Esperion Announces FDA Approval of NEXLETOL™ (bempedoic acid) Tablet, an Oral, Once-Daily, Non-Statin LDL-Cholesterol Lowering Medicine

February 21, 2020

– First Oral, Once-Daily, Non-Statin LDL-Cholesterol Lowering Medicine Approved in the U.S. in Nearly 20 Years for Indicated Patients –
– NEXLETOL Lowers LDL-Cholesterol with a First-in-Class Mechanism –
– Fills an Unmet Need for Affordable Medicines for Millions of Patients with ASCVD or HeFH –
– NEXLETOL will be Commercially Available in the U.S. March 30, 2020 –
– Conference Call and Webcast on Monday, February 24 at 8:00 a.m. Eastern Time –

ANN ARBOR, Mich., Feb. 21, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) announced today that the U.S. Food and Drug Administration (FDA) approved NEXLETOL™ (bempedoic acid) tablet, an oral, once-daily, non-statin LDL-Cholesterol (LDL-C) lowering medicine. 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. NEXLETOL is the first oral, once-daily, non-statin LDL-C lowering medicine approved since 2002 for indicated patients.

NEXLETOL is a first-in-class ATP Citrate Lyase (ACL) inhibitor that lowers LDL-C by inhibition of cholesterol synthesis in the liver.

“NEXLETOL delivers upon a commitment we’ve made to millions of patients for a new treatment alternative if they struggle with bad cholesterol and have ASCVD or HeFH,” said Tim Mayleben, president and chief executive officer of Esperion. “Even with maximally tolerated statins, which may mean no statin at all, some of these patients can’t achieve their LDL-C goals. Today’s approval provides them with a new medicine to go along with a healthy diet. We express our sincere gratitude to all of the patients and physicians who put their confidence in Esperion’s team of lipid experts.”

LDL-C is a waxy, fat-like substance that’s found in the body. Elevated LDL-C contributes to a buildup of this fat in the arteries and can lead to cardiovascular events including heart attack and stroke. Despite standard of care treatments, including statin therapy, it is estimated nearly 15 million patients (approximately one in four patients) in the U.S. cannot achieve guideline recommended LDL-C levels.

“The FDA approval of NEXLETOL provides an important option for patients living with elevated LDL-C and ASCVD or increased risk for cardiovascular disease because of HeFH,” said Christie M. Ballantyne, M.D., chairman of Esperion’s Phase 3 Executive Committee and professor and chief of cardiology at Baylor College of Medicine in Houston. “There are millions of patients who are unable to reach their LDL-C targets despite available medicines. NEXLETOL is the first oral, once-daily, non-statin treatment option for indicated patients in nearly two decades.”

The approval of NEXLETOL is supported by a global pivotal Phase 3 LDL-C lowering program conducted in more than 3,000 patients. In these studies, NEXLETOL provided an average of 18 percent placebo corrected LDL-C lowering when used with moderate or high intensity statins. Results from the Phase 3 development program have been published in *The New England Journal of Medicine* (040 Study), and *The Journal of the American Medical Association* (047 Study).

NEXLETOL was generally well-tolerated in clinical studies. Label warnings and precautions include hyperuricemia, with the development of gout in a small percentage of patients, as well as increased risk of tendon rupture or injury. Overall in Phase 3 studies, the adverse events reported most frequently in patients who received NEXLETOL were generally reported at similar rates in patients who received placebo. The most common adverse events reported with NEXLETOL (incidence ≥ 2% and greater than placebo) were upper respiratory tract infections, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. The majority of adverse events reported with NEXLETOL were mild to moderate in severity and balanced in occurrence with adverse events in patients receiving placebo. For additional information on NEXLETOL, please see Full Prescribing Information at Esperion.com.

Today’s approval underscores Esperion’s commitment to deliver NEXLETOL to adult patients suffering from ASCVD or HeFH and who are unable to reach their LDL-C goal on maximally tolerated statins. Esperion is working with health insurance providers to help ensure broad insurance coverage and patient access to NEXLETOL. Eligible patients with commercial drug insurance coverage for NEXLETOL may pay as little as $10 per fill, up to a 3-month supply. Additionally, Esperion is committed to achieving the lowest branded tier coverage for Medicare patients. Esperion will provide resources to patients whose physician recommends treatment with NEXLETOL. These resources include educational materials, a dedicated call center, as well as a co-pay program for eligible patients.

NEXLETOL will be commercially available in the U.S., by prescription only, on March 30, 2020.

Esperion’s second LDL-C lowering medicine, the bempedoic acid / ezetimibe combination tablet, is currently under review by the U.S. FDA; the PDUFA goal date is February 26, 2020.

Conference Call and Webcast Information

Esperion's Lipid Management Team will host a conference call and webcast on Monday, February 24 at 8:00 a.m. Eastern Time to discuss the approval and upcoming commercial launch. The call can be accessed by dialing (877) 312-7508 (domestic) or (253) 237-1184 (international) five minutes prior to the start of the call and providing the access code 4088218. A live audio webcast can be accessed on the investors and media section of the Esperion website at investor.esperion.com. Access to the webcast replay will be available approximately two hours after completion of the call and will be archived on the Company's website for approximately 90 days.

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. Completed Phase 3 studies conducted in more than 3,000 patients, with over 2,000 patients treated with NEXLETOL, demonstrated an average 18 percent placebo corrected LDL-C lowering when used in patients on moderate or high-intensity statins. 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 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 ≥ 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).

CLEAR Cardiovascular Outcomes Trial

The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined. Esperion initiated a global cardiovascular outcomes trial (CVOT) to assess the effects of NEXLETOL 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 or 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. with atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) 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 regulatory approval pathway for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, the therapeutic potential of, and the clinical development plan 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 the NDAs and the MAAs, 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, if approved. 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 studies, that positive results from a clinical study of bempedoic acid may not be sufficient for EMA approval or necessarily be predictive of the results of future or ongoing clinical studies, that notwithstanding the completion of Esperion's Phase 3 clinical development program for LDL-C lowering, the FDA or EMA require additional development in connection with seeking regulatory approval, or approval of an expanded indication, that

existing cash resources may be used more quickly than anticipated, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. 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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