CLEAR Outcomes Accepted as Late-Breaking Clinical Trial at ACC.23 Annual Scientific Session & Expo together with the World Congress of Cardiology (ACC.23/WCC)

December 19, 2022

– Positive CLEAR Outcomes data to be presented as a Late-Breaking Clinical Trial (LBCT) at ACC.23/WCC on March 4, 2023 –

– Bempedoic acid becomes the first ATP citrate lyase inhibitor and first oral non-statin to meet the major adverse cardiovascular events (*MACE-4) primary endpoint –*

ANN ARBOR, Mich., Dec. 19, 2022 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that the landmark Cholesterol Lowering via Bempedoic acid, an ACL-Inhibiting Regimen (CLEAR) Outcomes trial, which met its primary endpoint, has been accepted as a late-breaking clinical trial at ACC.23/WCC based on the impact and novelty of the research; rigor of the design/methods; major clinical endpoints; and the quality of the statistical plan.

CLEAR Outcomes kicks off the Late-Breaking Clinical Trial sessions in the Great Hall in New Orleans and will stream live on the ACC.23/WCC virtual platform, commencing at 9:30 AM Central Time on March 4, 2023. Esperion is eager to share CLEAR Outcomes data in greater detail with the overall scientific community and regulatory authorities.

“On behalf of the entire Esperion team, we are pleased to present the practice-changing results from our innovative and unprecedented outcomes trial to the medical and scientific community at ACC,” said Sheldon Koenig, Esperion’s president and chief executive officer. “Patients who are unable to tolerate or reach their goals with statins have increased risk for adverse cardiovascular outcomes. With these positive outcomes data, bempedoic acid, the active ingredient in NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe), becomes the first oral non-statin to meet the MACE-4 primary endpoint and one of the few oral options to not only reduce LDL-C but also cardiovascular risk. Considered against the backdrop of multiple recent unsuccessful cardiovascular outcomes studies, these results indicate that bempedoic acid provides broad cardiovascular risk reduction on top of significant LDL-C control for patients. Since releasing the positive topline results, we have fielded enthusiastic inquiries from health care providers and scientific leaders which we believe predicts strong prospects for brand growth,” he concluded.

CLEAR Outcomes is a Phase 3, event-driven, randomized, multicenter, double-blind, placebo-controlled trial designed to evaluate whether treatment with bempedoic acid reduces the risk of cardiovascular events in patients with or who are at high risk for cardiovascular disease, unable to maximize or tolerate a statin (inability to tolerate two or more statins, one at a low dose) and elevated LDL-cholesterol levels (fasting blood LDL-C ≥ 100 (2.6 mmol/L)). The study included over 14,000 patients at over 1,200 sites in 32 countries.

INDICATION
NEXLETOL and NEXLIZET are indicated as adjuncts 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 and NEXLIZET on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION
Contraindications: NEXLETOL has no 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.

Warnings and Precautions: Hyperuricemia: Bempedoic acid, a component of NEXLETOL and 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 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 NEXLETOL or NEXLIZET at the first sign of tendon rupture. Avoid NEXLETOL and NEXLIZET in patients who have a history of tendon disorders or tendon rupture**.**

***Adverse Reactions*:** In NEXLETOL 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.
In the NEXLIZET clinical trial, the most commonly reported adverse reactions observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, a component of NEXLIZET, and occurring more frequently than with placebo, were urinary tract infection, nasopharyngitis, and constipation.
Adverse reactions reported in clinical trials of ezetimibe, and occurring at an incidence greater than with placebo, included upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, fatigue, and influenza. Other adverse reactions reported in postmarketing use of ezetimibe included hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria; erythema multiforme; myalgia; elevated creatine phosphokinase; myopathy/rhabdomyolysis; elevations in liver transaminases; hepatitis; abdominal pain; thrombocytopenia; pancreatitis; nausea; dizziness; paresthesia; depression; headache; cholelithiasis; cholecystitis.

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 either NEXLETOL or 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 NEXLETOL or NEXLIZET be taken during breastfeeding. Discontinue NEXLETOL or NEXLIZET when pregnancy is recognized, unless the benefits of therapy outweigh the potential risks to the fetus. Based on the mechanism of action of bempedoic acid, NEXLETOL and NEXLIZET 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 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. For more information, please visit 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 future operations, commercial products and expected growth, clinical development, 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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