U.S. FDA Approves Broad New Labels for NEXLETOL® and NEXLIZET® to Prevent Heart Attacks and Cardiovascular Procedures in Both Primary and Secondary Prevention Patients, Regardless of Statin Use

March 22, 2024

– New Labels Expand Treatable Population to ~70 Million Patients in U.S. –

– First LDL-C Lowering Non-Statin Indicated for Primary Prevention Patients –

– Approvals Based on Positive CLEAR Outcomes Data and Reflect a Highly Differentiated Product Profile –

– Positive CHMP Opinion Received; European Cardiovascular (CV) Risk Reduction Label Determination Anticipated in Q2 2024 –

– Conference Call and Webcast on Monday, March 25 at 8:00 a.m. ET –

ANN ARBOR, Mich., March 22, 2024 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that the United States Food and Drug Administration (FDA) has approved broad new label expansions for NEXLETOL® (bempedoic acid) Tablets and NEXLIZET® (bempedoic acid and ezetimibe) Tablets based on positive CLEAR Outcomes data that include indications for cardiovascular risk reduction and expanded LDL-C lowering in both primary and secondary prevention patients. In addition, the enhanced labels support the use of NEXLETOL and NEXLIZET either alone or in combination with statins. They also include new indications for primary hyperlipidemia, alone or in combination with a statin, and are the only LDL-C lowering non-statin drugs indicated for primary prevention patients.

“We are pleased to receive approval for our highly anticipated label expansions in the U.S., which will enable more than 70 million patients to now be eligible for NEXLETOL and NEXLIZET,” said Sheldon Koenig, President and CEO. “Importantly, these approvals expand the accessibility of our highly effective drugs to primary prevention patients, or to those who are at high risk of having a cardiovascular event, but who have not yet had one. These approvals also eliminate the statin use requirement, allowing patients to take NEXLETOL or NEXLIZET either with or without a statin, which significantly reduces previously existing prescribing limitations. We are confident these approvals position NEXLETOL and NEXLIZET as the non-statins of *first choice* within the cardiovascular risk reduction treatment paradigm.”

“We are thrilled with these significantly expanded labels and look forward to being able to now reach millions more patients with our life-saving drugs. In anticipation of these approvals, we have significantly ramped up our sales force, developed a powerful suite of new promotional materials, created a bold new consumer campaign, enhanced our patient support programs, and continued working with payers to ensure improved patient access.”

“NEXLETOL and NEXLIZET are once-daily, accessible, oral medications that reduce LDL-C and cardiovascular risk, but without the side effects most common to statins. NEXLETOL and NEXLIZET are also the first oral non-statin LDL-C lowering drugs to be approved by the FDA to reduce the risk of CV events in both primary and secondary prevention patients. We believe this significantly differentiated profile is a game changer for patients and healthcare providers alike and that we expect sales to meaningfully inflect as a result. I want to thank the entire Esperion team for its unwavering commitment to patients and to getting us to this stage. I have the utmost confidence in our future success.”

The Company’s pending label expansions in Europe remain on track, with a positive opinion received from the Committee for Medicinal Products for Human Use (CHMP) on March 21, 2024. The Company anticipates a final determination by the European Medicines Agency in the second quarter of 2024.

The U.S. approvals of NEXLIZET and NEXLETOL for cardiovascular risk reduction and LDL-C lowering were based on data generated from the CLEAR Outcomes trial, which was published in the New England Journal of Medicine in March 2023, assessing the effect of NEXLETOL on cardiovascular outcomes in nearly 14,000 patients with, or at high risk, of cardiovascular disease. Patients were followed for a median duration of 3.4 years and bempedoic acid (contained in NEXLETOL and NEXLIZET) was generally safe and well tolerated. In the study, LDL-C was reduced by 20%, hsCRP was reduced by 22%, and glucose was not elevated by bempedoic acid compared to placebo. Patients who received bempedoic acid in the trial experienced a relative risk reduction of:

- 15% for MACE-3 (death from a cardiovascular cause, nonfatal stroke, or nonfatal myocardial infarction)
- 27% for nonfatal myocardial infarction
- 19% for coronary revascularization
- 39% for MACE-3 in primary prevention patients

Conference Call and Webcast Information
Esperion will host a conference call and webcast on Monday, March 25 at 8:00 a.m. ET to discuss these FDA approvals and its

new and expanded indications for NEXLETOL and NEXLIZET. Please click here to participate in the conference call.

The live webcast can also be accessed on the Investors and Media section of the Esperion website. Access to the webcast replay will be available approximately two hours after completion of the call and will be archived on the Company's website for approximately 90 days.

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.

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 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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A video accompanying this announcement is available at

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