

Esperion Presents Important New Data from CLEAR Outcomes at ACC.24 Highlighting Value of NEXLETOL® (bempedoic acid) Tablets in Diverse Populations Including Women, Hispanics/Latinx and Patients with Obesity

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- Patients With Obesity Who Took NEXLETOL Were 23% Less Likely to Experience a Major Adverse Cardiovascular Event (MACE-4) Compared to
 Placebo
 - NEXLETOL Demonstrated Clinical Benefit in Historically Underrepresented Groups: Women and Hispanic/Latinx Patients With and Without Cardiovascular Disease (CVD) –
 - CLEAR Outcomes Sets New Standards for Diversity and Inclusion with Enrollment of 48% Women and 17% Hispanic/Latinx Patients -

ANN ARBOR, Mich., April 07, 2024 (GLOBE NEWSWIRE) -- Esperion (Nasdaq: ESPR) today announced the presentation of results from three pre-specified subgroups from CLEAR Outcomes at the 2024 American College of Cardiology's Annual Scientific Sessions (ACC.24): women, Hispanic/Latinx, and patients with obesity. These results align with the American College of Cardiology's robust diversity, equity and inclusion programs to drive cultural change across the profession and ensure that the cardiovascular care team is as diverse as the patients they care for and that all patients are represented in cardiovascular research. The data also reinforce the mission of the ACC: transforming cardiovascular care for all.

"These analyses showcase the benefit of NEXLETOL and the bempedoic acid component of NEXLIZET® (bempedoic acid and ezetimibe) Tablets in several important yet often understudied populations," said JoAnne Foody, MD, FACC, FAHA, Chief Medical Officer of Esperion. "Bempedoic acid is the only FDA approved non-statin LDL lowering therapy to demonstrate reductions in MACE in both primary prevention and secondary prevention patient populations. In women and Hispanic/Latinx patients with or at risk for CVD, bempedoic acid decreased LDL-cholesterol (LDL-C) and inflammatory markers, did not worsen glucose or weight, and in turn reduced the risk of major adverse cardiovascular events (MACE). These results continue to reinforce the importance of early and aggressive LDL-C lowering in order to reduce cardiovascular events, underscoring the paradigm of 'even lower, even earlier is even better."

Harold Bays, MD, FOMA, FTOS, FACC, FNLA, FASPC, Louisville Metabolic and Atherosclerosis Research Center, University of Louisville School of Medicine, presented "Bempedoic Acid for Prevention of Cardiovascular Events in Patients with Obesity: A CLEAR Outcomes Subset Analysis." Nearly 45% of patients in CLEAR Outcomes had obesity (body mass index greater than or equal to 30 kg/m²) at the start of the study. In this analysis, patients with obesity treated with bempedoic acid were 23% less likely to experience MACE-4 (cardiovascular (CV) death, nonfatal myocardial infarction (MI), nonfatal stroke, or coronary revascularization) compared to placebo. "Given that obesity is an epidemic and a risk factor for cardiovascular disease, clinicians and their patients can make more informed therapeutic decisions upon knowing the CVD outcomes among patients with obesity who receive specific cardiometabolic therapies," said Dr. Bays.

Fatima Rodriguez, MD, MPH, Stanford Medicine, presented "Characteristics and Outcomes for Hispanic/Latinx Participants with Statin Intolerance Receiving Bempedoic Acid: Results from a CLEAR Outcomes Pre-Specified Subgroup Analysis." Hispanic/Latinx patients represented almost 17% of those enrolled in the CLEAR Outcomes trial. The Hispanic population is the largest ethnic minority in the U.S., yet is a population historically underrepresented in clinical trials. This subgroup analysis showed a similar 21% lowering of LDL-C with bempedoic acid compared to placebo in Hispanic/Latinx and non-Hispanic/Latinx alike, confirming the CV risk reduction benefit of LDL-C lowering and the high tolerability of bempedoic acid, regardless of ethnicity. This analysis was published in the *Journal of the American College of Cardiology (JACC)*.

Leslie Cho, MD, Cleveland Clinic, presented "Characteristics and Outcomes for Statin-Intolerant Women Receiving Bempedoic Acid in the CLEAR Outcomes Trial." CLEAR Outcomes is notable for the highest percentage enrollment (48%) of females among contemporary lipid-lowering cardiovascular outcomes trials. In the CLEAR Outcomes trial, the risk of MACE-4 was similarly reduced for women treated with bempedoic acid compared to placebo, thus confirming its LDL-C lowering benefit on CV risk reduction, regardless of sex. This analysis was simultaneously published in Circulation.

INDICATION

NEXLIZET and NEXLETOL are indicated:

- The bempedoic acid component of NEXLIZET and NEXLETOL is indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
 - o established cardiovascular disease (CVD), or
 - o at high risk for a CVD event but without established CVD.
- As an adjunct to diet:
 - NEXLIZET, alone or in combination with other LDL-C lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH.
 - NEXLETOL, in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH.

NEXLIZET and NEXLETOL are contraindicated in patients with a prior hypersensitivity to bempedoic acid or ezetimibe or any of the excipients. Serious hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported.

Hyperuricemia: Bempedoic acid, a component of NEXLIZET and NEXLETOL, may increase blood uric acid levels, which may lead to gout. Hyperuricemia may occur early in treatment and persist throughout treatment, returning to baseline following discontinuation of treatment. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.

Tendon Rupture: Bempedoic acid, a component of NEXLIZET and NEXLETOL, is associated with an increased risk of tendon rupture or injury. Tendon rupture may occur more frequently in patients over 60 years of age, in those taking corticosteroid or fluoroquinolone drugs, in patients with renal failure, and in patients with previous tendon disorders. Discontinue NEXLIZET or NEXLETOL at the first sign of tendon rupture. Consider alternative therapy in patients who have a history of tendon disorders or tendon rupture.

The most common adverse reactions in the primary hyperlipidemia trials of bempedoic acid, a component of NEXLIZET and NEXLETOL, in ≥2% of patients and greater than placebo were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.

Adverse reactions reported in ≥2% of patients treated with ezetimibe (a component of NEXLIZET) and at an incidence greater than placebo in clinical trials were upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, fatigue, and influenza.

In the primary hyperlipidemia trials of NEXLIZET, the most commonly reported adverse reactions (incidence ≥3% and greater than placebo) observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, were urinary tract infection, nasopharyngitis, and constipation.

The most common adverse reactions in the cardiovascular outcomes trial for bempedoic acid, a component of NEXLIZET and NEXLETOL, at an incidence of ≥2% and 0.5% greater than placebo were hyperuricemia, renal impairment, anemia, elevated liver enzymes, muscle spasms, gout, and cholelithiasis.

Discontinue NEXLIZET or NEXLETOL when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. Because of the potential for serious adverse reactions in a breast-fed infant, breastfeeding is not recommended during treatment with NEXLIZET or NEXLETOL.

Report pregnancies to Esperion Therapeutics, Inc. Adverse Event reporting line at 1-833-377-7633.

Esperion Therapeutics

At Esperion, we discover, develop, and commercialize innovative medicines to help improve outcomes for patients with or at risk for cardiovascular and cardiometabolic diseases. The status quo is not meeting the health needs of millions of people with high cholesterol – that is why our team of passionate industry leaders is breaking through the barriers that prevent patients from reaching their goals. Providers are moving toward reducing LDL-cholesterol levels as low as possible, as soon as possible; we provide the next steps to help get patients there. Because when it comes to high cholesterol, getting to goal is not optional. It is our life's work. For more information, visit esperion.com and esperion.com and follow us on X at twitter.com/Esperion.com and follow us on X at twitter.com/Esperion.com and follow us on X at

CLEAR Cardiovascular Outcomes Trial

CLEAR Outcomes is part of the CLEAR clinical research program for NEXLETOL[®] (bempedoic acid) Tablet and NEXLIZET[®] (bempedoic acid and ezetimibe) Tablet. The CLEAR Program seeks to generate important clinical evidence on the safety and efficacy of bempedoic acid, a first in a class ATP citrate lyase inhibitor contained in NEXLETOL and NEXLIZET and its potential role in addressing additional critical unmet medical needs. More than 60,000 people will have participated in the program by the time of its completion. The CLEAR Program includes 5 label-enabling Phase III studies as well as other key Phase IV studies with the potential to reach more than 70 million people with or at risk for CVD based on elevated LDL-C.

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 marketing strategy and commercialization plans, current and planned operational expenses, future operations, commercial products, clinical development, including the timing, designs and plans for the CLEAR Outcomes study and its results, plans for potential future product candidates, financial condition and outlook, including expected cash runway, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. 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, the net sales, profitability, and growth of Esperion's commercial products, clinical activities and results, supply chain, commercial development and launch plans, the outcomes and anticipated benefits of legal proceedings and settlements, 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.

Esperion Contact Information:

Investors: Alexis Callahan investorrelations@esperion.com (406) 539-1762

Media: Tiffany Aldrich <u>corporateteam@esperion.com</u> (616) 443-8438