Esperion Partners with CSL Seqirus to Commercialize NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) in Australia

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– Esperion to Receive an Upfront Payment and Near-Term Milestones Along with a Profitable Transfer Price on Product Sales –

ANN ARBOR, Mich., March 03, 2025 (GLOBE NEWSWIRE) -- Esperion Therapeutics (NASDAQ: ESPR) today announced it has entered into a license and distribution agreement with CSL Seqirus (ASX:CSL) for the exclusive rights to commercialize NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) in Australia and New Zealand. Under the terms of the agreement, Esperion will receive an upfront and near-term milestone payments and will be responsible for supplying finished product to CSL Seqirus at a profitable transfer price.

In Australia, cardiovascular disease affects 1.2 million people and is a leading cause of death. In New Zealand, an estimated 175,000 adults are living with cardiovascular disease, and one in three deaths are caused by cardiovascular disease.

"We're committed to helping reduce the burden of cardiovascular disease in Australia and New Zealand, and we are delighted to be working with Esperion to help make new treatment options available. These products are an important addition to CSL Seqirus' portfolio of in-licensed medicines," said Danielle Dowell, CSL Seqirus Executive Director of Commercial Operations Asia Pacific.

"We are excited to partner with CSL Seqirus to provide physicians and patients with additional options to treat high LDL-C cholesterol and reduce the risk of cardiovascular disease in Australia and New Zealand," said Sheldon Koenig, President and CEO of Esperion. "This partnership expands the reach of our potentially lifesaving medications to another large market, further enhancing our global reach."

Details of the Agreement and Financial Terms
Under the terms of the license and distribution agreement, Esperion will grant CSL Seqirus exclusive commercialization rights to NEXLETOL and NEXLIZET in Australia and New Zealand. CSL Seqirus will be responsible for commercialization, including regulatory approval, reimbursement and marketing.

Esperion will receive an upfront payment and be eligible for milestone payments of up to approximately $5 million. Following local regulatory approval, Esperion will be responsible for supplying finished product to CSL Seqirus at a profitable transfer price.

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 CSL Seqirus
CSL Seqirus is part of CSL Limited (ASX: CSL). As one of the largest influenza vaccine providers in the world, CSL Seqirus is a major contributor to the prevention of influenza globally and a transcontinental partner in pandemic preparedness. With state-of-the-art production facilities in the U.S., the U.K. and Australia, and leading R&D capabilities, CSL Seqirus utilizes egg, cell and adjuvant technologies to offer a broad portfolio of differentiated influenza vaccines in more than 20 countries around the world.

In Australia, CSL Seqirus operates the only local manufacturing facility for seasonal and pandemic influenza vaccine, and produces a range of unique medicines in the national interest, including antivenoms and the world's only human vaccine for Q fever. Our commitment to Australia's health also extends to providing access to paediatric and adult vaccines, and innovative pharmaceuticals for patients living with allergies, cardiovascular disease, severe pain, dry eye disease, iron deficiency, kidney and rare diseases.

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 esperionscience.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, 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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