Esperion Announces Submissions of Two NDAs and Official Completion of Two MAA Validations for Both Bempedoic Acid and the Bempedoic Acid / Ezetimibe Combination Tablet

February 28, 2019

ANN ARBOR, Mich., Feb. 28, 2019 (GLOBE NEWSWIRE) -- Esperion (Nasdaq: ESPR) today announced that the company has successfully completed important and key global marketing applications including the submission of two New Drug Applications (NDAs) for bempedoic acid and the bempedoic acid / ezetimibe combination tablet to the U.S. Food and Drug Administration (FDA). Bempedoic acid and the bempedoic acid / ezetimibe combination tablet are being developed as complementary, cost-effective, convenient, once-daily, oral therapies for the treatment of patients with elevated low-density lipoprotein cholesterol (LDL-C) who need additional LDL-C lowering despite the use of currently accessible therapies. Based on Esperion's bempedoic acid submission date of February 20, 2019 as well as the bempedoic acid / ezetimibe combination tablet submission date of February 26, 2019, the Company expects to receive notification from FDA on whether the submissions were filed for review in May 2019.

Esperion also announced that the European Medicines Agency (EMA) has completed formal validation of Esperion's two Marketing Authorization Applications (MAAs) and officially started the review procedure for both bempedoic acid and the bempedoic acid / ezetimibe combination tablet. The MAAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet were submitted to the EMA on February 11, 2019. The MAAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet are being reviewed via the centralised procedure with an opinion of the Committee for Medicinal Products for Human Use (CHMP) expected by Day 210 (plus the standard clock-stops for response to the List of Questions). After the adoption of a CHMP opinion, a final decision regarding the MAA is carried out by the European Commission.

"The NDA submissions and completion of the MAA validations for both bempedoic acid and the bempedoic acid / ezetimibe combination tablet are truly inspirational accomplishments for our team of Lipid Management Experts and we would like to thank the patients, families and healthcare providers who participated in our clinical studies, as well as our colleagues, investigators and clinical trial sites for their help in the development of these innovative medicines," said Tim M. Mayleben, President and Chief Executive Officer of Esperion. "We look forward to working closely with regulatory authorities as we continue to advance our once-daily, oral bempedoic acid-based therapies to help the millions of patients who are inadequately treated with, or unable to gain access to, current LDL-C lowering therapies."

Esperion's Global Pivotal Phase 3 LDL-C Lowering Program to Support FDA and EMA Submissions

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 consistent, complementary LDL-C-lowering efficacy of bempedoic acid and the bempedoic acid / ezetimibe combination tablet 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 included five studies of approximately 4,000 patients, four for bempedoic acid and one for the bempedoic acid / ezetimibe combination tablet.

- Two pivotal studies evaluated bempedoic acid (Studies 1 and 2) 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 evaluated bempedoic acid (Studies 3 and 4) 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 evaluated the bempedoic acid / ezetimibe combination tablet (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.

Bempedoic acid and the bempedoic acid / ezetimibe combination tablet new drug applications have been submitted to the United States Food and Drug Administration, as well as are under regulatory review for marketing authorization by the European Medicines Agency.

Bempedoic Acid / Ezetimibe 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 combination tablet is our lead, non-statin, orally available, once-daily, LDL-C lowering therapy. Inhibition of ATP Citrate Lyase 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 up-regulates 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 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 to 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., 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 intolerant — leaving them at high risk for cardiovascular events. 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.

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 complementary, cost-effective, convenient, 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 tablet, 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 Statement: Esperion

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 tablet and bempedoic acid and the therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination tablet and bempedoic acid, including Esperion's timing, designs, plans and announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, 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 tablet, 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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