

# Esperion Announces Commercial Availability of the NEXLETOL™ (bempedoic acid) Tablet and Pledges a Conscientious Launch During Unprecedented Moment in Healthcare

March 30, 2020

- First Oral, Once-Daily, Non-Statin LDL-Cholesterol Lowering Medicine in the U.S. in Nearly 20 Years for Indicated Patients Awaiting a New Option –
  Esperion Aims to Set New Industry Standard by Pricing NEXLETOL for Patient Affordability and Access –
- Company Repurposes Healthcare Provider Education and Support Material Encouraging Remote Education and Virtual Visits with our Lipid Experts
  During This Extraordinary Time —

ANN ARBOR, Mich., March 30, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) announced today that NEXLETOL™ (bempedoic acid) tablet, an oral, once-daily, non-statin LDL-Cholesterol (LDL-C) lowering medicine is now available in U.S. pharmacies. Esperion is committed to respecting the valuable time of healthcare providers in the current environment while also remaining steadfast to the patients awaiting new options to manage their bad cholesterol.

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.

"We are dedicated to providing patient access and affordability for the millions of patients continuing to struggle with their bad cholesterol especially during this unique time," said Mark Glickman, chief commercial officer of Esperion. "There were no new oral non-statin options for LDL-C lowering in nearly 20 years, and we know NEXLETOL is an anticipated solution for the appropriate patients that have not been able to reach their LDL-C goals and could benefit from NEXLETOL immediately."

Elevated LDL-C contributes to a buildup of fat in the arteries and is a key risk factor for cardiovascular disease, which is the leading cause of death in the U.S. and one of the most expensive chronic conditions. Despite standard of care treatments, including statin therapy, 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.

Esperion is committed to providing oral, once-daily non-statin LDL-C lowering treatment options that are affordable and accessible. NEXLETOL is available at a list price of around \$10 per day to payers. Eligible patients with commercial drug insurance coverage for NEXLETOL may pay as little as \$10 per fill, up to a 3-month supply. For those that need NEXLETOL, Esperion's mission is to considerably reduce cost as a burden for patients as they strive to achieve their long-term LDL-C goals.

"We recognize this is an incredibly demanding time for healthcare providers and are committed to respecting their time by adapting our introduction of NEXLETOL to provide the most flexible learning approach possible," Glickman said. "We are convinced as the healthcare community begins to discover the benefits of this medicine for their patients, it will become clear the immediate future should be brighter for many people battling bad cholesterol."

There are several ways to reach us based on your preference. Healthcare providers with questions regarding NEXLETOL can call 833-377-7633 (833 ESPRMED) and select OPTION 1 where our medical information team is available from Monday-Friday (except holidays) 8:00 a.m. to 8:00 p.m. Eastern Time to assist you. If preferred, you can submit your questions by email, via <a href="mailto:medinfo@esperion.com">medinfo@esperion.com</a>. If interested in speaking with a sales representative from Esperion please call 833-377-7633 (833 ESPRMED) and select OPTION 2. Press OPTION 3, for Copay questions. Visit <a href="https://www.esperion.com">www.esperion.com</a> for general information about our company.

# 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:
  - Hyperuricemia: 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: 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:
  - 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 <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088 or report side effects to Esperion at 833-377-7633 (833 ESPRMED).

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

#### **CLEAR Cardiovascular Outcomes Trial**

The effect of bempedoic acid 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 over 14,000 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 <a href="https://www.esperion.com">www.esperion.com</a> and follow us on Twitter at <a href="https://www.twitter.com/EsperionInc">www.twitter.com/EsperionInc</a>.

## **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 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) Fox KM, et al. Treatment patterns and low-density lipoprotein cholesterol (LDL-C) goal attainment among patients receiving high- or moderate-intensity statins. Clin Res Cardiol 2018; 107: 380–388.

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