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

April 6, 2020

– First Oral, Once-Daily, Non-Statin LDL-Cholesterol Lowering Medicine Approved in Europe in Almost Two Decades for Indicated Patients –

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

– Pharmacology Section Highlights NILEMDO Reduced HbA1c on Average of 0.2% Versus Placebo in Patients with Diabetes –

– 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 NILEMDO™ (bempedoic acid) tablet, an oral, once-daily, non-statin LDL-cholesterol (LDL-C) lowering medicine. NILEMDO is a first-in-class ATP Citrate Lyase (ACL) inhibitor that lowers LDL-C by inhibition of cholesterol synthesis in the liver.

The European Commission approved NILEMDO 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 or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

“Millions of patients across the European Economic Area have needed a new daily, non-statin pill to help them achieve their LDL-C goals,” said Tim M. Mayleben, president and chief executive officer of Esperion. “For those who require additional non-statin lowering of their bad cholesterol, NILEMDO will fit easily into their daily routines whether that is with their statin or without because they are statin intolerant. Esperion is committed to finding new ways to affordably manage lipids and won’t stop until everyone can achieve their goals.”

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. NILEMDO provides patients and their physicians an important new oral, once-daily non-statin option.

“NILEMDO finally provides a preferred daily pill that easily fits into the routines of those struggling with high levels of bad cholesterol, which includes patients 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. “NILEMDO is a first-in-class medicine and an oral alternative that we have not had in nearly two decades.”

The approval of NILEMDO is supported by a global pivotal Phase 3 LDL-C lowering program conducted in more than 3,600 patients. NILEMDO provides additional LDL-C lowering of up to 28 percent compared to placebo when added onto other lipid-lowering therapies. Results from the Phase 3 development program have been published in *The New England Journal of Medicine*, *The Journal of the American Medical Association*, *The Journal of the American Heart Association* and *Atherosclerosis*.

The benefit with NILEMDO 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. NILEMDO also reduced non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B) and total cholesterol (TC). Notably, the pharmacology section of the NILEMDO 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%).

NILEMDO was generally well-tolerated in clinical studies. The most commonly reported adverse reactions with NILEMDO during pivotal trials were hyperuricaemia, pain in extremity and anaemia. The majority of adverse reactions reported with NILEMDO were mild to moderate in severity and balanced in occurrence with adverse events in patients receiving placebo. More patients on NILEMDO compared to placebo discontinued treatment due to muscle spasms, diarrhea, pain in extremity and nausea, although differences between NILEMDO and placebo were not significant.

Daiichi Sankyo Europe has licensed exclusive commercialization rights to NILEMDO and NUSTENDI™ (bempedoic acid and ezetimibe) tablet 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 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.

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

Media Contact:
Ben Church
Esperion
734-864-6774
bchurch@esperion.com