



## Esperion Announces Three Data Presentations of the NEXLETOL™ (bempedoic acid) Tablet and the NEXLIZET™ (bempedoic acid and ezetimibe) Tablet at the American College of Cardiology's 69th Annual Scientific Session Together with World Congress of Cardiology

March 28, 2020

ANN ARBOR, Mich., March 28, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today announced that two pooled analyses from four Phase 3 clinical trials of NEXLETOL and results from the Phase 2 (1002-058) study of NEXLIZET were presented at the American College of Cardiology's 69<sup>th</sup> Scientific Session Together with World Congress of Cardiology (ACC.20/WCC).

A poster titled "Bempedoic Acid 180 mg + Ezetimibe 10 mg Fixed Combination Drug Product vs Ezetimibe Alone or Placebo in Patients with Type 2 Diabetes and Hypercholesterolemia" was presented by Harold E Bays, MD, FOMA, FTOS, FACC, FACE, FNLA. The poster highlighted that in the Phase 2 (1002-058) study, NEXLIZET significantly lowered LDL-Cholesterol (LDL-C) by a mean 40% compared to placebo, reduced high-sensitivity C-reactive protein (hsCRP) by 25% compared to baseline and resulted in no worsening of glycemic control. The incidence of adverse events rates were generally comparable to placebo.

In addition, a poster, titled "Factors Influencing Bempedoic Acid-Mediated Reductions in High-sensitivity C-reactive Protein: Analysis of Pooled Patient-level Data from 4 Phase 3 Clinical Trials" was presented by Eric S. G. Stroes, MD, PhD. The poster highlighted that in the pooled Phase 3 studies, NEXLETOL significantly lowered hsCRP in patients with hypercholesterolemia regardless of the presence or intensity of background statin therapy. In patients whose hsCRP levels were  $\geq 2$  mg/L at baseline, the analysis showed NEXLETOL significantly reduced this marker of inflammation by 42% at 12 weeks.

The third poster, titled "Bempedoic Acid Efficacy and Safety in Patients at High Risk for CVD Treated with or Without Ezetimibe: Pooled Analysis of 4 Phase 3 Clinical Trials" was presented by Maciej Banach, MD, PhD, FAHA, FESC. The pooled analysis showed that in the Phase 3 studies, NEXLETOL provided significant additional LDL-C lowering as well as significantly lowered other lipid (total cholesterol, non-HDL-C Apo B, HDL-C) endpoints, regardless of the presence of background ezetimibe. Importantly, the safety profile of NEXLETOL was similar with or without background ezetimibe therapy.

"We are pleased with the final results of the Phase 2 study that highlight NEXLIZET achieved an impressive 40 percent LDL-C lowering, a significant 25 percent reduction in hsCRP and did not worsen glycemic control in patients with Type 2 diabetes. The additional pooled analyses from the Phase 3 LDL-C lowering development program demonstrate NEXLETOL can be safely added to multiple LDL-C medicines, which is important to help more patients reach their LDL-C goals," said Tim Mayleben, president and chief executive officer of Esperion. "These additional analyses further affirm the efficacy and safety of our medicines for the millions of patients needing to lower their bad cholesterol."

### **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 LDL receptors. Phase 3 studies detailed in the label were 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 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  $\geq 2\%$  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:
  - *Simvastatin*: Avoid concomitant use of NEXLETOL with simvastatin greater than 20 mg.
  - *Pravastatin*: Avoid concomitant use of NEXLETOL with pravastatin greater than 40 mg.
- Use in Specific Populations
  - *Pregnancy*: Based on mechanism of action, may cause fetal harm.
  - *Lactation*: Breastfeeding is not recommended with NEXLETOL.

Patients or their physicians 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).

Click here to see the [full prescribing information](#) for NEXLETOL™ (bempedoic acid) tablet.

### **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 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.

### **Important Safety Information**

- 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  $\geq 2\%$  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 great than 20 mg
  - *Pravastatin*: Avoid concomitant use of NEXLIZET with pravastatin greater than 40 mg.
  - *Cyclosporine*: Monitor cyclosporine concentrations in patients receiving NEXLIZET and cyclosporine.
  - *Fibrates*: If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, consider alternative lipid-lowering therapy.
- Use in Specific Populations
  - *Pregnancy*: Based on mechanism of action, may cause fetal harm.
  - *Lactation*: Breastfeeding is not recommended with NEXLIZET.

Click here to see the [full prescribing information](#) for NEXLIZET™ (bempedoic acid and ezetimibe) tablet. Patients or their physicians 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 ESPRMD).

## **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 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<sup>1</sup>. In the United States, more than 50 percent of atherosclerotic cardiovascular disease (ASCVD) patients and heterozygous familial hypercholesterolemia (HeFH) patients who are not able to reach their guideline recommended LDL-C levels with statins alone need less than a 40 percent reduction to reach their LDL-C threshold goal<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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