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Esperion Therapeutics Announces Initiation of Phase 2 Clinical Study of Bempedoic Acid in Patients Treated With High-Dose Statin Therapy

ANN ARBOR, Mich., Jan. 12, 2016 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ:ESPR), a pharmaceutical 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 initiation of its Phase 2 pharmacokinetics/pharmacodynamics (PK/PD) study (ETC-1002-035) of bempedoic acid in patients treated with atorvastatin 80 mg, the most commonly prescribed high-dose statin. The Company expects to announce top-line results from the study by mid-year.

"Bempedoic acid has significant potential to be a new therapeutic option, not only for patients who are unable to tolerate statin therapy, but also as an 'add-on' for those patients already taking a statin who need additional LDL-C lowering," said Tim M. Mayleben, president and chief executive officer of Esperion. "We expect completion of this study will demonstrate incremental efficacy when added to a high-dose statin, which is important to extend the clinical profile of bempedoic acid and market potential in patients who are not adequately treated with maximum statin therapy."

ETC-1002-035 is a Phase 2 randomized, double-blind, parallel group study evaluating 60 patients on stable atorvastatin 80 mg per day. All patients in the study will receive 80 mg of atorvastatin for four weeks. Patients will then be randomized to receive either 180 mg of bempedoic acid, or placebo, for four weeks. The study will enroll patients at approximately 20 centers across the U.S. The primary objectives of the study are to assess the LDL-C lowering efficacy of bempedoic acid versus placebo on a background of atorvastatin 80 mg, as well as multiple-dose plasma PK of atorvastatin 80 mg alone and in combination with bempedoic acid. Secondary objectives include assessing the effect of bempedoic acid on lipid and cardiometabolic biomarkers, including high-sensitivity C-reactive protein; characterizing the tolerability and safety of bempedoic acid; and evaluating the steady-state plasma PK of bempedoic acid.

Next month, the Company also intends to initiate a Phase 1 clinical pharmacology study of bempedoic acid (ETC-1002-037), which will be an open label, drug-drug interaction study to assess the safety and tolerability of bempedoic acid at steady-state, as well as the PK of single doses of the highest-doses of the most commonly prescribed statins: atorvastatin 80 mg, rosuvastatin 40 mg, simvastatin 40 mg, and pravastatin 80 mg. The Company expects to announce top-line results from the study by mid-year.

Esperion's Commitment to Cardiometabolic Disease

Esperion is committed to improving the lives of patients with hypercholesterolemia by developing therapies to lower LDL-C. Esperion scientists discovered bempedoic acid and the LDL-C lowering therapy is in late stage development. Esperion plans to develop both bempedoic acid and a fixed dose combination of bempedoic acid and ezetimibe with a particular focus on patients with hypercholesterolemia who are considered intolerant of statin therapy. It is estimated that approximately 10% of patients who are prescribed statins, 3.5 million patients in the U.S., are considered statin intolerant.

About Esperion Therapeutics

Esperion Therapeutics, Inc. is a pharmaceutical company focused on developing and commercializing first-in-class, oral, LDL-C lowering therapies for the treatment of patients with hypercholesterolemia. Bempedoic acid, the Company's lead product candidate, is an inhibitor of ATP Citrate Lyase, a well-characterized enzyme on the cholesterol biosynthesis pathway. Bempedoic acid inhibits cholesterol synthesis, decreases intracellular cholesterol, up-regulates LDL-receptors, and causes increased LDL-C clearance and reduced plasma levels of LDL-C. For more information, please visit www.esperion.com and follow us on Twitter at https://twitter.com/EsperionInc.

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, and clinical development plan for, bempedoic acid and the fixed-dose combination of bempedoic acid and ezetimibe, the design and timing of the announcement of top-line results from ETC-1002-035, and the design, timing of the initiation and read-out of top-line results of the Company's

Phase 1 drug-drug interaction study. Any express or implied 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, delays or failures in patient enrollment in the Company's studies, the risk that FDA may require additional studies or data, including prior to approval that might cause approval to be delayed, that Esperion may need to change the design of its Phase 3 program, including upon feedback from regulatory authorities, that positive results from a clinical study of bempedoic acid and the fixed-dose combination of bempedoic acid and ezetimibe may not necessarily be predictive of the results of future clinical studies, particularly in different or larger patient populations, or in all statin doses, including high doses, or the risk that other unanticipated developments or data could interfere with the scope of development and commercialization of bempedoic acid and the fixed-dose combination of bempedoic acid and ezetimibe, as well as other risks detailed in Esperion's filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. 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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