Esperion Announces Publication in the Journal of the American Medical Association Cardiology of Pooled Efficacy Analysis from the Phase 3 LDL-C Lowering Clinical Development Program of NEXLETOL® (bempedoic acid) Tablets

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ANN ARBOR, Mich., July 01, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that pooled efficacy analysis from the four Phase 3 clinical studies of NEXLETOL, an oral, once-daily LDL-cholesterol lowering medicine, was published in the *Journal of the American Medical Association (JAMA) Cardiology*. The four Phase 3 clinical studies evaluated the efficacy and safety of NEXLETOL versus placebo in 3623 patients with hypercholesterolemia while receiving stable lipid-lowering therapy and at high cardiovascular risk or with hypercholesterolemia and statin intolerance. NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

The publication highlighted that NEXLETOL added to maximally tolerated statins, including moderate- or high- intensity or no background statin demonstrated significant additional LDL-C lowering levels versus placebo. In patients on background statin therapy, NEXLETOL lowered LDL-cholesterol (LDL-C) by a mean of 18 percent compared to placebo ($p<0.001$). In statin intolerant patients, NEXLETOL lowered LDL-C by a mean of 24 percent compared to placebo ($p<0.001$). Furthermore, decreases in non-HDL-C, total cholesterol, Apo B and hsCRP were greater with NEXLETOL versus placebo. Finally, overall and common adverse events occurred at similar rates in patients treated with NEXLETOL and placebo.

“The body of evidence keeps growing to show that NEXLETOL has the power to alter how LDL-C lowering is handled in patients that simply aren’t seeing the desired results from statins alone,” said Tim Mayleben, president and chief executive officer of Esperion. “In addition, to have these data in *JAMA Cardiology* brings recognition to the fact that while statins help millions achieve their LDL-C goals, there is a significantly underserved patient group that truly need convenient and complementary, oral, once-daily non-statin medicines to achieve their LDL-C goals.”

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.

Indication and Limitation of Use

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. The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

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™ (bempedoic acid) tablet was higher in patients with a prior history of gout although gout also occurred more frequently than placebo in patients treated with NEXLETOL™ (bempedoic acid) tablet who had no prior gout history.
    - Tendon rupture has occurred. Discontinue NEXLETOL™ (bempedoic acid) tablet at the first sign of tendon rupture. Avoid NEXLETOL™ (bempedoic acid) tablet in patients who have a history of tendon disorders or tendon rupture.
- Adverse Reactions:
    - The most common (incidence ≥ 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 ESPRMED).

Please see the full Prescribing Information for NEXLETOL by clicking here.

CLEAR Cardiovascular Outcomes Trial

The effect of NEXLETOL or NEXLIZET on cardiovascular morbidity and mortality has not been determined. Esperion initiated a global cardiovascular outcomes trial (CVOT) to assess the effects of bempedoic acid on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease (CVD) who are only able to tolerate less than the lowest approved daily starting dose of a statin and are considered "statin averse." The CVOT — known as CLEAR Cardiovascular Outcomes Trial — is an event-driven, global, randomized, double-blind, placebo-controlled study that completed enrollment in August 2019 of 14,032 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

Esperion Therapeutics

Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced Lipid Management Team at Esperion is committed to developing new LDL-C lowering medicines that will make a substantial impact on reducing global cardiovascular disease, the leading cause of death around the world. For more information, please visit www.esperion.com and follow us on Twitter at www.twitter.com/EsperionInc.

Esperion Therapeutics' Commitment to Patients with Hyperlipidemia

High levels of LDL-C can lead to a build-up of fat and cholesterol in and on artery walls (known as atherosclerosis), potentially leading to cardiovascular events, including heart attack and stroke. In the U.S., 96 million people, or more than 37 percent of the adult population, have elevated LDL-C. There are approximately 18 million people in the U.S. living with elevated levels of LDL-C despite taking maximally tolerated lipid-modifying therapy — including individuals considered statin averse — leaving them at high risk for cardiovascular events.[1] In the United States, more than 50 percent of ASCVD patients who are not able to reach their LDL-C with statins alone need less than a 40 percent reduction to reach their LDL-C threshold[2].
Esperion's mission as the Lipid Management Company is to deliver oral, once-daily medicines that complement existing oral drugs to provide the additional LDL-C lowering that these patients need.

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 the clinical development and commercialization plans for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of expanded indications for their effect on cardiovascular events, and Esperion's expectations for the market for medicines to lower LDL-C, including the commercial launch and market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet in the United States and European Union. 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, delays or failures in Esperion's clinical development and commercialization plans, or approval of expanded indications, that existing cash resources may be used more quickly than anticipated, the impact of COVID-19 on our business, clinical activities and commercial development 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.

References

(1) Esperion market research on file: research project interviewing 350 physicians. Esperion Therapeutics, Inc. Sept-Oct 2018.

(2) Data on file: analysis of NHANES database. Esperion Therapeutics, Inc. 2018.

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