Esperion Announces Commercial Availability of NEXLIZET™ (bempedoic acid and ezetimibe) Tablets and Ushers in New Era of Oral Combination Medicine for LDL-Cholesterol Lowering

June 4, 2020

– First-Ever Non-Statin Combination Medicine, Providing 38 Percent Mean LDL-C Lowering –
– Esperion Aims to Set New Industry Standard by Pricing NEXLIZET for Patient Affordability and Access with Minimal to No Paperwork Requirements for Health Care Providers –
– Launch Date Accelerated by One Month at Health Care Providers Request –

ANN ARBOR, Mich., June 04, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) announced today that NEXLIZET™ (bempedoic acid and ezetimibe) tablets, the first approved oral, once-daily, non-statin LDL-Cholesterol (LDL-C) lowering combination medicine is now available in U.S. pharmacies. NEXLIZET provides significant efficacy with a positive risk-benefit profile and requires minimal to no paperwork for health care providers (HCPs) during this incredibly demanding and unprecedented time when patients start to re-focus on their long-term health needs and underlying conditions. Additionally, NEXLIZET is introduced with broad payer coverage for both eligible insured patients and those with Medicare Part D at an affordable price and co-pay.

As the first non-statin LDL-C lowering fixed dose combination medicine ever approved by the FDA, NEXLIZET offers healthcare providers the opportunity to simultaneously use complementary medicines in a single oral tablet with no titration. 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 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 Preventive Cardiology.*

“I am excited to have a newly approved statin add-on combination medicine. “NEXLIZET offers substantial LDL-lowering efficacy with a positive risk-benefit profile. It is a single pill with a single co-pay and is indicated for patients struggling to reach their cholesterol goals despite diet plus maximally-tolerated statin therapy,” said Eliot A. Brinton, MD, FAHA, FNLA, FACE, President of the Utah Lipid Center, past-President of the American Board of Clinical Lipidology and advisor to Esperion. “I anticipate that NEXLIZET will become a go-to option after statins because it provides double the LDL-C lowering efficacy of ezetimibe, without the need for titration. It also has favorable safety and excellent access at a low cost for patients.”

“More than ever, health care providers are seeking more options to help the millions of patients reach their cholesterol goals and address their long-term health needs,” said Mark Glickman, chief commercial officer of Esperion. “NEXLIZET is highly anticipated, so we are responding by accelerating its commercial availability. HCPs can easily prescribe NEXLIZET because it does not require any extra paperwork or injection training, potentially limiting the need for additional human contact during these unique times.”

NEXLIZET is the second commercially available product from Esperion. The company introduced NEXLETOL™ (bempedoic acid) Tablets on March 30, 2020 at the height of the Covid-19 pandemic and was the first new oral, once daily non-statin medicine approved in nearly 20 years for indicated patients. Esperion is committed to providing oral, once-daily non-statin LDL-C lowering treatment options that are affordable and accessible. Eligible patients with commercial drug insurance coverage may pay as little as $10 per fill, up to a 3-month supply. For those that need NEXLIZET or 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.

There are several ways to learn about NEXLIZET based on your preference. Healthcare providers with questions regarding NEXLIZET 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 medinfo@esperion.com. 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 www.esperion.com for general information about our company.

NEXLIZET™ (bempedoic acid and ezetimibe) Tablets

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.

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 (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, and 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** or call 1-800-FDA-1088 or report side effects to Esperion at 833-377-7633 (833 ESPRMED).

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 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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