Esperion Announces Late-Breaking Oral Presentation of Final Results of Phase 3 Long-Term Safety Study of Bempedoic Acid at the European Society of Cardiology Congress

August 25, 2018

— Bempedoic Acid Achieved Additional 20% On-Treatment LDL-C Lowering on Background of Maximally Tolerated Statins —

— Study 1 (CLEAR Harmony) Provided the Largest Evidence to Date that Bempedoic Acid Is Safe when Added on to Maximally Tolerated Statins —

— Bempedoic Acid Provides Additional Oral Therapeutic Option to Safely Lower LDL-C in High-Risk ASCVD Patients Treated with Statins —

MUNICH, Germany, Aug. 25, 2018 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today announced that the final results from the pivotal Phase 3 Study 1 (1002-040 or CLEAR Harmony) were presented at the European Society of Cardiology (ESC) Congress in Munich, Germany. This Phase 3 study evaluated the long-term safety, tolerability and efficacy of bempedoic acid 180 mg versus placebo in high-risk patients with atherosclerotic cardiovascular disease (ASCVD) who are inadequately controlled with current lipid-modifying therapies, including maximally tolerated statins. The late-breaking oral presentation was delivered by Professor Kausik K. Ray, MBChB, MD, MPhil, Professor of Public Health at the School of Public Health, Imperial College London and a Consultant Cardiologist. Topline results were announced earlier this year in May.

“The final data from Study 1 provide greater reassurance about the safety of bempedoic acid and reconfirm the efficacy over a longer period of time,” said Professor Ray. “Our findings – supported by other ongoing bempedoic acid studies – may very soon offer clinicians an additional oral lipid lowering agent with which to treat high-risk patients.”

New data presented today as part of the final Study 1 results showed patients on bempedoic acid who were on a maximally tolerated statin dose had significantly fewer instances of new-onset or worsening diabetes than those on placebo who were on a maximally tolerated statin dose (5.4 percent compared to 3.3 percent; p<0.02). In addition, serious AEs, including neoplasms, were balanced between the two study arms. A detailed listing of all adjudicated cardiovascular events was provided, again showing balance between the two study arms.

Details on the presentation are as follows:

Title: Late Breaking Pharmacological Science: CLEAR Harmony – Long-term safety, tolerability and efficacy of bempedoic acid vs. placebo in high cardiovascular risk patients with LDL-C above 1.8 mmol/L on maximally tolerated statin therapy
Date: August 25, 2018
Time: 11:45 am (CET)
Location: Messe München, Bratislava-Village 2

Design of Global Pivotal Phase 3 Study 1 (1002-040)

The 52-week, global, pivotal Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the long-term safety and tolerability of bempedoic acid 180 mg/day versus placebo in high-risk patients with ASCVD and/or heterozygous familial hypercholesterolemia (HeFH) with LDL-C levels of at least 70 mg/dL (1.8 mmol/L) who are inadequately controlled with current lipid-modifying therapies, including maximally tolerated statin therapy. The study was conducted at 117 sites in the U.S., Canada and Europe. A total of 2,230 patients were randomized 2:1 to receive bempedoic acid or placebo. The secondary objective was to assess the 12-week LDL-C lowering efficacy of bempedoic acid versus placebo. Tertiary objectives were to assess the effect of bempedoic acid on other lipid parameters and risk markers, including hsCRP.

An open-label extension study (1002-050) was initiated in early 2017 and is fully enrolled with 1,462 patients.

About Esperion's Global Pivotal Phase 3 LDL-C Lowering Program

Esperion initiated its global, pivotal, Phase 3 clinical development program in January 2016 to evaluate the safety, tolerability and consistent, complementary LDL-C-lowering efficacy of bempedoic acid and the bempedoic acid / ezetimibe combination pill in patients with atherosclerotic cardiovascular disease (ASCVD), or who are at a high risk for ASCVD, with hypercholesterolemia who continue to have elevated levels of LDL-C despite the use of maximally-tolerated statins and ezetimibe, leaving them at high risk for cardiovascular events. The program includes five studies in approximately 4,000 patients, four for bempedoic acid and one for the bempedoic acid / ezetimibe combination pill.

- Two pivotal studies evaluating bempedoic acid (Studies 1 & 2) in 3,009 patients with ASCVD on maximally-tolerated statins, with top-line results reported in May 2018, and expected in September 2018, respectively;
- Two pivotal studies evaluating bempedoic acid (Studies 3 & 4) in 614 patients with ASCVD, or at a high risk for ASCVD, considered statin intolerant, with top-line results reported in May and March 2018, respectively;
- One pivotal study evaluating the bempedoic acid / ezetimibe combination pill (053 Study) in 382 patients with ASCVD, or at high risk for ASCVD, on maximally tolerated statins, with topline results expected in August 2018.

Esperion plans to submit New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) for bempedoic acid and the bempedoic acid / ezetimibe combination pill for LDL-C-lowering indications during the first quarter of 2019. Additionally, Esperion plans to submit Marketing Authorization Applications (MAAs) to the European Medicines Agency (EMA) during the second quarter of 2019.

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ATP Citrate Lyase (ACL) inhibitor that reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Similar to statins, bempedoic acid also reduces hsCRP, a key marker of inflammation associated with cardiovascular disease. Completed Phase 2 and Phase 3 studies conducted in over 4000 patients, and approximately 2,900 patients treated with bempedoic acid, have produced LDL-C lowering results of up to 30 percent as monotherapy, 48 percent in combination with ezetimibe as monotherapy, and an additional 20 percent on maximally tolerated statins.

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. The company initiated a 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 Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (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 up to 1,000 sites in approximately 30 countries.

Esperion's Commitment to Patients with Hypercholesterolemia

High levels of LDL-C can lead to a build-up of fat and cholesterol in and on artery walls (known as atherosclerosis), potentially leading to cardiovascular events, including heart attack or stroke. In the U.S., 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. There are approximately 13 million people in the U.S. with atherosclerotic cardiovascular disease (ASCVD) who live with elevated levels of LDL-C despite taking maximally-tolerated lipid-modifying therapy — including individuals considered statin intolerant — leaving them at high risk for cardiovascular events. More than 6 million patients with ASCVD and/or HeFH on maximally tolerated statins require less than 30 percent additional LDL-C lowering to achieve treatment goals.

Esperion's mission as the Lipid Management Company is to deliver once-daily, oral therapies that complement existing oral drugs to provide the additional LDL-C lowering that these patients need.

The Lipid Management Company

Esperion 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 cardiovascular disease; the leading cause of death around the world. Bempedoic acid and the company's lead product candidate, the bempedoic acid / ezetimibe combination pill, are targeted therapies that have been shown to significantly lower 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 regulatory approval pathway for the bempedoic acid / ezetimibe combination pill and bempedoic acid and the therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination pill and bempedoic acid, including Esperion's timing, designs, plans and announcement of results regarding its global pivotal Phase 3 clinical development program for bempedoic acid and the bempedoic acid / ezetimibe combination pill, Esperion's timing and plans for submission of NDAs to the FDA and MAAs to the EMA and Esperion's expectations for the market for therapies to lower LDL-C, including the market adoption of bempedoic acid and the bempedoic acid / ezetimibe combination pill, if approved. 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 Esperion's studies, that positive results from a clinical study of bempedoic acid may not be sufficient for FDA or EMA approval or necessarily be predictive of the results of future or ongoing clinical studies, that existing cash resources may be used more quickly than anticipated, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. 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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