

NEXLETOL® (bempedoic acid) Tablets Highlighted in EAS 2020 Presentation of Analysis Demonstrating Significant Cholesterol Lowering in People with Familial Hypercholesterolemia

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- NEXLETOL® exhibited a 22% mean reduction in LDL-C levels in patients with Heterozygous Familial Hypercholesterolemia at week-12 -

ANN ARBOR, Mich., Oct. 07, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced results of pooled data from two of the company's Phase 3 trials were presented at the virtual 88th Annual Congress of the European Atherosclerosis Society (EAS 2020). Both trials demonstrated significant lowering of cholesterol by NEXLETOL® (bempedoic acid) Tablets in people with the most common form of inherited high cholesterol.^{1,2} The data from this pooled analysis of over 3,000 patients with Atherosclerotic Cardiovascular Disease (ASCVD) and/or Heterozygous Familial Hypercholesterolemia (HeFH) were presented by Professor P. Barton Duell, Professor of Medicine, Oregon Health & Science University and member of Esperion's Phase 3 Steering Committee.

During the EAS presentation, it was highlighted that NEXLETOL significantly reduced low-density lipoprotein cholesterol (LDL-C) by a mean of 22% compared to placebo in people with HeFH taking maximally tolerated statins with or without other lipid-lowering therapies (LLTs). Mean LDL-C reductions from baseline to week 12 were also significantly greater with NEXLETOL vs placebo for patients without HeFH (placebo-corrected difference: -18%). Consistent with previous clinical studies, NEXLETOL was generally well tolerated in people with HeFH, with no new safety signals seen.¹ HeFH is a common condition affecting over 30 million people worldwide who are at increased risk of a cardiovascular event such as a heart attack.³ Additionally, it was shown that many patients with HeFH do not achieve adequate LDL-C lowering despite multidrug therapy, demonstrating a great need for efficacious non-statin LDL-C-lowering medications.

Approved earlier this year by the U.S. Food and Drug Administration (FDA) and launched at the height of the COVID-19 pandemic, NEXLETOL is the first oral, once-daily, non-statin LDL-C lowering medicine available to indicated patients in nearly 20 years. The approval of NEXLETOL was supported by a global pivotal Phase 3 LDL-C lowering program conducted in more than 3,000 patients with ASCVD and/or HeFH. In these studies, NEXLETOL provided an average of 18% placebo corrected LDL-C lowering when used with moderate or high intensity statins. The most common (incidence ≥ 2% and greater than placebo) adverse reactions were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia and elevated liver enzymes. NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not yet been determined. Please see important safety information below.

"Untreated HeFH increases the risk of ASCVD 10-20 fold compared to people who do not have HeFH, primarily as a consequence of severe lifelong hypercholesterolemia," said Professor P. Barton Duell, Professor of Medicine, Oregon Health & Science University, Portland, OR USA, who presented the data at EAS 2020. "Aggressive LDL-C lowering is the key intervention to prevent ASCVD events in patients with HeFH, but this is often difficult to achieve, so new LDL-C lowering therapies are needed."

"We know that patients with HeFH face increased risk for ASCVD, yet according to the Familial Hypercholesterolemia Foundation, 90 percent of these patients remain undiagnosed," said Ashley Hall, Chief Development Officer, Esperion. "There is a growing body of evidence demonstrating that NEXLETOL can be a part of the solution to reduce LDL-C levels in the millions of patients with this genetic condition, once they are aware of the problem."

To learn more about Familial Hypercholesterolemia, we encourage you to visit the FH Foundation, a patient-centered nonprofit organization focused on increasing awareness of HeFH at www.thefhfoundation.org.

The 88th EAS Congress is a virtual event due to travel restrictions. For more information please visit <https://eas2020.com/>.

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. 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 $\geq 2\%$ 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:
 - 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.](#)

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.² 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 goal³.

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, Esperion's expectations for the market for medicines to lower LDL-C and the impact of bempedoic acid tablet in such market, including the commercial launch and the market adoption of bempedoic acid 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

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¹ Barton Duell P, *et al.* Efficacy and Safety of Bempedoic Acid in Patients with Heterozygous Familial Hypercholesterolemia: Analysis of Pooled Patient-level Data From Phase 3 Clinical Trials. Presentation at the European Atherosclerosis Society 88th Congress Virtual Meeting. October 2020.

² Di Taranto, MD, *et al.* Familial hypercholesterolemia: A complex genetic disease with variable phenotypes. *European Journal of Medical Genetics*. 2020. 63;4:103831.

³ McGowan, MP, *et al.* Diagnosis and treatment of heterozygous familial hypercholesterolemia. *Journal of the American Heart Association*. 2019. 8;24:e013225.

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