Esperion Partners with Neopharm to Commercialize NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) in Israel

December 12, 2024

– Esperion to Receive an Upfront Payment and Near-Term Milestones Along with Tiered Royalties on Product Sales –

– Israel-Based Commercial Organization Brings Successful Track Record Commercializing Pharmaceutical Products for More Than 80 Years –

ANN ARBOR, Mich., Dec. 12, 2024 (GLOBE NEWSWIRE) -- Esperion Therapeutics (NASDAQ: ESPR) today announced it has entered into a licensing agreement with Neopharm Israel for the exclusive rights to commercialize NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) in Israel. Under the terms of the agreement, Esperion will receive an upfront and near-term milestone payments and will be eligible to receive tiered royalties on sales of NEXLETOL/NEXLIZET in Israel.

“We are excited to bring the cardiovascular benefits of NEXLETOL and NEXLIZET to the millions of Israelis at risk of heart attacks and cardiovascular disease, which remain the leading cause of death globally,” said Efi Shnaidman, CEO at Neopharm. “We look forward to partnering with the Esperion team as they share our commitment to bringing innovative new medicines to patients. At Neopharm, we have a successful track record bringing new therapies to market in Israel and are confident we can build the market in Israel to establish NEXLETOL and NEXLIZET as efficacious and safe therapeutic options that will help Israeli patients reach their LDL-C goals and reduce their cardiovascular risk.”

“We are very pleased to partner with Neopharm as they have a long history of successfully commercializing innovative medicines in Israel,” said Sheldon Koenig, President and Chief Executive Officer of Esperion. “This agreement expands our global reach and reinforces Esperion’s commitment to helping patients at risk for cardiovascular and cardiometabolic diseases.”

Details of the Agreement and Financial Terms
Under the terms of the licensing agreement, Esperion will grant Neopharm exclusive commercialization rights to NEXLETOL and NEXLIZET in Israel, Gaza, and West Bank. Neopharm will be responsible for commercialization in these areas.

Esperion will receive a one-time upfront cash payment within thirty (30) Calendar Days following the signing of agreement with Neopharm. Additionally, Esperion will receive a one-time payment within thirty (30) Calendar Days following the grant of the Marketing Approval (MA) and inclusion for the first time in the National Healthcare Reimbursement Basket (NHB) without any access limitations beyond those in the MA. Finally, Esperion will receive royalties on net territory sales.

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 Neopharm Israel
Founded in 1941, Neopharm Israel is one of the leading pharmaceutical companies in Israel. For over 80 years, it have provided the Israeli market with a wide range of products and integrated services for patients in need with a proven track record of successful market access and launches. Neopharm's achievements have enabled it to earn the position of partner-of-choice and all-in-house solution for multinational pharmaceuticals and biotechnology companies seeking to enter or expand their presence in Israel. It has consistently grown the value of its products, increased turnover and enhanced its market leadership in Israel.

Neopharm Israel is part of the privately owned Neopharm Group which, through its family of companies, engages in the research and development, manufacturing, marketing, sales and distribution of a broad range of products in the healthcare market in more than 60 countries worldwide. The Neopharm Group operates in three major segments: Pharmaceutical, Consumer Healthcare and Medical Devices, which together generate annual revenues exceeding four hundred million US dollars. The Group has offices in Israel and in Europe, and employs over 700 employees worldwide.

About 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.

Esperion Contact Information:
Investors:
Alina Venezia
investorrelations@esperion.com
(734) 887-3903

Media:

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