



Essentialis Receives Special Protocol Assessment Agreement From the FDA for Phase 3 Trial of DCCR

SAN DIEGO, Oct. 25 /PRNewswire/ -- Essentialis, Inc. announced today that the company has reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for a Phase 3 efficacy study required for product registration for its product candidate, Diazoxide Choline Controlled Release Tablet (DCCR), for the treatment of patients with very high triglycerides. Essentialis and FDA agreed upon the patient population to study, inclusion and exclusion criteria, study duration, dosage, endpoints and their analyses.

"We are very pleased with the FDA's decision, as we believe the data which will be obtained in the proposed trial is anticipated to support the approval of DCCR in the patient population studied, the millions of people with very high triglycerides," commented Neil Cowen, Ph.D., President and Chief Scientific Officer for Essentialis. Currently, there are a limited number of therapeutic options for the treatment of very high triglycerides, but only DCCR works primarily by significantly reducing the production by the liver of harmful triglyceride-rich lipoprotein particles. "Due to the unique mechanism of action, DCCR has the potential to be an important advance in the treatment of patients with very high triglycerides" he added.

Aaron Berg, Chief Commercial Officer for Essentialis added, "We would like to thank FDA reviewers for their guidance during the SPA approval process and are pleased that the Agency has indicated an agreement to proceed with this Phase 3 pivotal study for DCCR. The positive outcome of the SPA process means Essentialis has now reached a major developmental milestone for DCCR." Essentialis is currently seeking a partner to assist with Phase 3 and near-term commercialization.

About the Phase 3 Study

The double-blind study includes 2 dose levels of DCCR as well as placebo and active control arms. Half of the patients in the study will be statin treated, providing data supporting approval for co-administration with statin. The primary endpoint is percent change from baseline for triglycerides. Secondary endpoints include percent change in non-HDL cholesterol and Apo B. Exploratory endpoints include such non-lipid cardiovascular risk factors as blood pressure and waist circumference. All efficacy endpoints will be measured at 12 weeks. There will be a 40 week extension focused on evaluation of safety during which the placebo treated patients transition to

active control.

About Special Protocol Assessments

An SPA is a binding written agreement between the sponsor and the FDA on the design, execution and analysis for a clinical trial that is to form the basis of a new drug application. Final marketing approval depends on the results of efficacy, the safety profile, and an evaluation of the risk/benefit of treatment in the Phase 3 program.

About DCCR

DCCR is a crystalline salt of diazoxide in a controlled-release, once-a-day tablet formulation.

DCCR is covered by multiple issued US patents, which provide composition of matter protection until 2028. Essentialis evaluated DCCR in several controlled and double-blind, placebo-controlled studies which provided clear evidence of both the safety and efficacy of DCCR in the proposed indication. Diazoxide has been approved for the treatment of insulinoma in adults and PHHI in children and neonates. More than 100,000 patient-years of treatment with diazoxide support the safety of DCCR in long term use.

About Essentialis, Inc.

Essentialis is a pharmaceutical company based in San Diego, CA focused on the development of breakthrough medicines targeted to the ATP-sensitive potassium channel, a metabolically-regulated membrane protein whose modulation has the potential to treat and prevent a wide range of cardiovascular and metabolic diseases. For more information visit

www.essentialistherapeutics.com

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