

## Esperion Announces FDA Approval of the NEXLIZET™ (bempedoic acid and ezetimibe) Tablet, an Oral, Once-Daily, Non-Statin LDL-Cholesterol Lowering Medicine

February 26, 2020

- NEXLIZET Lowered LDL-C by 38 Percent Compared to Placebo when Added on to Maximally Tolerated Statins -
  - First Non-Statin, LDL-Cholesterol Lowering Combination Medicine Ever Approved -
- Esperion's Second Oral, Once-Daily, Non-Statin LDL-Cholesterol Lowering Medicine Approved in the U.S. Following NEXLETOL™ (bempedoic acid) Tablet Approval on February 21, 2020 -
  - Further Underscores Esperion's Commitment to Patient Affordability -
  - Conference Call and Webcast on Thursday, February 27 at 8:00 a.m. Eastern Time -

ANN ARBOR, Mich., Feb. 26, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today announced that the U.S. Food and Drug Administration (FDA) approved NEXLIZET™ (bempedoic acid and ezetimibe) tablet, an oral, once-daily, non-statin LDL-Cholesterol (LDL-C), lowering medicine. NEXLIZET 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 NEXLIZET on cardiovascular morbidity and mortality has not been determined. NEXLIZET is the first non-statin, LDL-C lowering combination medicine ever approved. This approval follows the approval of NEXLETOL™ (bempedoic acid) tablet last week.

NEXLIZET contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine.

"The approval of NEXLIZET underscores Esperion's commitment to providing patients and their healthcare providers with innovative non-statin medicines that fit into their everyday routines to lower elevated levels of bad cholesterol in adult patients with ASCVD or HeFH on maximally tolerated statins. This is the first non-statin combination medicine ever approved for lowering LDL-C," said Tim M. Mayleben, president and chief executive officer of Esperion. "We are truly grateful to all of the patients and healthcare providers 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, it is estimated nearly 15 million ASCVD or HeFH patients on maximally tolerated statins in the U.S. cannot achieve guideline recommended LDL-C levels.

"NEXLIZET provides significant additional LDL-C lowering for adult patients with ASCVD or HeFH when added to maximally tolerated statin medicine, including those patients for whom maximally tolerated statin may be no statin at all," 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. "I believe this one-of-a-kind combination medicine which has two complementary, non-statin medications can provide highly effective additional reductions in LDL-C when added to statin therapy. It also has the conventional, oral, once-daily administration which can prove beneficial to patients struggling to meet their cholesterol goals with the currently available statin options in their daily regimen."

The approval of NEXLIZET is supported by the Phase 3 Fixed Combination Drug Product LDL-C Lowering program, as well as safety data from the NEXLETOL (bempedoic acid) tablet global pivotal Phase 3 LDL-C lowering program and the existing ezetimibe safety profile. NEXLIZET lowered LDL-C by a mean of 38 percent compared to placebo when added on to maximally tolerated statins. Results have been published in *The European Journal of Preventative Cardiology*.

NEXLIZET was generally well-tolerated in a pivotal Phase 3 study. Label warnings and precautions include hyperuricemia, with the development of gout in a small percentage of patients, as well as an increased risk of tendon rupture or injury. The most common adverse events reported in the development program (incidence  $\geq$  2% and greater than placebo) were generally reported at similar rates in patients who received placebo and were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes, diarrhea, arthralgia, sinusitis fatigue, influenza. The majority of adverse events reported with NEXLIZET were mild to moderate in severity. For additional information on NEXLIZET, please see [Full Prescribing Information](#) at [Esperion.com](#).

Today's approval further underscores Esperion's commitment to deliver our medicines to adult patients suffering from ASCVD or HeFH and who are unable to reach their LDL-C goals on maximally tolerated statins. Esperion is working with health insurance providers to help ensure broad insurance coverage and patient access to our medicines. Eligible patients with commercial drug insurance coverage for our medicines may pay as little as \$10 per fill, up to a 3-month supply. To ensure access, both NEXLETOL and NEXLIZET will be priced at parity. 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 (bempedoic acid) or NEXLIZET. These resources include educational materials, a dedicated call center, as well as a co-pay program for eligible patients.

NEXLIZET will be commercially available for U.S. patients in July 2020. NEXLETOL will be commercially available for U.S. patients on March 30, 2020. Both NEXLETOL and NEXLIZET will be available by prescription only.

### Conference Call and Webcast Information

Esperion's Lipid Management Team will host a conference call and webcast on Thursday, February 27 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 1079274. 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™ (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](http://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.](#)

## **NEXLIZET™ (bempedoic acid and ezetimibe) Tablet**

NEXLIZET contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine. Phase 3 data demonstrated NEXLIZET lowered LDL-C by a mean of 38 percent compared to placebo when added on to maximally tolerated statins. NEXLIZET is the first non-statin, LDL-cholesterol lowering combination medicine ever approved. NEXLIZET was approved by the FDA in February 2020.

### Indication and Limitation of Use

NEXLIZET 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 NEXLIZET on cardiovascular morbidity and mortality has not been determined.

- Contraindications:
  - Known hypersensitivity to ezetimibe tablets.
- 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 NEXLIZET was higher in patients with a prior history of gout although gout also occurred more frequently than placebo in patients treated with NEXLIZET who had no prior gout history.
  - Tendon rupture has occurred. Discontinue NEXLIZET at the first sign of tendon rupture. Avoid NEXLIZET in patients who have a history of tendon disorders or tendon rupture.
- Adverse Reactions:
  - The most common adverse events reported in the development program were generally reported at similar rates in patients who received placebo (incidence ≥ 2% and greater than placebo) were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes, diarrhea, arthralgia, sinusitis fatigue, influenza.
- Drug Interactions:

- Simvastatin: Avoid concomitant use of NEXLIZET with simvastatin greater than 20 mg.
- Pravastatin: Avoid concomitant use of NEXLIZET with pravastatin greater than 40 mg.
- Cyclosporine: Monitor cyclosporine concentrations.
- Fibrates: If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, consider alternative lipid-lowering therapy.

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

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

### **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](http://www.esperion.com) and follow us on Twitter at [www.twitter.com/EsperionInc](https://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. 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<sup>2</sup>.

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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