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# Esperion Therapeutics Presents Full Results of Phase 2 Clinical Study Demonstrating that ETC-1002 Lowered LDL-C by an Average of 32 Percent and Was Well Tolerated in Patients with Hypercholesterolemia and History of Statin Intolerance

*Data Presented in Oral Presentation Session at AHA's Scientific Sessions*

DALLAS & 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 hypercholesterolemia, today announced full results of a Phase 2 clinical study of its lead product candidate ETC-1002 in patients with hypercholesterolemia and a history of statin intolerance. The study, ETC-1002-006, met its primary endpoint, demonstrating that ETC-1002 significantly lowered LDL-C compared to placebo by an average of 32 percent and was well tolerated. The data were presented today in an oral presentation at the 2013 Scientific Sessions of the American Heart Association in Dallas by principal investigator Paul D. Thompson, M.D. Esperion previously announced positive topline results from this study in June 2013.

"To achieve a 32% reduction in LDL cholesterol with a non-statin is very impressive and more reduction than any other currently approved lipid lowering agent except the statins. This drug may have promise for people who have trouble tolerating statins and could be important given that more than 2 million people in the United States are estimated to be statin intolerant," said Dr. Thompson, director of cardiology, at Hartford Hospital, and professor of medicine at the University of Connecticut. "Statin intolerant patients have very few therapeutic options and an oral treatment that significantly lowers LDL-C and is well tolerated could be very useful in this patient population."

"We continue to build on the positive results from this Phase 2 clinical study and recently initiated a large Phase 2b clinical study in statin intolerant and statin tolerant patients," said Tim M. Mayleben, president and chief executive officer of Esperion. "This Phase 2b clinical study will further evaluate the potential of ETC-1002 in statin intolerant patients, a patient population that we believe is underserved by currently available therapies and who remain at elevated risk for cardiovascular disease."

**ETC-1002-006 Study Design and Results**

This Phase 2a proof-of-concept clinical study was designed to evaluate the LDL-C lowering efficacy, safety and tolerability of ETC-1002 compared with placebo in patients with hypercholesterolemia and a history of intolerance to two or more statins. The study also assessed the ability of patients with a history of statin intolerance to achieve their NCEP ATP-III LDL-C goal. Study participants were dosed for eight weeks starting at 60 mg for two weeks, followed by 120 mg, 180 mg and 240 mg for two weeks each (or placebo only for eight weeks). A total of 56 patients were evaluated in the study, of whom 37 were randomized to receive ETC-1002 and 19 to receive placebo.

Thirty-one ETC-1002 patients and 15 placebo patients completed eight weeks of treatment. Three patients in the placebo group and none in the ETC-1002 group withdrew from the study for muscle-related reasons (e.g., musculoskeletal pain, muscle fatigue, muscle weakness, myalgia).

Final results showed that ETC-1002 lowered LDL-C by statistically significant 32 percent compared with 3 percent in the placebo group (p=0.0001). Approximately two-thirds of patients reached their ATP-III NCEP LDL-C goal. In the ETC-1002 group, high sensitivity C-reactive protein (hsCRP), a recognized marker for inflammation, was significantly reduced after eight weeks by 42 percent (p=0.0022). Levels of ApoB and Non-HDL-C, other important biomarkers, were also significantly reduced.

Overall adverse event rates were comparable between the ETC-1002 and placebo groups, with muscle-related adverse events similar between groups. No serious adverse events (SAE) were observed among placebo patients; one SAE occurred in the ETC-1002 treatment group that was considered unrelated to the study medication.

**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. Approximately 85 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.

**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 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, consistent and clinically meaningful reductions in LDL-C cholesterol and high sensitivity C-reactive protein (hsCRP), a key marker of inflammation associated with cardiovascular disease, have been observed. 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.

Last month, Esperion initiated ETC-1002-008, the Company's first Phase 2b clinical study. The study is evaluating parallel doses of ETC-1002 over 12 weeks as monotherapy or in combination with ezetimibe in approximately 322 patients with hypercholesterolemia and a history with or without statin intolerance (to two or more statins due to muscle-related adverse events). The goals of this study are to compare the LDL-C lowering efficacy of ETC-1002 with ezetimibe, a common therapy for statin intolerance, and to characterize tolerability. Top-line results are expected in late 2014.

**Webcast Briefing Details**

Esperion will host a reception on Monday, November 18, from 7:00 to 9:00 p.m. Central Time separate from the AHA Scientific Sessions. During the prepared remarks, the Company will provide development program updates and featured guest, Dr. Thompson, will provide a recap of the ETC-1002-006 full results. A live webcast of the prepared remarks will commence at 7:30 p.m. Central Time. To access the live conference call via phone, please dial (866) 740-1260 from the United States and Canada. The participant passcode is 3906884. Please dial in 10 minutes prior to the start of the call. To access the live and subsequently archived webcast of the conference call, please go to the Investor section of the Company's website. Please connect to the website at least 15 minutes prior to the call to allow for any software download that may be necessary. The replay of the webcast will be available on the Company's website for 90 days following the live event.

**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. 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 the Securities and Exchange Commission on November 6, 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.

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