U.S. FDA Updates LDL-C Lowering Indication for Esperion's NEXLETOL® (bempedoic acid) Tablet and NEXLIZET® (bempedoic acid and ezetimibe) Tablet

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– Updated Label Adds Primary Hyperlipidemia, Removes Maximally Tolerated Statin Requirement, Removes Limitation of Use –

– Cardiovascular (CV) Risk Reduction Labels Remain on Track: in U.S. with PDUFA Date of March 31; in Europe with Anticipated Approval in 1H 2024 –

ANN ARBOR, Mich., Dec. 13, 2023 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) announced today that the U.S. Food and Drug Administration (FDA) has approved an updated LDL-cholesterol lowering indication for NEXLETOL and NEXLIZET to include the treatment of primary hyperlipidemia as a qualifier for existing approved populations. Additionally, the maximally tolerated qualifier for statin use has been removed, and the prior limitation of use stating "the effect of NEXLIZET or NEXLETOL on cardiovascular morbidity and mortality has not been determined" has also been removed.

This update is effective immediately and is the result of the FDA's efforts to modernize and synchronize drug labels, as well as Esperion's commitment to expanding the indications for NEXLETOL and NEXLIZET. "We are pleased that the FDA has approved these modifications to our current indications for NEXLETOL and NEXLIZET, which reinforce the proven efficacy and safety of these treatments," said Sheldon Koenig, President and CEO.

These labeling modifications do not impact the full pending label approvals for cardiovascular risk reduction indications for NEXLETOL and NEXLIZET, which remain on track for anticipated approval in the first quarter of 2024. In June 2023, the Company announced its submission of four Supplemental New Drug Applications based on the landmark Cholesterol Lowering via Bempedoic acid, an ACL-Inhibiting Regimen (CLEAR) Outcomes trial, which demonstrated that bempedoic acid, contained in both NEXLETOL and NEXLIZET, can significantly reduce cardiovascular risk across a range of primary and second endpoints. These applications were accepted by the FDA which issued a PDUFA, or action, date of March 31, 2024. The Company's EMA applications also remain on track, with anticipated approval in the first half of 2024.

INDICATION
NEXLETOL /NEXLIZET is indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

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 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.

Esperion Contact Information:
Investors:
Alexis Callahan
investorrelations@esperion.com
(406) 539-1762

Media:
Tiffany Aldrich
corporateteam@esperion.com
(616) 443-8438