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Omthera Pharmaceuticals, Inc. Initiates Phase III ESPRIT Trial of Add-on Epanova™ to Statin Therapy in Patients with Hypertriglyceridemia

Bedminster, NJ, August 15, 2011 -- Omthera Pharmaceuticals, Inc., a privately-held emerging specialty pharmaceuticals company, announced today that the first patient has been enrolled in its ESPRIT (**E**panova combined with a **S**tatins in **P**atients with **H**yper**T**riglycer**I**demia to Reduce **N**on-HDL **C**holes**T**erol) Phase III clinical trial of Epanova™, in patients with hypertriglyceridemia (TG level ≥ 200 and < 500 mg/dL) despite treatment with a statin. The trial has been granted a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration.

Epanova, a novel formulation of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), is Omthera's lead compound, currently in development as a prescription omega-3 free fatty acid for the treatment of patients with very high triglycerides (≥ 500 mg/dL). The Company's Pivotal Phase III EVOLVE (**E**pano**V**a f**O**r **L**owering **V**ery high triglycerid**E**s) trial for this indication, which received SPA approval in November 2010, is ongoing, and will form the basis for filing a new Drug Application ("NDA") with the U.S. Food & Drug Administration. The results of the ESPRIT trial are not required for regulatory approval, but rather, if positive, would serve to expand the use of Epanova to a larger patient population.

The Phase III ESPRIT trial will be a six-week, randomized, double-blind, placebo-controlled, parallel group study to assess the efficacy and safety of add-on Epanova to statin therapy in patients with persistent hypertriglyceridemia despite statin therapy and who remain at high risk for cardiovascular disease. The primary objective is to evaluate the efficacy of adding Epanova (2g or 4g daily) to statin monotherapy for lowering Non-HDL cholesterol ("Non-HDL-C"). Secondary objectives are to evaluate the safety of the Epanova and statin combination therapies, and to evaluate the effects of the combination therapies on other lipids and lipoproteins. The trial is expected to enroll 642 subjects and will be conducted at approximately 100 sites in the U.S.



Principal investigator for the ESPRIT study, Dr. Stephen Nicholls, Assistant Professor of Molecular Medicine and the Cardiovascular Director of the Cleveland Clinic Coordinating Center for Clinical Research and a consultant for Omthera Pharmaceuticals, noted, “Millions of Americans treated with statins, are still at risk for cardiovascular events. Non-HDL-C is an important target of drug therapy for patients on a statin with TG between 200 and 500 mg/dL. The results of this trial, if positive, could further support the use of omega-3 free fatty acids as a treatment for these patients.”

Dr. Michael Davidson, Chief Medical Officer and co-Founder of Omthera, stated, “The development of Epanova, which has the potential to become the best in class omega-3 fatty acid, is well underway. Data generated earlier this year demonstrated that Epanova has superior bioavailability compared to the market leader, Lovaza®, and our EVOLVE trial, intended to support our planned NDA filing, has been actively enrolling subjects. Today, with the initiation of the ESPRIT trial, we have now taken a further step to potentially expand the indication to include patients with persistent hypertriglyceridemia and high risk for cardiovascular disease, who are on statin therapy, for which there are currently no approved prescription omega-3 drugs.”

About Epanova™

Epanova is a patent protected, novel, ultra-pure mixture of the free fatty acid forms of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Omthera has developed a substantial body of data on Epanova, which points to an improved and more predictable bioavailability as compared to the ethyl ester form found in prescription Omega 3 products currently available. Triglyceride lowering with Epanova was previously observed in two large, placebo-controlled, randomized, double-blind, Phase III studies involving 748 Crohn's Disease patients with normal triglyceride levels for ≥52 weeks; approximately 400 of which were treated with Epanova for remission of disease. In all studies performed to date, Epanova has demonstrated a very good safety and tolerability profile.

About Hypertriglyceridemia

Hypertriglyceridemia refers to a condition in which patients have high blood levels of triglycerides and is associated with increased risk of heart disease. It is one component of a range of lipid disorders collectively referred to as dyslipidemia. The overall dyslipidemia population in the U.S. is believed to be in excess of 100 million, with over 27 million of those diagnosed with hypertriglyceridemia (TGs greater than 200mg/dL) and an estimated 5 million with very high triglyceride levels (TGs greater than 500mg/dL). Very high triglycerides are associated with an increased risk of pancreatitis. Regulatory approval for the treatment of very high triglycerides is based on a significant reduction in the serum triglyceride levels.



About Special Protocol Assessments (SPA)

A Special Protocol Assessment (SPA) is a binding written agreement between the sponsor and the FDA indicating that the sponsor’s proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval. Final marketing approval depends on efficacy results, adverse event profiles and an evaluation of the benefit/risk of a treatment as demonstrated in the trial. For further information regarding the SPA process, please visit FDA’s website, www.fda.gov.

About Omthera Pharmaceuticals, Inc.

Founded in 2008, Omthera Pharmaceuticals, Inc. is a privately held, emerging specialty pharmaceuticals company focusing its efforts on the clinical development of new therapies for dyslipidemia. Led by a team of experts with exceptional experience in developing new therapies for lipid disorders, Omthera is dedicated to developing innovative therapies for the millions of patients who have elevated triglyceride levels and increased risk of cardiovascular disease. In March 2011, the Company initiated a pivotal Phase III clinical trial for its lead product candidate, Epanova™, an Omega-3 fatty acid compound in development as a triglyceride-lowering adjunct therapy to diet in patients with very high triglycerides (≥ 500 mg/dL). In August, 2011, Omthera initiated a Phase III trial for Epanova in patients with high triglycerides (≥ 200 mg/dL and ≤ 500 mg/dL) currently on statin therapy. Omthera holds worldwide rights to Epanova under a license from Chrysalis Pharma AG, a privately held Swiss company that is the owner of the product. For more information, please visit www.omthera.com.

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