



Esperion Announces Two NEXLETOL® (bempedoic acid) Data Presentations at the American College of Cardiology's 71st Annual Scientific Session & Expo

April 3, 2022

New Analyses of thousands of patients spanning Phase 2 and pooled Phase 3 data demonstrate that NEXLETOL safely and significantly lowers LDL-C compared to placebo in patients with renal impairment or hypertension

ANN ARBOR, Mich., April 03, 2022 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today presented two new analyses from its clinical development program of bempedoic acid (NEXLETOL®) at the American College of Cardiology's 71st Annual Scientific Session & Expo (ACC.22).

The first analysis titled, "Safety and Efficacy of Bempedoic Acid in Patients with Renal Impairment," was presented by Peter P. Toth, MD, PhD, FCCP, FAHA, FESC, FACC. This analysis of a total of 3,619 patients included in four Phase 3 studies demonstrated that bempedoic acid 180 mg significantly lowered low-density lipoprotein cholesterol (LDL-C) ($p < 0.0001$) regardless of renal function. While patients with severe renal impairment (eGFR < 30 mL/min/1.73 m²) or end-stage renal disease receiving dialysis were not recruited for these trials, bempedoic acid was effective and generally well tolerated in the large group of patients with Stage 2 or Stage 3 renal impairment (estimated glomerular filtration rates (eGFR) between 30 and < 90 mL/min/1.73 m²).

A second analysis titled, "Safety and Efficacy of Bempedoic Acid in Patients with Hypertension," was presented by Keith C. Ferdinand, MD, FACC, FAHA, FASH, FNLA. In 3,623 patients with ASCVD included in pooled data from four Phase 3 studies, 78% had a history of hypertension. In these patients, bempedoic acid 180 mg significantly lowered LDL-C. Bempedoic acid was associated with substantial decreases in LDL-C ($p < 0.0001$) regardless of a patient's hypertension history. The presentation included an analysis of a Phase 2 study of patients with hypertension, where a significant reduction in LDL-C was found among patients with blood pressure $\geq 140/90$ and $\leq 180/110$ mmHg.

"We are encouraged by the findings from our clinical development program across Phase 2 and Phase 3 trials that bempedoic acid can be utilized to lower LDL-C in these high risk hypertensive and renal patients," said JoAnne Foody, MD, FACC, FAHA, chief medical officer of Esperion. "These additional analyses continue to emphasize the efficacy and safety of bempedoic acid across a wide range of at-risk patients who require additional options to lower their LDL-C."

Approved by the U.S. Food and Drug Administration (FDA), NEXLETOL is the first oral, once-daily, non-statin LDL-C-lowering medicine available to indicated patients in nearly 20 years. The approval of NEXLETOL was supported by a global pivotal Phase 3 LDL-C-lowering program conducted in more than 3,000 patients with ASCVD and/or HeFH. In these studies, NEXLETOL provided an average of 18% placebo-corrected LDL-C lowering when used with moderate or high-intensity statins. NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not yet been determined. Please see important safety information below.

NEXLETOL® (bempedoic acid) Tablet

NEXLETOL is a first-in-class ATP Citrate Lyase (ACL) inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors. NEXLETOL is the first oral, once-daily, non-statin LDL-C lowering medicine approved in the U.S. in nearly 20 years for patients with ASCVD or HeFH. NEXLETOL was approved by the FDA in February 2020, and by the European Commission in April 2020 under the name NILEMDO® (bempedoic acid) with a different label. Daiichi Sankyo Europe has licensed exclusive commercialization rights to bempedoic acid in the European Economic Area, Switzerland, Turkey, and United Kingdom, from Esperion.

INDICATION

NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. Limitations of Use: The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Hyperuricemia: NEXLETOL may increase blood uric acid levels. 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: NEXLETOL is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with NEXLETOL versus 0% of patients treated with placebo, and involved the rotator cuff (the shoulder), biceps tendon, or Achilles tendon. Tendon rupture occurred within weeks to months of starting 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 NEXLETOL at the first sign of tendon rupture. Avoid NEXLETOL in patients who have a history of tendon disorders or tendon rupture.

Adverse Reactions: In clinical trials, the most commonly reported adverse reactions were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Reactions reported less frequently, but still more often than with placebo, included benign prostatic hyperplasia and atrial fibrillation.

Drug Interactions: Simvastatin and Pravastatin: Concomitant use results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.

Lactation and Pregnancy: It is not recommended that NEXLETOL be taken during breastfeeding. Discontinue NEXLETOL when pregnancy is

recognized, unless the benefits of therapy outweigh the potential risks to the fetus. Based on the mechanism of action, NEXLETOL may cause fetal harm.

Please see full Prescribing Information for NEXLETOL by clicking [here](#).

Esperion Therapeutics

Esperion works hard to make our medicines easy to get, easy to take and easy to have. We discover, develop, and commercialize innovative medicines and combinations to lower cholesterol, especially for patients whose needs aren't being met by the status quo. Our entrepreneurial team of industry leaders is inclusive, passionate and resourceful. We are singularly focused on managing cholesterol so you can improve your health easily.

Esperion commercializes NEXLETOL[®] (bempedoic acid) and NEXLIZET[®] (bempedoic acid and ezetimibe) Tablets and is the leader in the development of convenient oral, once-daily non-statin LDL-cholesterol lowering drugs for patients with high levels of bad cholesterol. For more information, please visit www.esperion.com and follow us on Twitter at www.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 commercial products, clinical development, 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 impact of the ongoing COVID-19 pandemic on our business, revenues, results of operations and financial condition, the net sales, profitability, and growth of Esperion's commercial products, clinical activities and results, supply chain, commercial development and launch plans, 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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