Esperion Presents CLEAR Outcomes Analysis of Inflammation as Predictor of Cardiovascular Risk at American Heart Association Scientific Sessions 2023

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– A Prespecified, Exploratory Analysis of Participants Reports Those with Higher Baseline Inflammation More Likely to Experience a Major Cardiovascular Event (MACE), Cardiovascular Death, and All-Cause Mortality Compared to Those with the Lowest Inflammation –

– 21.6% Reduction in Vascular Inflammatory Marker High Sensitivity C-reactive Protein (hsCRP) in Patients Taking Bempedoic Acid –

– Results Simultaneously Published in Circulation –

ANN ARBOR, Mich., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced the presentation of results from a pre-specified, exploratory analysis of CLEAR Outcomes at the 2023 American Heart Association (AHA) Scientific Sessions. Results were also simultaneously published in *Circulation* which can be accessed here.

"The analysis presented at AHA and published in *Circulation* highlights yet another important benefit of bempedoic acid (contained in NEXLETOL® and NEXLIZET®): its potential to reduce vascular inflammation in patients, including in those who are intolerant of statins," said JoAnne Foody, MD, FACC, FAHA, Chief Medical Officer of Esperion. "Inflammation is an important contributing factor to cardiovascular risk. CLEAR Outcomes demonstrates that bempedoic acid not only reduces LDL-C levels but also reduces an established marker of inflammation, which is a key differentiator compared to other LDL-lowering therapies such as ezetimibe monotherapy and PCSK9 inhibitors."

"We know in 2023 that 'lower is better' is true both for cholesterol and for inflammation," said Paul Ridker, MD, MPH, of the Brigham and Women's Hospital and the Harvard Medical School and a pioneer in the role of inflammation inhibition as a method going beyond cholesterol to improve patient outcomes. "In the future, it can be anticipated that virtually all atherosclerosis patients will receive aggressive inflammation inhibition along with aggressive cholesterol reduction," Ridker added.

Dr. Ridker presented a pre-specified analysis in an oral presentation titled, "Inflammation and Cholesterol as Predictors of Cardiovascular Events and Risk Reduction with Bempedoic Acid Among Statin Intolerant Patients: An Analysis of the CLEAR Outcomes Trial." The analysis focused on vascular inflammation, as measured by the inflammatory marker hsCRP as a major determinant of atherosclerotic risk regardless of background statin use. In the exploratory analysis, participants with baseline hsCRP in the top 25% of all participants were 43% more likely to experience MACE, twice as likely to experience cardiovascular death, and 121% more likely to experience all-cause mortality compared to those in the lowest 25%. In CLEAR Outcomes, patients who were randomized to bempedoic acid experienced a 21.6% reduction in hsCRP compared to placebo at 6 months.

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

IMPORTANT SAFETY INFORMATION
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.
Hyperuricemia: Bempedoic acid, a component of NEXLIZET and NEXLETOL, may increase blood uric acid levels which may lead to gout. 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 and NEXLETOL, is associated with an increased risk of tendon rupture or injury. Tendon rupture occurred within weeks to months of starting NEXLIZET or 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 NEXLIZET or NEXLETOL at the first sign of tendon rupture. Avoid NEXLIZET or NEXLETOL in patients who have a history of tendon disorders or tendon rupture.

The most common adverse reactions In clinical trials of bempedoic acid (a component of NEXLIZET and NEXLETOL) in ≥2% of patients and greater than placebo, were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.

Adverse reactions reported in ≥2% of patients treated with ezetimibe (a component of NEXLIZET) and at an incidence greater than placebo in clinical trials were upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity fatigue, and influenza.

In clinical trials of NEXLIZET, the most commonly reported adverse reactions (incidence ≥3% and greater than placebo) observed that not observed in clinical trials of bempedoic acid or ezetimibe, were urinary tract infection, nasopharyngitis, and constipation.

Discontinue NEXLIZET or NEXLETOL when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. Because of the potential for serious adverse reactions in a breast-fed infant, breastfeeding is not recommended during treatment with NEXLIZET or NEXLETOL. Report pregnancies to the Esperion Therapeutics, Inc. Adverse Event reporting line at 1-833-377-7633.

Esperion Therapeutics
At Esperion, we discover, develop, and commercialize innovative medicines to help improve outcomes for patients with or at risk for cardiovascular

and cardiometabolic diseases. The status quo is not meeting the health needs of millions of people with high cholesterol – that is why our team of passionate industry leaders is breaking through the barriers that prevent patients from reaching their goals. Providers are moving toward reducing LDL-cholesterol levels as low as possible, as soon as possible; we provide the next steps to help get patients there. Because when it comes to high cholesterol, getting to goal is not optional. It is our life's work. For more information, visit esperion.com and esperionscience.com and follow us on X at twitter.com/EsperionInc.

CLEAR Cardiovascular Outcomes Trial

CLEAR Outcomes is part of the CLEAR clinical research program for NEXLETOL® (bempedoic acid) Tablet and NEXLIZET® (bempedoic acid and ezetimibe) Tablet. The CLEAR Program seeks to generate important clinical evidence on the safety and efficacy of bempedoic acid, a first in a class ATP citrate lyase inhibitor contained in NEXLETOL and NEXLIZET and its potential role in addressing additional critical unmet medical needs. More than 60,000 people will have participated in the program by the time of its completion. The CLEAR Program includes 5 label-enabling Phase III studies as well as other key Phase IV studies with the potential to reach more than 70 million people with or at risk for CVD based on elevated LDL-C.

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, the outcomes of legal proceedings, 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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