Esperion Presents Two CLEAR Outcomes Study Late-Breakers at European Society of Cardiology Congress 2023

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– In total cardiovascular event analysis, bempedoic acid shows 20% risk reduction in MACE-4 and 17% risk reduction in MACE-3 –

– In an analysis of patients with diabetes, bempedoic acid shows 17% risk reduction in MACE-4 and 20% risk reduction in MACE-3 –

– No increase in development of new onset diabetes in patients randomized to bempedoic acid compared to placebo –

ANN ARBOR, Mich., Aug. 26, 2023 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced the presentation of results from two oral presentations at the Late-Breaking Science Session entitled, “Clinical trial updates on prevention and lipid lowering” at the European Society of Cardiology (ESC) 2023 Congress, taking place August 25-28, 2023, in Amsterdam, Netherlands.

“We are pleased to share additional results from our landmark CLEAR Outcomes study in late-breaker presentations at ESC 2023,” said Sheldon Koenig, President and CEO of Esperion. “These prespecified analyses further reinforce the cardiovascular risk reduction benefits of bempedoic acid in high-risk patients, not only upon an initial cardiovascular event as described in the *NEJM* publication, but also in those who experience more than one cardiovascular event and in patients with diabetes. Importantly, bempedoic acid use was not associated with an increased rate of new onset diabetes, which is a key differentiating feature compared to statins. We continue to believe bempedoic acid will have an increasingly important place in the treatment paradigm to reduce cardiovascular risk in a broad range of high-risk patients.”

Stephen Nicholls, MBBS, PhD (Victorian Heart Institute, Monash University) presented a prespecified analysis in a late-breaker presentation titled, “Impact of bempedoic acid on total cardiovascular events in high-risk patients: analysis of the CLEAR Outcomes trial.” The results reflect the totality of the benefit of bempedoic acid on CV risk reduction, not just the first event. Treatment with bempedoic acid is associated with a risk reduction of 20% in total MACE-4 events (composite of major adverse cardiovascular events including non-fatal myocardial infarction, non-fatal stroke, coronary revascularization and cardiovascular death), 17% in total MACE-3 events (composite of major adverse cardiovascular events including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death), 31% in total myocardial infarctions, and 22% in total coronary revascularizations.

“High risk patients face the prospect of not just one clinical event in the future, but in many cases, patients experience multiple events in the future. This data reinforces the importance of cholesterol lowering in high risk patients with the potential to prevent multiple events moving forward,” said Dr. Stephen Nicholls.

A second late-breaker presentation, titled “Cardiovascular Benefits and Risk of New Onset Diabetes by Glycaemic Status with Bempedoic Acid: Prespecified Analyses of the CLEAR OUTCOMES trial,” was presented by Kausik K Ray, MD, FMedSci (Imperial College London). Of the 13,970 patients included in CLEAR Outcomes, 45.6% had diabetes, 41.5% were pre-diabetic, and 12.9% had normoglycemia. In this pre-specified analysis, bempedoic acid demonstrated a benefit in patients with diabetes at baseline, showing a 17% reduction in risk of MACE-4 and 20% reduction in risk of MACE-3. In addition, bempedoic acid did not increase rates of new onset diabetes in patients without diabetes, and was generally comparable to placebo (11.1% vs 11.5%, respectively). Finally, bempedoic acid did not result in increased HbA1c levels at 12 months or at end of study in patients considered to have pre-diabetes or normoglycemia.

“Patients with diabetes have twice the risk of cardiovascular disease and lose on average half a decade of life compared to those without and when cardiovascular disease also co exists this loss of life years is a decade and a half” said Dr. Kausik K Ray. “Lowering LDL-C with statins is beneficial in people with diabetes and reduces cardiovascular disease. To date most treatments have been as add on to statins in people with diabetes so the present findings with bempedoic acid are noteworthy for several reasons. Firstly, these analyses show that when statins cannot be tolerated, bempedoic acid used as monotherapy can provide clinically meaningful reductions in cardiovascular disease in people with diabetes. Secondly, we know statins can increase the risk of diabetes. Although bempedoic acid works in the same pathway as statins no signal for increased risk of diabetes was noted, providing assurance for the use of bempedoic acid in people without diabetes that cardiovascular benefits do not come at the cost of worsening glucose control.”

INDICATION

Bempedoic acid 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 bempedoic acid on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: *Hyperuricemia:* Bempedoic acid 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 bempedoic acid at the first sign of tendon rupture. Avoid bempedoic acid 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 bempedoic acid be taken during breastfeeding. Discontinue bempedoic acid when pregnancy is recognized, unless the benefits of therapy outweigh the potential risks to the fetus. Based on the mechanism of action, bempedoic acid may cause fetal harm.

Please see full Prescribing Information here.

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 Twitter 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 regulatory submissions and potential approvals, 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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