



Esperion Presents Important New Science Highlighting Potential Benefits of NEXLETOL® (bempedoic acid) Tablets at American Heart Association Scientific Sessions 2021

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- Analysis of pooled Phase 3 data showed that NEXLETOL [bempedoic acid (BA)] alone lowered LDL-C levels comparable to that of a moderate- or high-intensity statin ($\geq 30\%$) in nearly 1 out of 3 of patients -
- In patients with metabolic syndrome NEXLETOL lowered hemoglobin A1c (HbA1c), fasting plasma glucose and low-density lipoprotein cholesterol (LDL-C), at week 12 -
- In healthy patients treatment with BA reduced fasting LDL-C, non- high-density lipoprotein cholesterol (HDL-C), and baseline high-sensitivity C-reactive protein (hsCRP) at week 2 -

ANN ARBOR, Mich., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced the presentation of three abstracts highlighting NEXLETOL tablets at the American Heart Association (AHA) Scientific Sessions 2021 taking place on November 13-15, 2021.

“As one of the few companies solely focused on LDL-C lowering in high-risk cardiovascular patients, Esperion continues to advance the science of lipid lowering and the value of our therapies. These presentations provide important new information for clinicians as they look to provide oral therapies to reduce LDL-C,” said Dr. JoAnne Foody, chief medical officer of Esperion. “The data presented during AHA highlight not only the important LDL-C lowering benefits of bempedoic acid across multiple patient populations, but also highlight the potential cardiometabolic effects of our compounds with reductions in glucose and hsCRP. Bempedoic acid, through inhibition of the enzyme ATP citrate lyase pathway, uniquely acts at the interface of lipid and carbohydrate metabolism and offers promise for future targeting of patients with cardiometabolic risk.”

In the abstract, “Factors Associated with Enhanced Low-density Lipoprotein Cholesterol Lowering With Bempedoic Acid Among Patients Enrolled in Phase 3 Studies,” LDL-C lowering with BA was examined using pooled data from four Phase 3 studies in 3,488 patients on background maximally tolerated statins. Overall, from baseline to Week 12, BA lowered LDL-C levels comparable to that of a moderate- or high-intensity statin ($\geq 30\%$) in 28.9% of patients. In patients not receiving background statins, greater than 50% of patients achieved at least 30% LDL-C lowering with BA. A multivariate analysis showed that many factors, including the absence of baseline statin use, gender, history of diabetes mellitus, baseline ezetimibe (EZE), and higher hsCRP were associated with increased rates of achieving at least a 30% reduction in LDL-C with BA treatment (odds ratio [95% CI], 2.49 [1.94, 3.19; $P < .0001$]).

In “Efficacy and Safety of Bempedoic Acid in Patients With Metabolic Syndrome,” pooled data from four Phase 3 studies were used to analyze the lipid-lowering efficacy, safety, and effect of BA on glycemic parameters and hsCRP according to baseline metabolic status. The analysis of 3,623 patients (excluding diabetes mellitus patients) determined the incidence of treatment emergent adverse events (TEAEs) was comparable in both subgroups. Overall, BA demonstrated comparable safety in both metabolic subgroups and greater lowering of LDL-C, HbA1c, and fasting plasma glucose (FPG) levels in patients with metabolic syndrome (MetS) vs nonMetS.

The abstract, “Pharmacokinetics, Pharmacodynamics, and Safety of Bempedoic Acid in a Phase 1 Clinical Trial in Healthy Japanese, Chinese, and White Subjects,” analyzed data from a double-blind, placebo-controlled study in a total of 40 healthy subjects randomized 3:1 to receive BA or placebo. Reductions in fasting LDL-C, non-HDL-C and hsCRP were observed with BA and the drug was well tolerated. PK differences were explained after normalizing by subject body weight and were not associated with any clinically meaningful differences in the efficacy or safety profiles of BA.

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.

Important Safety Information

- Warnings and Precautions:
 - Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate. The risk for gout events with NEXLETOL was higher in patients with a prior history of gout although gout also occurred more frequently than placebo in patients treated with NEXLETOL who had no prior gout history.
 - Tendon rupture has occurred. 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:
 - The most common (incidence \geq 2% and greater than placebo) adverse reactions are upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia and elevated liver enzymes.
- Drug Interactions:
 - Avoid concomitant use of NEXLETOL with simvastatin greater than 20 mg.
 - Avoid concomitant use of NEXLETOL with pravastatin greater than 40 mg.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 or report side effects to Esperion at 833-377-7633 (833 ESPRIMED).

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

Esperion Therapeutics

Esperion is The Lipid Management Company. Our goal is lipid management for everybody, that's why we work 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. 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 commercialization plans. 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 COVID-19 on our business, 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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