Esperion Supports Collaborative Study with an Integrated and Learning Health Care Delivery System in Northern California to Study the Effects of NEXLIZET® (bempedoic acid and ezetimibe) in Reducing LDL-Cholesterol Following a Recent Acute Coronary Syndrome

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– The CLEAR ACS trial is designed to evaluate the efficacy of NEXLIZET on short-term LDL-C lowering following those with a recent ACS event and at very high risk of recurrent CV event in a diverse patient population that is often underrepresented in clinical trials –

ANN ARBOR, Mich., April 25, 2022 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced support for a study to evaluate the effects of bempedoic acid and ezetimibe (NEXLIZET) on short-term LDL-cholesterol lowering in patients following a recent acute coronary syndrome (ACS) event. The "Cholesterol Lowering via Bempedoic Acid/Ezetimibe, an ACL-Inhibiting Regimen after Acute Coronary Syndrome Study" will be known as CLEAR ACS.

CLEAR ACS is a prospective, Electronic Health Record (EHR)-based, randomized, double-blind, placebo-controlled, parallel-group, pragmatic clinical trial being conducted at an integrated and learning health care delivery system in northern California. The primary objective of the CLEAR ACS study is to determine the efficacy, safety, and tolerability of NEXLIZET in a real-world cohort enriched with older adults, women, and ethnic/racial minority populations, in patients with a recent ACS event.

The trial will enroll 500 patients with a recent ACS event. After receiving blinded study drug or placebo for 12 weeks, all enrolled participants will be switched to open-label NEXLIZET for a 12-week extension phase for a total study duration of 24 weeks. The primary efficacy endpoint is the percent (%) change from baseline to week 12 in low density lipoprotein cholesterol (LDL-C). Secondary endpoints will include changes to lipids and other biomarkers as well as exploratory evaluation of impact on cardiovascular outcomes.

"The CLEAR ACS trial will potentially generate critical data of safety and efficacy of the bempedoic acid and ezetimibe combination therapy in lowering LDL-C in a very high risk, diverse patient population that is often underrepresented in clinical trials," said JoAnne Foody, MD, FACC, FAHA, chief medical officer of Esperion. "Most importantly, this study will address significant knowledge gaps in current research into the effects of NEXLIZET on several key underserved patient groups."

"Esperion is pleased to collaborate with this leading, well-respected system on the CLEAR ACS trial, which will provide vital information on the effects of NEXLIZET in a broader and more diverse high risk patient population," said Sheldon Koenig, president and CEO of Esperion. "We are eager to support efforts to expand the body of research on NEXLIZET in this underrepresented patient group."

For additional details about the study, please visit clincialtrials.gov.

INDICATION
NEXLIZET 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 NEXLIZET on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION
Contraindications: NEXLIZET is contraindicated in patients with a known hypersensitivity to ezetimibe tablets. Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported with ezetimibe, a component of NEXLIZET.

Warnings and Precautions: *Hyperuricemia:* Bempedoic acid, a component of NEXLIZET, 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: Bempedoic acid, a component of NEXLIZET, is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with bempedoic acid 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 bempedoic acid. 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 NEXLIZET at the first sign of tendon rupture. Avoid NEXLIZET in patients who have a history of tendon disorders or tendon rupture.

Adverse Reactions: Most common (incidence ≥2% and greater than placebo) adverse reactions are upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes, diarrhea, arthralgia, sinusitis, fatigue, and influenza.

Drug Interactions: *Simvastatin and Pravastatin:* Concomitant use with bempedoic acid results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use of NEXLIZET with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.
Cyclosporine: Caution should be exercised when using NEXLIZET and cyclosporine concomitantly due to increased exposure to both ezetimibe and cyclosporine. Monitor cyclosporine concentrations in patients receiving NEXLIZET and cyclosporine. In patients treated with cyclosporine, the potential effects of the increased exposure to ezetimibe from concomitant use should be carefully weighed against the benefits of alterations in lipid levels provided by NEXLIZET.

Fibrates: Coadministration of NEXLIZET with fibrates other than fenofibrate is not recommended. Fenofibrate and ezetimibe may increase cholesterol excretion into the bile, leading to cholelithiasis. If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, gallbladder studies are indicated and alternative lipid-lowering therapy should be considered.
Cholestyramine: Concomitant use of NEXLIZET and cholestyramine decreases ezetimibe concentration. This may result in a reduction of efficacy. Administer NEXLIZET either at least 2 hours before, or at least 4 hours after, bile acid sequestrants.

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

Please see the full prescribing information for NEXLIZET® (bempedoic acid and ezetimibe) tablet.

Patients or their physicians are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 or report side effects to Esperion at 833-377-7633 (833 ESPRMED).

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 aren't 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, restructuring and 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, 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.

Contact:
Corporate Communications
corporateteam@esperion.com