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Esperion Announces Initiation of Phase 2 Triplet Oral Therapy Study of Bempedoic Acid/Ezetimibe/Atorvastatin

ANN ARBOR, Mich., March 07, 2017 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ:ESPR), the lipid management company focused on developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today announced the initiation of a Phase 2 clinical study (1002-038) to assess the efficacy and safety of triplet oral therapy with bempedoic acid, ezetimibe and atorvastatin in patients with hypercholesterolemia. This non-registrational study will enable the Company to explore the potential market dynamics of these complementary oral LDL-C lowering therapies together. Top-line results are expected by the fourth quarter of 2017.

"Our goal is to establish bempedoic acid as the go-to complementary oral therapy that will provide patients and physicians with the option to tailor combination therapies with the convenience of once-daily, oral dosing and the confidence in the LDL-C lowering and excellent tolerability we've come to expect from bempedoic acid," said Tim M. Mayleben, president and chief executive officer of Esperion. "We seek to demonstrate in this Phase 2 triplet oral therapy study of bempedoic acid, ezetimibe and the most commonly prescribed statin dose, atorvastatin 20 mg, significant LDL-C reductions, and consistently favorable safety and tolerability."

The six-week, Phase 2, randomized, double-blind, placebo-controlled study will evaluate the efficacy and safety of 180 mg of bempedoic acid, 10 mg of ezetimibe and 20 mg of atorvastatin (triplet oral therapy) versus placebo. The study is expected to enroll approximately 60 patients with hypercholesterolemia at approximately 20 sites across the U.S. The primary objective of the study is to assess the LDL-C lowering efficacy of the triplet oral therapy versus placebo. Secondary objectives include assessing the safety and tolerability of the triplet oral therapy versus placebo and effects on other risk markers, including non-high-density lipoprotein cholesterol (non-HDL-C), total cholesterol, apolipoprotein B (apoB) and high sensitivity C-reactive protein (hsCRP).

"The triplet oral therapy including bempedoic acid, ezetimibe and atorvastatin could provide a much-needed novel treatment option for physicians by providing the ability to tailor well-tolerated multiple oral therapies aimed at helping patients with hypercholesterolemia achieve their LDL-C goal that could provide a tolerability advantage," said Seth J. Baum, M.D., Founder and Chief Medical Officer of Excel Medical Clinical Trials, LLC and study investigator. "I look forward to the opportunity to include patients from our research group in this study, and to seeing the results later this year."

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. Completed Phase 1 and 2 studies in more than 800 patients treated with bempedoic acid have produced clinically relevant LDL-C lowering results of up to 30 percent as monotherapy, approximately 50 percent in combination with ezetimibe, and an incremental 20+ percent when added to stable statin therapy.

Esperion's Commitment to Patients with Hypercholesterolemia

In the United States, 78 million people, or more than 20 percent of the population, have elevated LDL-C; an additional 73 million people in Europe and 30 million people in Japan also live with elevated LDL-C. Esperion's mission as the lipid management company is to provide patients and physicians with convenient, complementary, cost-effective, once-daily, oral therapies to significantly reduce elevated levels of LDL-C in patients inadequately treated with current lipid-modifying therapies. It is estimated that 40 million patients in the U.S. are taking statins with approximately 5-20 percent of these patients only able to tolerate less than the lowest approved daily starting dose of their statin and considered "statin intolerant." Esperion-discovered and developed, bempedoic acid is a targeted LDL-C lowering therapy in Phase 3 development. The Company has two Phase 3 products in development: 1) bempedoic acid (monotherapy), an oral, once-daily pill, and 2) an oral, once-daily fixed dose combination pill of bempedoic acid and ezetimibe (BA+EZ).

The Lipid Management Company

Esperion Therapeutics, Inc. is the lipid management company passionately committed to developing and commercializing

convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global CVD; the leading cause of death around the world. Bempedoic acid, the Company's lead product candidate, is a targeted therapy that significantly reduces elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies. 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, including the Company's timing, designs, plans, and announcement of results regarding the 1002-038 Phase 2 clinical study and the therapeutic potential of triplet oral therapy of bempedoic acid, ezetimibe and atorvastatin. 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 the Company's studies, including the risk that U.S. Food and Drug Administration may require additional studies or data, that Esperion may need to change the design of its Phase 3 program, that positive results from a clinical study of bempedoic acid may not necessarily be predictive of the results of future clinical studies, particularly in different or larger patient populations, that existing cash resources may be used more quickly than anticipated, that Esperion's global Phase 3 long-term safety and tolerability program for bempedoic acid may not produce sufficient safety or tolerability results or show meaningful change in LDL-C or other key lipid measures of patients, or the risk that other unanticipated developments or data could interfere with the scope of development and commercialization of bempedoic acid, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. 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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