NEXLETOL® (bempedoic acid) Tablets Highlighted at AHA 2020 with Presentations of Analyses Demonstrating Significant Low-Density Lipoprotein Cholesterol (LDL-C) Lowering vs. Placebo in Phase 3 Study Subgroups

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- Significant mean reduction of 26.5% in LDL-C with bempedoic acid vs. placebo in pooled analysis of people who cannot tolerate statins[1] -

- Analysis by sex showed bempedoic acid significantly lowered LDL-C at week 12 in males and females vs. placebo[2] -*

ANN ARBOR, Mich., Nov. 13, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced results of pooled data from four of the company's Phase 3 trials were presented at the virtual American Heart Association Scientific Sessions 2020 (AHA 2020). Both analyses demonstrated significant lowering of low-density lipoprotein cholesterol (LDL-C) by NEXLETOL® (bempedoic acid) Tablets by week 12 in specific subgroups, including people who cannot tolerate statins and females, compared to placebo.

"Women are half of the population, and nearly 10 million patients in the U.S. with high LDL-C levels are not on statins due to tolerability issues,[3] yet these groups have been underrepresented in previous medical research,[4]" said Ashley Hall, Chief Development Officer for Esperion. "Our goal at Esperion is lipid management for everybody, and these analyses show significant LDL-C efficacy and acceptable safety for NEXLETOL in these subgroups."

In "Efficacy and Safety of Bempedoic Acid in Patients Who Cannot Tolerate Any Dose of a Statin: Pooled Analysis from Phase 3 Clinical Trials," (Abstract #P2139) data from a subgroup of more than 580 patients not receiving any dose of a statin showed a significant mean reduction of 26.5% ($p< 0.001$) in LDL-C by week 12 with NEXLETOL vs. placebo. NEXLETOL was generally well tolerated, with treatment-emergent adverse events (TEAEs) comparable across the bempedoic acid and placebo groups.[1]

The poster "Efficacy and Safety of Bempedoic Acid by Sex: Pooled Analyses From Phase 3 Trials" (Abstract #P742) showed NEXLETOL significantly lowered LDL-C at week 12 in both sexes compared with placebo for a pooled population of more than 3,600 patients across four studies. LDL-C lowering was numerically greater in females compared with males across both pools of the study: The placebo-corrected mean reduction was 27.7% for females vs. 22.1% for males (interaction p value=0.079) in the statin-intolerant pool, and 21.2% for females vs. 17.4% for males (interaction p value=0.044) in the pool of patients with atherosclerotic cardiovascular disease (ASVCD) and/or heterozygous familial hypercholesterolemia (HeFH) who were receiving background maximally tolerated statin. Bempedoic acid was generally well tolerated by both sexes.[2]

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.

*Note: Esperion strives to be inclusive in our both research and our language, and we follow the language guidance outlined in "Reporting Sex, Gender, or Both in Clinical Research?" from The Journal of the American Medicine Association (JAMA).

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:
- 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.

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 commercialization plans for bempedoic acid tablet. 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] Laufs U, et al. Efficacy and Safety of Bempedoic Acid in Patients who Cannot Tolerate Any Does of a Statin: Pooled Analysis from Phase 3 Clinical Trials. Presentation at the American Heart Association Virtual Scientific Sessions 2020. November 2020.

[2] Goldberg AC, et al. Efficacy and Safety of Bempedoic Acid by Sex: Pooled Analyses From Phase 3 Trials. Presentation at the American Heart Association Virtual Scientific Sessions 2020. November 2020.

[3] ZS Associates primary and secondary research, Sep-Oct 2018. Primary research N = 350 healthcare practitioners

[4] J Tamargo, G Rosano, T Walther, J Duarte, A Niessner, JC Kaski, C Ceconi, H Drexel, K Kjeldsen, G Savarese, C Torp-Pedersen, D Atar, BS Lewis, S Agewall, Gender differences in the effects of cardiovascular drugs, *European Heart Journal - Cardiovascular Pharmacotherapy*, Volume 3, Issue 3, July 2017, Pages 163–182, https://doi.org/10.1093/ehjcvp/pvw042

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