Esperion's Bempedoic Acid Receives Level 1a Recommendation in Updated ESC/EAS Guidelines for Management of Dyslipidaemias

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– Bempedoic Acid Receives Strongest Endorsement from ESC/EAS Guidelines Based on Compelling and Practice-Changing Evidence –

– Guideline Recognition of 'Strike Early and Strike Strong' Approach with Early Combination Lipid-Lowering Therapy Affirms Continued Development of Company's Oral Triple Combination Therapies in U.S. –

ANN ARBOR, Mich., Aug. 29, 2025 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today welcomed the inclusion of bempedoic acid as the only non-statin newly recommended for LDL-C lowering and cardiovascular risk reduction in the 2025 Focused Update of the 2019 European Society of Cardiology (ESC)/European Atherosclerosis Society (EAS) Guidelines for the Management of Dyslipidaemias.

"Recognition from Europe's premier cardiovascular medical association further validates the clinical benefit of bempedoic acid in cardiovascular risk reduction," said Sheldon Koenig, President and CEO of Esperion. "This recommendation marks a significant milestone for our European partner, Daiichi Sankyo Europe, as they continue to expand access across Europe, and is equally meaningful for our efforts in the U.S., where we anticipate the European guidelines will inform upcoming U.S. cholesterol treatment guidelines."

Key ESC/EAS Recommendations for LDL-C Lowering

1. Non-statin therapies with proven cardiovascular benefit (including bempedoic acid), taken alone or in combination, are recommended for patients who are unable to take statin therapy to lower LDL-C levels and reduce the risk of CV events. The choice should be based on the magnitude of additional LDL-C lowering needed. Class I, Level A
2. Bempedoic acid is recommended in patients who are unable to take statin therapy to achieve the LDL-C goal. Class I, Level B
3. The addition of bempedoic acid to the maximally tolerated dose of statin with or without ezetimibe should be considered in patients at high or very high risk in order to achieve the LDL-C goal. Class IIa, Level C

The guidelines, entitled "2025 Focused Update of the 2019 ESC/EAS Guidelines for the Management of Dyslipidaemias," were published in *European Heart Journal* by ESC and EAS. The full guidelines are available via open access here.

European updated guidelines emphasize the importance of earlier, aggressive combination therapy, an industry shift which Esperion foresaw and strategically positioned itself to lead by developing the first oral lipid lowering triple combination pill in the US. These polypills are designed to potentially provide unprecedented LDL-C lowering, improved adherence with a single pill, and an earlier introduction into the treatment cycle. These advanced therapies will provide physicians and patients with a flexible suite of oral options to improve outcomes and long-term success, including monotherapy (NEXLETOL® (bempedoic acid) tablets), dual therapy (NEXLIZET® (bempedoic acid and ezetimibe) tablets), and the upcoming triple combination of bempedoic acid, ezetimibe, and either atorvastatin or rosuvastatin.

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.

About Esperion Therapeutics
Esperion Therapeutics, Inc. is a commercial stage biopharmaceutical company focused on bringing new medicines to market that address unmet needs of patients and healthcare professionals. The Company developed and is commercializing the only U.S. Food and Drug Administration (FDA) approved oral, once-daily, non-statin medicines for patients who are at risk for cardiovascular disease and are struggling with elevated low density lipoprotein cholesterol (LDL-C). These medications are supported by the nearly 14,000 patient CLEAR Cardiovascular Outcomes Trial. Esperion continues to build on its success with its next generation program which is focused on developing ATP citrate lyase inhibitors (ACLYi). New insights into the structure and function of ACLYi fully enables rational drug design and the opportunity to develop highly potent and specific inhibitors with allosteric mechanisms.

Esperion continues to evolve into a leading global biopharmaceutical company through commercial execution, international partnerships and collaborations and advancement of its pre-clinical pipeline. For more information, visit esperion.com and follow Esperion on LinkedIn and X.

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, expected profitability, 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 profitability, 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.

Esperion Contact Information:
Investors:
Alina Venezia
investorrelations@esperion.com

(734) 887-3903

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