Esperion Highlights New Exploratory Data from CLEAR Outcomes Trial Highlighting Value of NEXLETOL® (bempedoic acid) in Oral Featured Science Session and Multiple Poster Presentations at AHA Scientific Sessions 2024

November 18, 2024

– An Exploratory Analysis Reports Patients with PAD Who Took Bempedoic Acid Were 36% Less Likely to Experience a Major Adverse Limb Event Compared to Placebo –

ANN ARBOR, Mich., Nov. 18, 2024 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced the presentation of an analysis from the CLEAR Outcomes study focused on patients with Peripheral Artery Disease (PAD) who were unable or unwilling to take statin medications. These data were presented today in an oral featured science presentation at the 2024 American Heart Association (AHA) Scientific Sessions, which took place from November 16-18, 2024, in Chicago, IL. Additionally, two exploratory analyses from the CLEAR Outcomes trial and a real-world analysis of bempedoic acid usage were presented at the conference.

"Major adverse limb events are an important cause of morbidity and disability in patients with PAD. Recent analyses support LDL-C as a target for reducing the risk of limb outcomes and that achieving very low LDL-C should be a priority in our patients with PAD. Many patients will need combination therapy in order to achieve LDL-C goals and the current analyses from CLEAR Outcomes supports bempedoic acid as an oral, safe, and well tolerated option for lowering LDL-C and the risk of major adverse limb events in patients with PAD," said Marc P. Bonaca, MD, MPH, FAHA, FACC, the lead author for the PAD analyses for the CLEAR Outcomes trial and Executive Director at CPC Clinical Research and Director of Vascular Research at University of Colorado School of Medicine.

"The ongoing presentation of exploratory analyses from our CLEAR Outcomes trial at important medical meetings, such as AHA, offers us an exceptional opportunity to showcase the clinical benefits and value of NEXLETOL and NEXLIZET® (bempedoic acid and ezetimibe**)** before an audience of the key physicians who treat patients in need of managing their cardiovascular risk," said Sheldon Koenig, President and Chief Executive Officer of Esperion.

Key data presented at the 2024 AHA Scientific Sessions

Featured Science Presentation

"Bempedoic Acid and Limb Outcomes in Statin-Intolerant Patients with Peripheral Artery Disease." – presented on behalf of all authors by Marc P. Bonaca, MD, MPH, FAHA, FACC, CPC Clinical Research

Highlights: This analysis focused on the incidence of major adverse limb events (MALE) in patients with pre-existing PAD enrolled in the CLEAR Outcomes trial. Bempedoic acid reduced MALE (e.g. worsening PAD symptoms leading to revascularization, chronic limb threatening ischemia, and acute limb ischemia events) by 36% compared to placebo.

Poster Presentations

"Liver Steatosis and Liver Fibrosis Predict Major Adverse Cardiovascular Events: Analysis of the CLEAR Outcomes Trial Population." – presented on behalf of all authors by Diederick (Rick) Grobbee, MD, PhD, FESC, University Medical Center Utrecht and Julius Clinical in The Netherlands. Results suggest bempedoic acid treatment resulted in a lower incidence of major adverse cardiovascular events (MACE) versus placebo in patients with higher liver steatosis scores at study enrollment.

"Statin Intolerance due to Muscle Symptoms Affects Management of Patients: Insights from the CLEAR Outcomes Trial" – presented on behalf of all authors by Ulrich Laufs, MD, PhD, Universitätsklinikum Leipzig, Leipzig Germany, describes the variable characteristics of statin intolerance in patients enrolled in CLEAR Outcomes and their clinical course in the study.
"Effectiveness of Lipid-lowering Therapy with Bempedoic Acid plus Ezetimibe in a Real-world Cohort" – presented on behalf of all authors by Evelyn Sarnes, PharmD, Esperion, used US claims data to evaluate the effectiveness of the combination of bempedoic acid plus ezetimibe in reducing or maintaining LDL-C <100 mg/dL. After 3 months 67% of patients on bempedoic acid and ezetimibe had LDL-C <100 mg/dL, a significant increase over the 30% at baseline, and by 12 months 55% had maintained LDL-C levels <100 mg/dL.

INDICATION
NEXLIZET and NEXLETOL are indicated:

- The bempedoic acid component of NEXLIZET and NEXLETOL is indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
    - established cardiovascular disease (CVD), or
    - at high risk for a CVD event but without established CVD.
- As an adjunct to diet:
    - NEXLIZET, alone or in combination with other LDL-C lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH.
    - NEXLETOL, in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH.

IMPORTANT SAFETY INFORMATION

NEXLIZET and NEXLETOL are contraindicated in patients with a prior hypersensitivity to bempedoic acid or ezetimibe or any of the excipients. Serious hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported.

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, returning to baseline following discontinuation of treatment. 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 may occur more frequently in patients over 60 years of age, in those taking corticosteroid or fluoroquinolone drugs, in patients with renal failure, and in patients with previous tendon disorders. Discontinue NEXLIZET or NEXLETOL at the first sign of tendon rupture. Consider alternative therapy in patients who have a history of tendon disorders or tendon rupture.

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

The most common adverse reactions in the cardiovascular outcomes trial for bempedoic acid, a component of NEXLIZET and NEXLETOL, at an incidence of ≥2% and 0.5% greater than placebo were hyperuricemia, renal impairment, anemia, elevated liver enzymes, muscle spasms, gout, and cholelithiasis.

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 Esperion Therapeutics, Inc. Adverse Event reporting line at 1-833-377-7633.

Please see full Prescribing Information for NEXLIZET and NEXLETOL.

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.

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 net sales, profitability, and growth of Esperion's commercial products, clinical activities and results, supply chain, commercial development and launch plans, the outcomes and anticipated benefits of legal proceedings and settlements, 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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