Esperion Announces Pooled Analyses from Phase 3 LDL-C Lowering Development Program of Bempedoic Acid to be Presented at the American Heart Association 2019 Scientific Sessions

November 4, 2019

ANN ARBOR, Mich., Nov. 04, 2019 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today announced that pooled analyses from four Phase 3 clinical trials of bempedoic acid will be presented at the American Heart Association (AHA) Scientific Sessions in Philadelphia on Sunday, November 17, 2019. Bempedoic acid is being developed as a cost-effective, convenient, once-daily, oral therapy for the treatment of patients with elevated low-density lipoprotein cholesterol (LDL-C) added onto maximally tolerated statin therapy. Bempedoic acid and the bempedoic acid 180 mg + ezetimibe 10 mg fixed dose combination (FDC) tablet's new drug applications (NDAs) are currently under regulatory review by the U.S. Food and Drug Administration (FDA), and the marketing authorisation applications (MAAs) are currently under centralized review by the European Medicines Agency (EMA).

Esperion completed its global, pivotal, Phase 3 clinical development program and announced positive cumulative results in October 2018. The program evaluated the safety, tolerability and LDL-C-lowering efficacy of bempedoic acid and the bempedoic acid / ezetimibe combination tablets in patients with hypercholesterolemia who either have atherosclerotic cardiovascular disease (ASCVD) or are at high risk of ASCVD, and 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 included over 4,000 patients across five studies, four for bempedoic acid.

Details on the oral presentation are as follows:

- **Title:** Bempedoic Acid and Glycemic Control: A Pooled Analysis of 4 Phase 3 Clinical Trials
- **Author:** Lawrence A Leiter, MD, FRCPC, FACP, FACE, FAHA
- **Date and Time**: November 17, 2019 at 11:00 a.m. ET
- **Location:** Science and Technology Hall A, Booth 605, Level 2, Pennsylvania Convention Center, Philadelphia, PA

Details on the poster presentation are as follows:

- **Title:** Efficacy of Bempedoic Acid: A Pooled Analysis of 4 Pivotal Phase 3 Clinical Trials
- **Author:** Maciej Banach, MD, PhD, FAHA, FESC, FNLA, FASA, FRSPH
- **Date and Time**: November 17, 2019 at 3:00 p.m. ET
- **Location:** Zone 3, Science and Technology Hall, Pennsylvania Convention Center, Philadelphia, PA

Bempedoic Acid

Bempedoic acid is our lead, non-statin, oral, once-daily, low-density lipoprotein cholesterol (LDL-C) lowering therapeutic candidate, currently under regulatory review by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). With a targeted mechanism of action, bempedoic acid is a first-in-class, ATP Citrate Lyase (ACL) inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptor. Bempedoic acid has been observed to reduce hsCRP, a key marker of inflammation associated with cardiovascular disease. Completed Phase 3 studies conducted in more than 4,000 patients, with over 2,600 patients treated with bempedoic acid, demonstrated up to 18 percent placebo corrected LDL-C lowering when used with moderate- and high-intensity statins and 21 to 28 percent placebo corrected LDL-C lowering when used with low dose or no background statin.

Bempedoic Acid / Ezetimibe Fixed Dose Combination Tablet

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe fixed dose combination tablet is a non-statin, orally available, once-daily, LDL-C lowering therapeutic candidate, currently under review by the FDA and EMA. Inhibition of ATP Citrate Lyase (ACL) by bempedoic acid lowers LDL-C by reducing cholesterol biosynthesis and 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. Phase 3 data demonstrated that this combination resulted in a 29 percent placebo corrected LDL-C lowering when used with maximally tolerated statins, a 44 percent LDL-C lowering when used with no background statin (post-hoc analysis), and a 34 percent reduction in high sensitivity C-reactive protein (hsCRP).

CLEAR Cardiovascular Outcomes Trial

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. Esperion 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 averse." The CVOT — known as CLEAR Cardiovascular Outcomes Trial — is an event-driven, global, randomized, double-blind, placebo-controlled study that completed enrollment in August 2019 of 14,032 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

Esperion Therapeutics' Commitment to Patients with Hyperlipidemia

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., 96 million people, or more than 37 percent of the adult population, have elevated LDL-C. There are approximately 18 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 averse — leaving them at high risk for

cardiovascular events[1]. In the United States, more than 50 percent of ASCVD patients who are not able to reach their LDL-C goals with statins alone need less than a 40 percent reduction to reach their LDL-C threshold[2].

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.

Esperion Therapeutics

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. 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 bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, the therapeutic potential of, and the clinical development plan for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of the NDAs and the MAAs, and Esperion's expectations for the market for therapies to lower LDL-C, including the market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, 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 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.

References

[1] Esperion market research on file: research project interviewing 350 physicians. Esperion Therapeutics, Inc. Sept-Oct 2018.

[2] Data on file: analysis of NHANES database. Esperion Therapeutics, Inc. 2018.

Investor Contact:
Alex Schwartz
Esperion
734-249-3386
aschwartz@esperion.com

Media Contact:
Elliot Fox
W2Opure
212-257-6724
efox@purecommunications.com