Esperion Announces Positive CHMP Opinion for the Marketing Authorisation Application for the Bempedoic Acid / Ezetimibe Fixed Dose Combination Tablet for the Treatment of Hypercholesterolemia and Mixed Dyslipidemia

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– Bempedoic Acid / Ezetimibe Fixed Dose Combination Tablet is an Oral, Once-Daily, Non-Statin Medicine that Lowers Bad Cholesterol with a First-in-Class Mechanism –

– Positive CHMP Opinion is Based on the Completed Pivotal Phase 3 Fixed Dose Combination Tablet LDL-Cholesterol Lowering Program –

– European Commission Decision on the Marketing Authorisation Application (MAA) Expected in April 2020; Daiichi Sankyo Europe to Lead EU Commercialization –

ANN ARBOR, Mich., Jan. 31, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for the MAA for the bempedoic acid / ezetimibe fixed dose combination tablet, recommending approval for the treatment of hypercholesterolemia and mixed dyslipidemia. The positive CHMP opinion was achieved with no Oral Explanation as the Rapporteurs found there were no substantive issues that needed to be discussed with the CHMP at the time of the vote.

The benefits with the bempedoic acid / ezetimibe fixed dose combination tablet are its ability to reduce levels of LDL-C, but also non-high density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B), and total cholesterol (TC) in patients with hypercholesterolaemia or mixed dyslipidaemia when administered alone and in combination with other lipid-modifying medicinal products. The most common side effects are hyperuricaemia and constipation.

The CHMP recommended granting the bempedoic acid / ezetimibe fixed dose combination tablet marketing authorisation for the treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe,
- alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone, or
- in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.

The CHMP is a scientific committee of the EMA that reviews medical product applications on their scientific and clinical merit. The European Commission will review the CHMP opinion and is expected to adopt a final decision in April 2020. The decision will be applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein.

The positive CHMP opinion for the bempedoic acid / ezetimibe fixed dose combination tablet is supported by the Phase 3 Fixed Dose Combination Tablet LDL-Cholesterol Lowering program. The bempedoic acid / ezetimibe fixed dose combination tablet positive opinion is based on data from the pivotal Phase 3 053 Study conducted in more than 300 patients, as well as safety data from the bempedoic acid global pivotal Phase 3 LDL-C Lowering program together with the established ezetimibe safety profile. The bempedoic acid / ezetimibe fixed dose combination tablet significantly reduced LDL-C 38 percent from baseline to week 12 compared with placebo. Results from the pivotal Phase 3 053 Study have been published in *The European Journal of Preventative Cardiology*.

Daiichi Sankyo Europe has licensed exclusive commercialization rights to bempedoic acid and the bempedoic acid /ezetimibe fixed dose combination tablets in the European Economic Area and Switzerland from Esperion. Daiichi Sankyo's European cardiovascular commercial capabilities include more than 1,000 professionals dedicated to the commercialization of cardiovascular medicines and includes synergies with an existing portfolio of novel oral anticoagulant and antiplatelet products. Upon approval, Daiichi Sankyo Europe intends to make bempedoic acid and the bempedoic acid / ezetimibe fixed dose combination tablets available to physicians and their patients in these geographies that need treatment for hypercholesterolemia and mixed dyslipidemia.

Bempedoic acid and the bempedoic acid / ezetimibe fixed dose combination tablets are being developed globally as affordable, convenient, oral, once-daily, non-statin medicines for the treatment of patients with elevated LDL-cholesterol (LDL-C) who are not at goal. Bempedoic acid and the bempedoic acid 180 mg + ezetimibe 10 mg fixed dose combination tablets new drug applications (NDAs) are also under regulatory review by the U.S. Food and Drug Administration (FDA) with PDUFA dates of February 21st and 26th 2020.

Bempedoic Acid

Bempedoic acid is our lead, non-statin, oral, once-daily, non-statin, LDL-C lowering therapeutic candidate, currently under regulatory review by the FDA and 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 high sensitivity C-reactive protein (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. Phase 3 results also show bempedoic acid reduced hsCRP 19 to 31 percent. Pooled phase 3 data highlighted that bempedoic acid reduced hemoglobin A1c (HbA1c) by 0.19% versus placebo in patients with diabetes (n=1,134) at 12 weeks.

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 an oral, once-daily, non-statin, 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 significantly reduced LDL-C 38 percent from baseline compared with placebo, as well as a 34 percent reduction in high sensitivity C-reactive protein.

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 Hypercholesterolemia and Mixed Dyslipidemia

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 oral, once-daily, non-statin, medicines 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.

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