Esperion Announces Bempedoic Acid (NEXLETOL®) Recommended as Oral Non-Statin Therapy for LDL-Cholesterol Lowering in American College of Cardiology Expert Consensus Decision Pathway

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ANN ARBOR, Mich., Aug. 26, 2022 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that bempedoic acid (NEXLETOL®) is now recommended as an important oral non-statin therapy for LDL-cholesterol (LDL-C) lowering in the management of atherosclerotic cardiovascular disease (ASCVD) by the American College of Cardiology (ACC) task force on expert consensus decision pathways (ECDP). The recommendation, an update to the 2017 ECDP, was released on August 25, 2022 and published online in the *Journal of the American College of Cardiology.*

"The recommendation of bempedoic acid for LDL-C lowering in individuals at high-risk for ASCVD reflects an important management strategy for providers and the millions of patients who cannot reach their LDL-C goals with a statin alone," said JoAnne Foody, MD, FACC, FAHA, Chief Medical Officer of Esperion. "LDL-C is causative in development of atherosclerotic CV disease and residual CV risk remains high if LDL-C remains elevated despite statins. While studies show reducing LDL-C levels with lipid-lowering agents lowers incidence of ASCVD events, most patients still do not reach their LDL-C goal. There is urgent need for the use of non-statin lipid-lowering therapies in appropriate patients to reduce LDL-C. The ACC ECDP recommendation underscores the importance of LDL-C lowering via multiple therapeutic options including oral therapies like bempedoic acid and ezetimibe and provides important guidance for the management of patients not served by current statin therapies."

"These guidelines will be helpful for providers and payers to understand the value of non-statin therapies in helping patients achieve LDL-C goals," said BJ Swartz, Chief Strategy Officer of Esperion. "They provide clear guidance on how new and existing non-statin adjunctive therapies will contribute to LDL-C goal attainment and have the potential to reduce cardiovascular risk in their patient populations."

The 2022 ACC Expert Consensus statement seeks to address current gaps in care for LDL-C lowering to reduce ASCVD risk and provides recommendations for clinicians and patients regarding the use of non-statin therapies in high-risk patients who have a minimal response to statins or are statin intolerant. The recommendation of bempedoic acid, the first oral, once-daily, non-statin LDL-C lowering medicine approved since 2002, is based on robust Phase III clinical trial evidence including evidence from the CLEAR Tranquility (Evaluation of the Efficacy and Safety of Bempedoic Acid [ETC-1002] as Add-on to Ezetimibe Therapy in Patients With Elevated LDL-C) and CLEAR Serenity (Evaluation of the Efficacy and Safety of Bempedoic Acid in Patients With Hyperlipidemia and Statin Intolerant) trials, which demonstrated that monotherapy with bempedoic acid 180 mg daily in patients with statin-associated muscle symptoms on no statin therapy reduced LDL-C levels by approximately 24.5% compared with placebo.

In addition to the ACC ECDP, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) recommend bempedoic acid for treating LDL-C to goal in their Dyslipidemia and Prevention of Cardiovascular Disease Algorithm. The potential ability of bempedoic acid to reduce cardiovascular risk in patients with statin-intolerance is currently being evaluated in a global cardiovascular outcomes trial (CVOT), known as CLEAR Outcomes. The Company anticipates top-line results from the trial in the first quarter of 2023.

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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. 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 1,200 sites in 32 countries.

INDICATION
NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. *Limitations of Use:* The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Hyperuricemia: NEXLETOL may increase blood uric acid levels. Hyperuricemia may occur early in treatment and persist throughout treatment, and may lead to the development of gout, especially in patients with a history of gout. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.
Tendon Rupture: NEXLETOL is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with NEXLETOL versus 0% of patients treated with placebo, and involved the rotator cuff (the shoulder), biceps tendon, or Achilles tendon. Tendon rupture occurred within weeks to months of starting NEXLETOL. Tendon rupture may occur more frequently in patients over 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with renal failure, and patients with previous tendon disorders. Discontinue NEXLETOL at the first sign of tendon rupture. Avoid NEXLETOL in patients who have a history of tendon disorders or tendon rupture.

Adverse Reactions: In clinical trials, the most commonly reported adverse reactions were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Reactions reported less frequently, but still more often than with placebo, included benign prostatic hyperplasia and atrial fibrillation.

Drug Interactions: Simvastatin and Pravastatin: Concomitant use results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.

Lactation and Pregnancy: It is not recommended that NEXLETOL be taken during breastfeeding. Discontinue NEXLETOL when pregnancy is recognized, unless the benefits of therapy outweigh the potential risks to the fetus. Based on the mechanism of action, NEXLETOL may cause fetal harm.

Please see full Prescribing Information here.

Esperion Therapeutics
Esperion works hard to make our medicines easy to get, easy to take and easy to have. We discover, develop, and commercialize innovative medicines and combinations to lower cholesterol, especially for patients whose needs are not being met by the status quo. Our entrepreneurial team of industry leaders is inclusive, passionate and resourceful. We are singularly focused on managing cholesterol so you can improve your health easily. Esperion commercializes NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) Tablets and is the leader in the development of convenient oral, once-daily non-statin LDL-cholesterol lowering drugs for patients with high levels of bad cholesterol. 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 marketing strategy and commercialization plans, current and planned operational expenses, future operations, commercial products, clinical development, including the timing, designs and plans for the CLEAR Outcomes study and its results, plans for potential future product candidates, financial condition and outlook, including expected cash runway, and other statements containing the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “suggest,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions. 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, the impact of the ongoing COVID-19 pandemic on our business, revenues, results of operations and financial condition, the net sales, profitability, and growth of Esperion’s commercial products, clinical activities and results, supply chain, commercial development and launch 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.

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