# Esperion Announces European Commission Approval of the NUSTENDI™ (bempedoic acid and ezetimibe) Tablet for the Treatment of Hypercholesterolemia and Mixed Dyslipidemia

April 6, 2020

*– First Non-Statin, LDL-C Lowering Combination Medicine Ever Approved in Europe –*

*– NUSTENDI Is Approved for Patients Who Require Additional LDL-Cholesterol Lowering on a Background Statin, Other Lipid-Lowering Therapies, or Considered Statin Intolerant –*

*– Daiichi Sankyo Europe to Lead EU Commercialization, Cardiovascular Sales Organization Exceeds 1,000 Professionals –*

*– Esperion to Receive $150 Million Milestone Payment Upon First Commercial Sale –*

ANN ARBOR, Mich., April 06, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) announced today the European Commission approved the NUSTENDI™ (bempedoic acid and ezetimibe) tablet, an oral, once-daily, non-statin LDL-cholesterol (LDL-C) lowering medicine for hypercholesterolemia and dyslipidemia in Europe. NUSTENDI contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine.

The European Commission approved NUSTENDI for use in 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.

“For the first time, a non-statin once-a-day pill with significant efficacy will be available across Europe to fight bad cholesterol,” said Tim M. Mayleben, president and chief executive officer of Esperion. “This is a major advancement for the millions of patients needing an additional option to use with their statin and know it’s important for them to achieve recommended LDL-C goals or for those that may be statin intolerant.”

The European Society of Cardiology and European Atherosclerosis Society recommend intensively lowering LDL-C to reduce cardiovascular risk. Even today, up to 80% of patients do not reach recommended LDL-C goals despite receiving treatments such as statins[1], and are at increased risk of a heart attack or stroke. NUSTENDI provides patients and their physicians an important new oral, once-daily non-statin option.

“There is a compelling need for a once-daily pill with the kind of efficacy NUSTENDI (bempedoic acid plus ezetimibe combination) can provide for millions of patients, including those that are statin intolerant,” said Professor Kausik K. Ray, MBChB, MD, MPhil, FRCP, Professor of Public Health at the School of Public Health, Imperial College London and a Consultant Cardiologist and member of the Phase 3 steering committee for Esperion. “This daily medicine will be beneficial for those that need additional lowering of bad cholesterol on top of statins but will also provide a convenient alternative for a significant number of people who cannot tolerate statins. These patients now have an efficacious oral option to lower their bad cholesterol. A single combination pill aides adherence, a critical factor to maintain long-term reductions in bad cholesterol.”

The approval of NUSTENDI is supported by the Phase 3 Fixed Combination Tablet LDL-C Lowering program, as well as safety data from the NILEMDO™ (bempedoic acid) tablet global pivotal Phase 3 LDL-C lowering program and the existing ezetimibe safety profile. NUSTENDI lowered LDL-C by a mean of 38 percent compared to placebo when added on to maximally tolerated statins. Results have been published in *The European Journal of Preventive Cardiology*.

The benefit with NUSTENDI is its ability to reduce levels of LDL-C in patients with hypercholesterolaemia or mixed dyslipidaemia when administered alone and in combination with other lipid-modifying medicinal products. NUSTENDI also reduced non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B) and total cholesterol (TC). Notably, the pharmacology section of the NUSTENDI label highlights that among the subset of patients with diabetes (n=1,134), lower levels of hemoglobin A1c (HbA1c) were observed as compared to placebo (on average 0.2%).

NUSTENDI was generally well-tolerated in clinical studies. The most commonly reported adverse reactions with NUSTENDI were hyperuricaemia and constipation. The majority of adverse reactions reported with NUSTENDI were mild to moderate in severity and balanced in occurrence with adverse events in patients receiving placebo. In pooled placebo-controlled clinical trials with bempedoic acid, a component of NUSTENDI, more patients on bempedoic acid compared to placebo discontinued treatment due to muscle spasms, diarrhea, pain in extremity and nausea, although differences between bempedoic acid and placebo were not significant.

Daiichi Sankyo Europe has licensed exclusive commercialization rights to NILEMDO and NUSTENDI 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. Under terms of the agreement, Esperion has already received a $150 million upfront payment, will receive $150 million milestone upon first commercial sale in the territory, up to $900 million in total milestones as well as tiered royalties between 15% – 25%.

**CLEAR Cardiovascular Outcomes Trial**

The effect of bempedoic acid on cardiovascular morbidity and mortality has not 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 are 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 over 14,000 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

**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 medicines 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 **www.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 the clinical development and commercialization plans 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 expanded indications for their effect on cardiovascular events, and Esperion's expectations for the market for medicines to lower LDL-C, including the commercial launch and market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet in the European Union. 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 clinical development and commercialization plans, or approval of expanded indications, that existing cash resources may be used more quickly than anticipated, the impact of COVID-19 on our business, clinical activities and commercial development plans, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and 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) Fox KM, et al. Treatment patterns and low-density lipoprotein cholesterol (LDL-C) goal attainment among patients receiving high- or moderate-intensity statins. Clin Res Cardiol. 2018; 107: 380–388.

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