Simulation Model based on Pooled Phase 3 Data Demonstrating NEXLETOL® (bempedoic acid) Tablet's Potential to Lower Absolute Cardiovascular Event Risk Presented at ACC.21

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- Patients with atherosclerotic cardiovascular disease (ASCVD) on maximally tolerated statins and treated with NEXLETOL predicted to experience a 3.3% further absolute reduction in 10-year cardiovascular event risk compared with statins alone (p<0.0001) -

- Patients considered intolerant to statin therapy treated with NEXLETOL predicted to experience a further 6.0% absolute reduction in 10-year cardiovascular event risk compared with placebo (p<0.0001) -

- Esperion's CLEAR Outcomes landmark cardiovascular outcomes trial (CVOT), evaluating bempedoic acid's impact on cardiovascular risk in statin-intolerant patients with ASCVD, is ongoing -

ANN ARBOR, Mich., May 15, 2021 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced the poster presentation of an analysis applying the validated Second Manifestations of ARTerial disease (SMART) model[1] and Cholesterol Treatment Trialists' (CTT) coefficient [2] to pooled Phase 3 data to assess the potential of NEXLETOL® (bempedoic acid) Tablet to reduce cardiovascular event risk at the American College of Cardiology's 70 th Annual Scientific Session (ACC.21).

The poster, entitled "Estimated Cardiovascular Benefits of Bempedoic Acid in Patients With Established Cardiovascular Disease," was presented by Dr. Laura H. Gunn, Associate Professor, Department of Public Health Sciences, and Affiliate Faculty, School of Data Science, University of North Carolina at Charlotte, and Honorary Research Fellow, School of Public Health, Imperial College London. Using the validated SMART model, Dr. Gunn and co-authors simulated the baseline 10-year risk score for major adverse cardiovascular events (MACE) for more than 3,000 patients with ASCVD.[3] The data were pooled from four completed pivotal Phase 3 studies of bempedoic acid, where change in low-density lipoprotein cholesterol (LDL-C) at Week 12 was the primary endpoint.[4-7] Patients were stratified into two groups: those taking maximally tolerated statins and those considered statin intolerant. Using observed changes in LDL-C at week 12, researchers applied the CTT coefficient to calculate an estimated 10-year cardiovascular event relative risk reduction rate. By applying the resulting relative risk reduction rate to the baseline SMART risk score, researchers were able to estimate the new absolute risk for each patient.[3]

In this poster presentation, among the group of patients taking maximally tolerated statins, baseline 10-year cardiovascular event risk based on the SMART model was estimated at 25.9% for those treated with bempedoic acid and 26.6% for those who received placebo. In the statin intolerant group, baseline 10-year cardiovascular event risk based on the SMART model was estimated at 31.9% for those treated with bempedoic acid and 30.9% for those who received placebo.[3] The simulation predicted that patients treated with bempedoic acid on top of maximally tolerated statins would experience a 3.3% further absolute reduction in 10-year cardiovascular event risk compared with statins alone (p< 0.0001).[3-5] For statin-intolerant patients, defined as patients receiving no more than low-dose statin including no statin, the simulation predicted a further 6.0% absolute reduction in 10-year cardiovascular event risk with bempedoic acid compared with placebo (p< 0.0001).[3,6-7]

"Using the well-established relationship between LDL-C lowering and ASCVD risk reduction, as well as validated models, these data from ASCVD patients in our Phase 3 pivotal trials estimate a significant risk reduction in major cardiovascular events with NEXLETOL treatment," said Ashley Hall, chief development officer of Esperion. "These data reinforce the potential incremental cardiovascular benefits of LDL-C lowering in high-risk ASCVD patients."

"Published analyses with validated models like SMART and CTT can help inform treatment decisions now, ahead of clinical data availability," said Professor Kausik K. Ray, MBChB, MD, Mphil, FRCP; Professor of Public Health at the School of Public Health, Imperial College London; Consultant Cardiologist; member of the CLEAR Outcomes steering committees; and senior author of the ACC presentation. "The data in this analysis are encouraging, particularly for physicians and their patients with ASCVD who want to lower cardiovascular event risk but have had difficulty managing LDL-C."

Based on readily available baseline characteristics, the SMART risk calculation estimates an individual ASCVD patient's 10-year risk of cardiovascular death, stroke, or myocardial infarction, also known as three-point MACE. The SMART risk score was developed based on data from a population of 5,788 patients who were part of the SMART study in the Netherlands during a 14-year period.[1] The model was validated and updated based on pooled data from more than 18,000 patients across four continents.[8] Because cardiovascular event risk can vary greatly across patients with previous cardiovascular disease, the SMART risk score allows physicians and patients to better estimate individual risk to tailor treatment and follow up.

The impact of NEXLETOL on cardiovascular morbidity and mortality has not been determined is currently being investigated as part of the ongoing CLEAR Outcomes study in more than 14,000 statin-intolerant patients with or at high risk for ASCVD.[9]

The 2020 approval of NEXLETOL in the U.S. was supported by a global pivotal Phase 3 LDL-C-lowering program conducted in more than 3,000 patients with ASCVD and/or heterozygous familial hypercholesterolemia (HeFH) on maximally tolerated statins. In these studies, NEXLETOL provided an average of 18% placebo-corrected LDL-C lowering at week 12 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. Please see important safety information below.

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, and by the European Commission in April 2020 under the name NILEMDO® (bempedoic acid) with a different label.[10] Daiichi Sankyo Europe has licensed exclusive commercialization rights to bempedoic acid in the European Economic Area, Switzerland and Turkey from Esperion, and is the full marketing authorization holder in these territories.

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 ≥ 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

ESPERION is The Lipid Management Company. Our goal is lipid management for everybody, that's why we work hard to make our medicines easy to get, easy to take and easy to have. We discover, develop and commercialize innovative medicines and combinations to lower cholesterol, especially for patients whose needs aren't being met by the status quo. Our entrepreneurial team of industry leaders is inclusive, passionate and resourceful. We are singularly focused on managing cholesterol so you can improve your health easily. 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

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[10] European Medicines Agency. NILEMDO® Summary of Product Characteristics. Last accessed May 2021: https://www.ema.europa.eu/en/documents/product-information/nilemdo-epar-product-information_en.pdf.

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