Esperion Announces Late-Breaking Oral Presentation of Final Study 3 Results (1002-046) of Bempedoic Acid at the American Heart Association Scientific Sessions 2018

November 10, 2018

ANN ARBOR, Mich., Nov. 10, 2018 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR), today announced that the final Phase 3 results from Study 3 (1002-046, also known as CLEAR Serenity) were presented at the American Heart Association (AHA) Scientific Sessions in Chicago. The late-breaking oral presentation was delivered by Professor Dr. med Ulrich Laufs, Director of the Department of Cardiology at Leipzig University, Leipzig, Germany. This study evaluated the LDL-C lowering efficacy and the safety and tolerability of bempedoic acid 180 mg versus placebo in high-risk patients with atherosclerotic cardiovascular disease (ASCVD), or at high risk for ASCVD with hypercholesterolemia, inadequately treated with maximally tolerated background LDL-C lowering therapy who are only able to tolerate less than the approved daily starting dose of a statin and considered statin intolerant. Topline results were previously announced in May 2018.

Details on the presentations are as follows:
Title: Efficacy and Safety of Bempedoic Acid in Patients With Hypercholesterolemia and Statin Intolerance
Date: November 10, 2018
Time: 8:15 a.m. ET
Location: McCormick Place Convention Center

“In Esperion’s CLEAR Serenity trial, bempedoic acid was shown to significantly lower both LDL-cholesterol and high-sensitivity C-reactive protein (hsCRP) in statin-intolerant patients. There is a significant need for additional treatments for the large number of patients with hypercholesterolemia who are not at their LDL-cholesterol treatment goals despite using maximally tolerated statins. This is particularly true for patients who cannot tolerate statins and have limited options available,” said Professor Laufs.

Design of Global Pivotal Phase 3 Study 3 (1002-046, also known as CLEAR Serenity)

The 24-week, global pivotal Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the LDL-C lowering efficacy and safety of bempedoic acid 180 mg/day versus placebo added to background lipid-modifying therapy in patients with hypercholesterolemia who are considered statin intolerant. The study was conducted at 67 sites in the U.S. and Canada. A total of 345 patients were randomized 2:1 to receive bempedoic acid or placebo. The primary efficacy objective was to assess the 12-week LDL-C lowering efficacy of bempedoic acid versus placebo. Secondary objectives included evaluating the 24-week LDL-C lowering efficacy of bempedoic acid versus placebo, the safety and tolerability of bempedoic acid versus placebo, and its effects on other risk markers after 12 weeks of treatment, including hsCRP.

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

Esperion initiated its global, pivotal, Phase 3 clinical development program – known as **C**holesterol **L**owering via B**E**mpedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) – 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. Patients evaluated had atherosclerotic cardiovascular disease (ASCVD), or were 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 Phase 3 LDL-C lowering development 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 – Study 1 (CLEAR Harmony) & Study 2 (CLEAR Wisdom) – in 3,008 patients with ASCVD on maximally-tolerated statins, with top-line results reported in May 2018 and October 2018, respectively;
- Two pivotal studies evaluating bempedoic acid – Study 3 (CLEAR Serenity) & Study 4 (CLEAR Tranquility) – in 613 patients with ASCVD, or at a high risk for ASCVD, considered statin intolerant, with top-line results reported in May 2018 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 top-line results reported 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 / Ezetimibe Combination Pill

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination pill is our lead, non-statin, orally available, once-daily, LDL-C lowering therapy. Inhibition of ATP Citrate Lyase (ACL) by bempedoic acid reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Inhibition of Niemann-Pick C1-Like 1 (NPC1L1) by ezetimibe results in reduced absorption of cholesterol from the gastrointestinal tract, thereby reducing delivery of cholesterol to the liver, which in turn upregulates the LDL receptors. Phase 3 data demonstrated that this safe and well tolerated combination results in a 35 percent lowering of LDL-C when used with maximally tolerated statins, a 43 percent lowering of LDL-C when used as a monotherapy, and a 34 percent reduction in high sensitivity C-reactive protein (hsCRP).

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 almost 4,800 patients, and approximately 3,100 patients treated with bempedoic acid, have produced an additional 20 percent LDL-C lowering when used with maximally tolerated statins, up to 30 percent LDL-C lowering as monotherapy, 35 percent LDL-C lowering in combination with ezetimibe when used with maximally tolerated statins, and up to 48 percent LDL-C lowering in combination with ezetimibe as monotherapy.

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 CLEAR Outcomes — is an event-driven, global, randomized, double-blind, placebo-controlled study expected tc enroll approximately 12,600 patients with hypercholesterolemia and high CVD risk at over 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, and the expected upcoming milestones described in this press release. 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 notwithstanding the completion of Esperion’s Phase 3 clinical development program for LDL-C lowering, the FDA or EMA may require additional development in connection with seeking regulatory approval, 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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