gold standard medicines for treating hypertriglyceridemia - no meaningful increase in LDL-C was observed in DCCR-treated subjects, irrespective of baseline triglyceride levels. In subjects with elevated LDL-C at baseline, DCCR treated subjects experienced a fall in LDL-C. Reductions in non-HDL-C and total-C were also observed in DCCR treated subjects together with a modest rise in HDL-C. In subjects on steady doses of statins, the effects of DCCR appeared to be additive to statin therapy. Weight and waist circumference reduction, blood pressure lowering, LFT and insulin resistance improvements were also demonstrated. DCCR was generally well tolerated, and most of the AEs were mild to moderate, resolving without sequelae. There were no SAEs and the discontinuation rate due to AEs was in line with historic lipid-lowering trials.

Separately, the company further announced the allowance of a US patent covering DCCR. The patent entitled "Salts of potassium ATP channel openers and uses thereof" contains claims to salts of diazoxide - including DCCR - as well as pharmaceutical formulations of such salts. Additional applications filed in the US and globally will further enhance the patent portfolio of Essentialis.

Commenting on these developments, Essentialis President and CEO, Dr Iain Dukes said "Essentialis has convincingly demonstrated the therapeutic utility of DCCR as a triglyceride lowering agent with a superior profile to existing approved drugs. The issuance of the patent covering DCCR provides timely coverage for its future commercial development"

Pivotal Phase 3 protocols for very high triglycerides and Phase 2 protocols for statin combination therapy are currently being finalized with input from experts and the FDA in parallel with partnering discussions.

## **About DCCR**

**DCCR, diazoxide choline controlled release, is an ATP-dependent potassium channel agonist with potential utility in several cardiovascular and metabolic diseases. Extensive Phase 1 testing and investigator-sponsored clinical studies have demonstrated the drug's potential to lower triglycerides, non-HDL cholesterol and LDL-cholesterol while raising HDL-cholesterol. In addition, placebo adjusted weight loss exceeding 5% in an 8-week placebo controlled study and 10% in a 6-month study has been demonstrated. Compositions of matter, formulation and method of use patents for DCCR have been filed worldwide. A fixed dose combination product with a statin is under development.**

## **About Very High Triglycerides**

**Hypertriglyceridemia, a disease where patients have high blood levels of triglycerides, is associated with increased risk of coronary heart disease even after LDL-cholesterol targets have been achieved. Very high triglycerides are associated with an increased risk of developing pancreatitis. There are approximately 5 million patients in the US with very high triglycerides. The leading products for treating very high triglycerides, Lovaza and fenofibrate, while effective, also cause significant elevations in LDL-cholesterol.**

## **About Essentialis**

**Essentialis is a pharmaceutical company based in Carlsbad, CA focused on the development of breakthrough medicines for the treatment of cardiovascular and metabolic diseases. The company's portfolio of products is targeted at the ATP-sensitive potassium channel, a metabolically-regulated membrane protein whose modulation has the potential to impact a wide range of cardiovascular and metabolic diseases. The company's lead product has completed Phase 2 studies in dyslipidemic subjects. The company is actively exploring partnering arrangements for DCCR and its portfolio of follow-on and back-up compounds.**

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