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Esperion Therapeutics Announces Initiation of a Phase 2 Clinical Study of ETC-1002 in Patients with Hypercholesterolemia and Hypertension

ANN ARBOR, 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-cholesterol) lowering therapies for the treatment of patients with hypercholesterolemia and other cardiometabolic risk markers, today announced dosing of the first patient in its Phase 2 clinical study of ETC-1002 in patients with hypercholesterolemia and hypertension, ETC-1002-014. The company expects to announce top-line results from the study in the second quarter of 2015.

"Many patients with high LDL-cholesterol levels also have hypertension. This clinical study will help to further elucidate the LDL-cholesterol lowering efficacy, safety and tolerability profile of ETC-1002 in patients with both hypercholesterolemia and hypertension," said Tim M. Mayleben, president and chief executive officer of Esperion.

The randomized, double-blind, parallel group, multicenter ETC-1002-014 study is evaluating parallel doses of ETC-1002 in approximately 144 patients. The primary objective of the study is to assess the LDL-cholesterol lowering efficacy of ETC-1002 monotherapy versus placebo in patients with both hypercholesterolemia and hypertension who are treated for six weeks. Secondary objectives include assessing the effect of ETC-1002 on blood pressure, other lipid and cardiometabolic biomarkers and characterizing the tolerability and safety of ETC-1002.

About the ETC-1002 Clinical Development Program

ETC-1002 is a novel, first-in-class, orally available, once-daily small molecule designed to lower levels of LDL-cholesterol and to avoid side effects associated with existing LDL-cholesterol 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-cholesterol levels.

In seven completed Phase 1 and 2 clinical studies in more than 300 patients, ETC-1002 has shown consistent and clinically meaningful reductions in LDL-cholesterol, as well as reductions 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 for up to 12 weeks in duration.

About Esperion Therapeutics

Esperion Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on developing and commercializing first-in-class, oral, LDL-cholesterol lowering therapies for the treatment of patients with hypercholesterolemia and other cardiometabolic risk markers. ETC-1002, Esperion's lead product candidate, is a unique, first-in-class, orally available, once-daily small molecule designed to lower LDL-cholesterol levels and avoid the side effects associated with therapies currently available for lowering LDL-cholesterol. ETC-1002 is being developed initially for the treatment of patients with hypercholesterolemia and a history of statin intolerance. Phase 2b clinical trials for ETC-1002 are currently underway and build upon the successful and comprehensive Phase 1 and Phase 2a programs. For more information, please visit www.esperion.com and follow us on Twitter at <https://twitter.com/EsperionInc>.

Esperion's Commitment to Cardiometabolic Disease

Esperion is committed to improving the lives of patients with cardiometabolic diseases. The Esperion team leverages its understanding of and experience with key biological pathways to discover or license and develop innovative therapies for the treatment of patients with unmet needs, especially those patients with hypercholesterolemia who have uncontrolled cholesterol levels despite the use of currently available therapies. Esperion has assembled a portfolio of programs including one product candidate in late-stage clinical development (ETC-1002) and two additional pre-clinical product candidates.

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, the study design and anticipated timing for reporting top-line results from ETC-1002-014 and the status and potential of Esperion's pre-clinical product candidates. 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2014. 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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