Esperion Announces Publication of CLEAR Harmony Open-Label Extension Study Data for Bempedoic Acid in the American Journal of Cardiology

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Analysis of open-label extension data demonstrated that bempedoic acid was generally well tolerated and demonstrated sustained efficacy with up to 2.5 years of continuous treatment

ANN ARBOR, Mich., May 02, 2022 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced the publication of data from the CLEAR Harmony Open-Label Extension (OLE) Study of bempedoic acid, also known as NEXLETOL®, in the *American Journal of Cardiology*.

The paper, “Long-term Safety and Efficacy of Bempedoic Acid in Patients with Atherosclerotic Cardiovascular Disease and/or Heterozygous Familial Hypercholesterolemia (From the CLEAR Harmony Open-Label Extension Study),” described the results from the 78-week, Phase 3, OLE study that followed the 52-week CLEAR Harmony Phase 3 study. In the CLEAR Harmony study, patients were randomized 2:1 to bempedoic acid or placebo for 52 weeks. During the OLE, patients who received bempedoic acid continued treatment (≤130 weeks) and patients who received placebo initiated bempedoic acid (≤78 weeks).The purpose of the CLEAR Harmony OLE study was to build on the findings from the CLEAR Harmony parent study and evaluate the long-term safety and efficacy of bempedoic acid for up to 130 weeks.

“The results from the CLEAR Harmony OLE study support the long-term safety and efficacy of bempedoic acid in lowering and maintaining LDL-C levels in patients,” said JoAnne Foody, M.D., FACC, FAHA, chief medical officer of Esperion. “Importantly, the safety profile of bempedoic acid in the OLE study was comparable to findings from the parent study and no new safety concerns were observed. Additionally, bempedoic acid produced stable reductions in LDL-C which remained durable for up to 130 weeks.”

Bempedoic acid was generally well tolerated, with a safety profile that was comparable to that observed in the parent study, and no new safety signals were identified. The results of the OLE study demonstrated that the decrease in LDL-C levels for patients who had received bempedoic acid in the 52-week parent study (n=970) remained relatively stable during the 78-week OLE study, with a mean (SE) percent change in LDL-C from parent study baseline to week 78 of the OLE study of -14.2 ± 0.9% [mean (SE) change from baseline of -16.0 ± 1.0 mg/dL]. Patients who received placebo in the parent study (n=492) experienced a similar degree of LDL-C lowering within 12 weeks of initiating open-label bempedoic acid treatment (-14.5 ± 1.0% [-15.4 ± 1.0 mg/dL]), which also remained stable during the OLE study, with a mean percent decrease in LDL-C from the parent study baseline to week 78 of the OLE study of -15.0 ± 1.1% (-16.1 ± 1.2 mg/dL).

INDICATION
Bempedoic acid 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 bempedoic acid on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Hyperuricemia: Bempedoic acid 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: Bempedoic acid is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with bempedoic acid 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 bempedoic acid. 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 bempedoic acid at the first sign of tendon rupture. Avoid bempedoic acid 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 bempedoic acid be taken during breastfeeding. Discontinue bempedoic acid when pregnancy is recognized, unless the benefits of therapy outweigh the potential risks to the fetus. Based on the mechanism of action, bempedoic acid may cause fetal harm.

Please see full Prescribing Information for bempedoic acid 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 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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