



September 3, 2013

Esperion Therapeutics Announces Positive Top-Line Results from Phase 2 Clinical Study of ETC-1002 as an Add-On to Statin Therapy in Patients with Hypercholesterolemia

Conference Call Today at 8:30 a.m. ET

PLYMOUTH, Mich.--(BUSINESS WIRE)-- Esperion Therapeutics, Inc. (Nasdaq: ESPR), a clinical-stage biopharmaceutical company, today announced positive top-line results from a Phase 2a study of ETC-1002 when added to statin therapy in patients with elevated levels of low density lipoprotein cholesterol (LDL-C or "bad cholesterol"). The study demonstrated that oral, once-daily ETC-1002 achieved incremental LDL-C lowering of 22 percent at eight weeks, compared with 0 percent in the placebo group, when added to 10 mg of atorvastatin ($p < 0.0001$). ETC-1002 was well tolerated over eight weeks of treatment when added to a statin and no serious adverse events (SAEs) were reported.

"Since a 10 mg dose of atorvastatin provides 30 to 35 percent LDL-C lowering, the addition of ETC-1002 could potentially provide LDL-C lowering of greater than 55 percent with an oral dosing regimen. While statin therapy remains the standard of care for high cholesterol, it is estimated that 11 million Americans are still unable to reach their LDL-C treatment goals despite taking a statin," said Roger S. Newton, PhD, FAHA, executive chairman and chief scientific officer of Esperion.

"This study answered important questions about the safety, tolerability and efficacy of ETC-1002 as an add-on to statin therapy," said Tim M. Mayleben, president and chief executive officer of Esperion. "We are now in a position to build on these positive results with a robust, parallel-dose design Phase 2b study to establish further the potential of ETC-1002 to provide incremental LDL-C lowering for patients already taking a statin and not at their LDL-C goal."

ETC-1002-007 Design

The ETC-1002-007 study was a randomized, double-blind, placebo-controlled, multicenter, Phase 2a study to evaluate the safety and tolerability of ETC-1002 when added to 10 mg of atorvastatin and assess the effect of ETC-1002 on the pharmacokinetics of atorvastatin in patients with hypercholesterolemia. Secondary objectives were to assess the effect of ETC-1002 on LDL-C and other cardiometabolic risk factors when added to atorvastatin. Fifty-eight patients with hypercholesterolemia were washed out of any lipid regulating therapies prior to a four week run-in period on 10 mg atorvastatin (mean baseline LDL-C levels of 106 mg/dL at week 0 prior to randomization). Forty-two of these patients were randomized to receive ETC-1002 plus 10 mg atorvastatin. All ETC-1002 treated patients received escalating daily doses of 60, 120, 180 and 240 mg ETC-1002, each over a two week period, for a total of eight weeks. Sixteen patients received placebo plus 10 mg atorvastatin also for eight weeks.

ETC-1002-007 Results

Adverse events (AEs) were generally mild and no SAEs were observed in either the ETC-1002 or placebo groups. Thirty-nine out of 42 ETC-1002 treated patients (93%) and 14 out of 16 placebo treated patients (88%) completed eight weeks of treatment. Two patients in the ETC-1002 plus atorvastatin group withdrew from the study due to AEs. One patient had an elevated liver enzyme laboratory finding that resolved when ETC-1002 and atorvastatin were discontinued. The other patient's AE was unrelated to ETC-1002. There was a weak pharmacokinetic interaction of ETC-1002 with atorvastatin. ETC-1002 treated patients achieved incremental LDL-C lowering of 22 percent at eight weeks, compared with 0 percent in the placebo group, when added to 10 mg of atorvastatin ($p < 0.0001$).

Limitations of Statin Therapy

Statins are the standard of care for LDL-C lowering treatment today and are highly effective at lowering LDL-C. The benefits of using statins to lower LDL-C levels and improve cardiovascular outcomes are well documented. However, a significant number of patients are unable to tolerate statins due to the side effects, primarily muscle pain or weakness. Based on data from the USAGE survey, as published in the Journal of Clinical Lipidology in 2012, we estimate that more than 2 million adults in the U.S. are statin intolerant. Additionally, many patients are unable to reach their LDL-C goal on statin therapy alone. The Centers for Disease Control and Prevention estimates that there are approximately 11 million patients in the U.S. who are currently on lipid-lowering therapy but are unable to achieve their LDL-C treatment goal. These patients remain at elevated risk for cardiovascular disease.

Conference Call Details

The Esperion management team will host a conference call and webcast today at 8:30 a.m. Eastern Time (ET) to discuss top-line results from the Phase 2a clinical study of ETC-1002 as an add-on to statin therapy in patients with hypercholesterolemia. The live event will be accessible on the Esperion website beginning at 8:30 a.m. at www.esperion.com, under the Investors section, or by calling (877) 312-7508 (domestic) or (253) 237-1184 (international). The access code is 28976349. A replay of the event will be available beginning at approximately 10:00 a.m. ET today from the Esperion website or by calling (855) 859-2056 (domestic) or (404) 537-3406 (international), using access code 28976349. The replay will be available through September 17, 2013.

About Esperion Therapeutics

Esperion Therapeutics, Inc. is a biopharmaceutical company focused on the research, development and commercialization of therapies for the treatment of patients with elevated LDL-C and who are at risk from other cardiometabolic risk factors. ETC-1002, Esperion's lead product candidate, is a unique, first-in-class, orally available, once-daily small molecule designed to lower levels of LDL-C and to avoid side effects associated with existing LDL-C lowering therapies. ETC-1002 is targeted for statin intolerant patients with elevated levels of LDL-C. For more information, please visit www.esperion.com.

Forward Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the therapeutic potential of ETC-1002, Esperion's plans to submit the full results of ETC-1002-007 for publication or presentation and the study design of Esperion's Phase 2b ETC-1002-009 clinical study. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause Esperion's actual results to differ significantly from those projected, including, without limitation, the risk that unanticipated developments could interfere with the development (and commercialization) of ETC-1002, as well as other risks detailed in Esperion's filings with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q filed with Securities and Exchange Commission on August 12, 2013. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Esperion disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

Media:
BrewLife
Denise Powell, 510-703-9491
dpowell@brewlife.com

Source: Esperion Therapeutics, Inc.

News Provided by Acquire Media