



Esperion Announces CLEAR Cardiovascular Outcomes Trial of NEXLETOL® (bempedoic acid) Meets Primary Endpoint

December 7, 2022

– Demonstrates statistically significant and clinically meaningful results –

– Bempedoic acid becomes the first ATP citrate lyase inhibitor and first oral non-statin to meet the major adverse cardiovascular events (MACE-4) primary endpoint –

– Presentation of comprehensive data at a key medical conference in the first quarter of 2023 –

ANN ARBOR, Mich., Dec. 07, 2022 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that the landmark Cholesterol Lowering via Bempedoic acid, an ACL-Inhibiting Regimen (CLEAR) Outcomes trial met its primary endpoint, demonstrating statistically significant risk reduction in MACE-4 in patients treated with 180 mg/day NEXLETOL compared to placebo.

"With the announcement of these positive topline results, bempedoic acid becomes the first ATP-citrate lyase inhibitor to demonstrate significant and clinically meaningful outcomes results for patients in whom existing lipid lowering therapies fall short," said Sheldon Koenig, President and CEO of Esperion. "We thank the thousands of patients and investigators worldwide for bringing this study to a successful close. We look forward to sharing this data with the medical community and submitting to appropriate regulatory authorities as quickly as possible in 2023. CLEAR Outcomes further strengthens the clinical evidence supporting the role of bempedoic acid for patients."

Cardiovascular disease remains the number one killer globallyⁱ. A large proportion of patients at risk for cardiovascular events based on elevated LDL-cholesterol and apolipoprotein b are not adequately treated with existing therapies. Despite recent therapeutic advances, there remains a significant need for new treatment options to help improve long-term cardiovascular outcomesⁱⁱ.

CLEAR Cardiovascular Outcomes Trial

CLEAR Outcomes is a Phase 3, event-driven, randomized, multicenter, double-blind, placebo-controlled trial designed to evaluate whether treatment with bempedoic acid reduces the risk of cardiovascular events in patients with or who are at high risk for cardiovascular disease with documented statin intolerance (inability to tolerate two or more statins, one at a low dose) and elevated LDL-cholesterol levels (fasting blood LDL-C \geq 100 (2.6 mmol/L)). The study included over 14,000 patients at over 1,200 sites in 32 countries.

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 [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. 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 future operations, 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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ⁱ Centers for Disease Control and Prevention, National Center for Health Statistics. About Multiple Cause of Death, 1999–2020. CDC WONDER Online Database website. Atlanta, GA: Centers for Disease Control and Prevention; 2022. Accessed November 2022.

ⁱⁱ Ray KK, Ference BA, Séverin T, Blom D, et al. World Heart Federation Cholesterol Roadmap 2022. Global Heart. 2022; X(X): X. DOI: <https://doi.org/10.5334/gh.1154>