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Esperion Therapeutics Announces Initiation of Phase 2b Clinical Study of ETC-1002 in Patients With or Without Statin Intolerance and Hypercholesterolemia

Represents Company's First Clinical Study in Robust Phase 2b Program

PLYMOUTH, Mich.--(BUSINESS WIRE)-- Esperion Therapeutics, Inc. (Nasdaq:ESPR), a clinical-stage biopharmaceutical company focused on developing and commercializing first-in-class, oral, low-density lipoprotein cholesterol (LDL-C) lowering therapies for the treatment of patients with hypercholesterolemia, today announced dosing of the first patient in a Phase 2b clinical study of ETC-1002, its lead product candidate, in patients with or without statin intolerance and hypercholesterolemia. The goals of this study, ETC-1002-008, are to compare the LDL-C lowering efficacy of ETC-1002 with ezetimibe and to demonstrate comparable tolerability to ezetimibe, a common therapy for statin intolerance, in the treatment of patients with elevated LDL-C levels. To be considered statin intolerant for ETC-1002-008, a patient must be intolerant to two or more statins, at least one of which was administered at or below the approved starting dose. ETC-1002 is an 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.

"Dosing of the first patient in our first Phase 2b clinical study is an important step toward our goal of developing ETC-1002 as an oral treatment for the two million patients with elevated LDL-C levels who are unable to tolerate statin therapy," said Tim M. Mayleben, president and chief executive officer of Esperion. "We believe ETC-1002 can specifically address the unmet medical needs of these patients, who are at elevated risk of cardiovascular disease. We look forward to reporting top-line results from this study by the end of 2014."

The randomized, double-blind, parallel-group, multicenter ETC-1002-008 study is evaluating parallel doses of ETC-1002 as monotherapy or in combination with ezetimibe in approximately 322 patients. The primary objective of the study is to assess the LDL-C lowering efficacy of ETC-1002 monotherapy versus ezetimibe monotherapy in hypercholesterolemic patients with or without statin intolerance treated for 12 weeks. Secondary objectives include assessing the effect of ETC-1002 on additional lipid and cardiometabolic biomarkers; characterizing the tolerability and safety of ETC-1002; and assessing the dose range of ETC-1002 to inform Phase 3 dosing. The trial is being conducted at approximately 75 clinical sites in the United States.

In June 2013, Esperion announced positive top-line results from a Phase 2a proof-of-concept clinical study of ETC-1002 in patients with hypercholesterolemia with a history of intolerance to two or more statins. The results of that study, ETC-1002-006, were used to inform the design of the Phase 2b ETC-1002-008 study. ETC-1002-06 met its primary endpoint, demonstrating that ETC-1002 lowered LDL-C by an average of 32 percent compared with an LDL-C reduction of 3 percent in the placebo group ($p < 0.0001$) and was well tolerated.

About Statin Intolerance

According to the USAGE survey, an academic study of approximately 10,000 current and former statin users published in 2012 in the Journal of Clinical Lipidology, approximately 12 percent of patients on statins discontinue therapy, with 62 percent of these patients citing side effects as the reason for discontinuation. More than 86 percent of patients who discontinued therapy because of side effects cited myalgia as the primary reason for discontinuing their statin. Based on these data, it is estimated that approximately 6 percent of statin users, or more than 2 million adults in the United States, ceased therapy because of myalgia and are therefore considered to be statin intolerant. Poor statin adherence can be associated with worse cardiovascular outcomes.

Therapies most often prescribed for patients with hypercholesterolemia and a history of statin intolerance have reported average LDL-C lowering of up to 18 percent in pivotal clinical studies.

About the ETC-1002 Clinical Development Program

ETC-1002 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 has a unique [dual mechanism of action](#) that has the potential to regulate both lipid and carbohydrate metabolism. ETC-1002 works by inhibiting ATP citrate lyase (ACL), a key enzyme in the cholesterol biosynthetic pathway, and activating a complementary enzyme, 5'-adenosine monophosphate-activated protein kinase (AMPK). Both enzymes are known to play significant roles in the synthesis of cholesterol and glucose

in the liver. By inhibiting cholesterol synthesis in the liver, ETC-1002 causes the liver to take up LDL particles from the blood, which reduces LDL-C levels.

In seven completed Phase 1 and 2 clinical studies, involving more than 300 patients who received ETC-1002, the agent has shown consistent and clinically meaningful reductions in LDL-C cholesterol, as well as reductions comparable to statins in levels of high sensitivity C-reactive protein (hsCRP), a key marker of inflammation associated with cardiovascular disease. Across all completed clinical studies, ETC-1002 has been well tolerated. To date, one serious adverse event, considered unrelated to ETC-1002, has been observed in 317 patients treated with ETC-1002 at doses of up to 240 mg and up to 12 weeks in duration.

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 levels of low-density lipoprotein cholesterol (LDL-C) and other cardiometabolic risk factors. ETC-1002, Esperion's lead product candidate, is a unique, first-in-class, orally available, once-daily small molecule therapy 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. Esperion has completed seven clinical studies to date, including four Phase 2a studies, and has initiated a robust Phase 2b clinical program. 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 and the study design and anticipated timing for reporting top-line results from ETC-1002-008. 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.

Esperion Therapeutics, Inc.
Media Contact:
BrewLife
Jessica Volchok, 310-774-3423
jvolchok@brewlife.com

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