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Esperion Announces Initiation of Global Cardiovascular Outcomes Trial for Bempedoic Acid

ANN ARBOR, Mich., Jan. 09, 2017 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ:ESPR), the lipid management company focused on developing and commercializing complementary oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today announced the initiation of the global cardiovascular outcomes trial (CVOT) to assess the effects of bempedoic acid on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease (CVD) who are only able to tolerate less than the lowest approved daily starting dose of a statin and considered "statin intolerant."

The CVOT — known as **C**holesterol **L**owering via B**E**mpedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes — is an event-driven, global, randomized, double-blind, placebo-controlled study expected to enroll approximately 12,600 patients with hypercholesterolemia and high CVD risk at more than 600 sites in approximately 30 countries. The study is expected to enroll over a 30-month period with a total estimated study duration of approximately 4.75 years. The expected average treatment duration will be 3.5 years with a minimum treatment duration of approximately 2.25 years. Patients enrolling in the study will be required to have a history of, or be at high-risk for, CVD with LDL-C levels between 100 mg/dL and 190 mg/dL despite background lipid-lowering therapy, resulting in an expected average baseline LDL-C level in all patients of approximately 135 mg/dL.

"The start of the CLEAR Outcomes CVOT is one of the last and most exciting steps in the development of bempedoic acid, and we are very pleased to have begun dosing patients," said Tim M. Mayleben, president and chief executive officer of Esperion. "We worked closely with Dr. Steven Nissen and the team at the Cleveland Clinic to develop this well-powered study to demonstrate the potential benefit of bempedoic acid in reducing events in a patient population with a significant unmet need — patients with hypercholesterolemia considered ‘statin intolerant' who are at high-risk for CVD. We believe bempedoic acid has the potential to provide a well-tolerated, complementary, once-daily, oral therapy for patients with "statin intolerance" and other high-risk patient populations with hypercholesterolemia."

The primary efficacy endpoint of the event-driven global study is the effect of bempedoic acid versus placebo on the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, hospitalization for unstable angina, or coronary revascularization; also referred to as "five-component MACE"). Similar to other CVOTs, CLEAR Outcomes is designed to provide greater than 85 percent power to detect an approximately 14 percent relative risk reduction in the primary endpoint in the bempedoic acid treatment group as compared to the placebo group, and is expected to complete with a minimum of 1,437 patients experiencing the primary endpoint.

The Company expects to submit a New Drug Application (NDA) for cardiovascular risk reduction to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA), on the basis of a successful completion of the CLEAR Outcomes CVOT, by 2022.

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class 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 a new convenient and complementary oral therapy 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 focused on developing and commercializing convenient and complementary 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, has a targeted mechanism of action 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 its global Phase 3 program and timing of an NDA submission for bempedoic acid. 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 in patient enrollment, the risk that FDA 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, the CVOT may not demonstrate that bempedoic acid leads to cardiovascular risk reduction, 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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