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Esperion Completes Enrollment of Pivotal Phase 3 Long-Term Safety and Tolerability Study of Bempedoic Acid in Patients with Hypercholesterolemia

Approximately 2,000 Patients Enrolled Ahead of Schedule Following Study Expansion in October 2016
Global Study Enrolled Patients with Hypercholesterolemia with ASCVD and/or HeFH at High CVD Risk
Top-Line Results Expected by Q2 2018

ANN ARBOR, Mich., Jan. 25, 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 completion of patient enrollment in the global pivotal Phase 3 long-term safety and tolerability study of bempedoic acid. Enrollment of this study was completed ahead of schedule in approximately 2,000 patients treated with bempedoic acid or placebo at high cardiovascular disease (CVD) risk with hypercholesterolemia whose LDL-C is not adequately controlled with current lipid-modifying therapies. Top-line results from this study are expected by Q2 2018.

"We are pleased to have fully enrolled the first of our global pivotal Phase 3 studies ahead of schedule. This milestone represents the kind of clinical operational excellence we have come to expect from our team, our sites and investigators, and our partner CRO," said Tim M. Mayleben, president and chief executive officer of Esperion. "The study was designed by our team of lipid management experts primarily to understand the long-term safety and tolerability of bempedoic acid and to also measure the percent change in LDL-C and other key lipid measures of patients at various time points throughout the duration of the 52-week study. We look forward to sharing top-line results by the second quarter of next year."

The 52-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study is evaluating the long-term safety and tolerability of 180 mg of bempedoic acid versus placebo in patients with atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH) at high CVD risk whose LDL-C is not adequately controlled with current lipid-modifying therapies. The study enrolled patients at approximately 100 sites in the U.S., Canada and Europe. The primary objective is to assess the safety and tolerability of patients treated with bempedoic acid for 52 weeks. Secondary objectives include assessing the LDL-C lowering efficacy of bempedoic acid on top of maximally tolerated statin and other lipid altering therapies at 12, 24 and 52 weeks versus placebo. 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), will also be evaluated.

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 its global Phase 3 long-term safety and tolerability program 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 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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