



Omthera Contacts:

Christian S. Schade
EVP & Chief Financial Officer
Omthera Pharmaceuticals
908-741-6402
cschade@Omthera.com

Omthera Media Relations:

Eric Goldman
Rx Communications Group, Inc.
917-322-2563
egoldman@rxir.com

Omthera Pharmaceuticals Completes Enrollment of Pivotal Phase III EVOLVE Trial for Epanova™ in Patients with Very High Triglycerides

Top-Line Data From 399 Patient Study Expected April 2012

Bedminster, NJ, November 29, 2011 -- Omthera Pharmaceuticals, Inc. a privately-held emerging specialty pharmaceuticals company, announced today that it has completed enrollment in its pivotal Phase III EVOLVE (EpanoVa fOr Lowering Very High triglyceridEs) clinical trial for Epanova™, the Company's lead compound for the treatment of patients with very high triglycerides. This study is being conducted under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration. Initial top-line data from the Phase III study is expected to be available in April 2012.

Commenting on the news, Jerry Wisler, Chief Executive Officer and co-Founder of Omthera Pharmaceuticals, said, "Today the company reached another important milestone in the clinical development of Epanova. We have been very encouraged by the positive clinical profile of Epanova to date, and completion of enrollment in this pivotal study moves us one step closer to bringing this best-in-class Omega-3 therapy to patients suffering from very high triglycerides. We very much look forward to seeing the top-line data-set in April."

The Phase III EVOLVE trial is a 12 week, multi-center, randomized, double-blind, placebo-controlled study, evaluating the efficacy and safety of three doses of Epanova in patients with fasting triglyceride (TG) levels of ≥ 500 mg/dL. Subjects in the trial have been randomized into four groups: Epanova 2g/day; Epanova 3g/day; Epanova 4g/day; or placebo 4 caps/day. The primary endpoint of the trial is the percentage change in triglyceride level from baseline to week 12. The secondary endpoint is the reduction to non-HDL cholesterol.



Dr. Michael Davidson, Chief Medical Officer and co-Founder of Omthera, said, “The prevalence of severe hypertriglyceridemia, globally, has risen dramatically over the past decade. Currently, approximately 1.7% of the U.S. population, alone, suffers from severe hypertriglyceridemia, equating to roughly 5 million Americans -- less than 20% of whom are receiving lipid lowering therapy. This represents a severe unmet medical need, which can be addressed by a more effective prescription Omega-3. We believe that Epanova will provide the best solution to this rapidly increasing health care problem.”

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. For more information, please visit www.omthera.com

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