Partners Announce TRANSFORM Trial to Evaluate Personalized Heart Disease Care Strategies at American Heart Association 2023

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– Data from Randomized Control Trial Will Advance Evidence for Evaluation and Treatment of Heart Disease by Studying Actual Disease: Atherosclerosis –

ANN ARBOR, Mich., Nov. 11, 2023 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) announced participation in the TRANSFORM trial at the American Heart Association's (AHA) 2023 Scientific Sessions. TRANSFORM is a randomized control trial – sponsored by Cleerly – that aims to enroll 7,500 patients who have pre-diabetes, type 2 diabetes, or metabolic syndrome and have no symptoms of heart disease. TRANSFORM aims to prove that a personalized care strategy based on a Cleerly analysis of a patient's actual disease state is better than traditional care based on typical risk factors for the primary prevention of cardiovascular events.

For TRANSFORM, Esperion is providing in-kind support of NEXLIZET® (bempedoic acid and ezetimibe) Tablet, which reduces low-density lipoprotein (LDL) cholesterol in adults. Other partners for TRANSFORM include:

- American Heart Association - Providing educational materials (Life's Essential 8) as part of Cleerly's membership in the Technology and Innovator's Network
- Agepha Pharmaceuticals - Providing in-kind support of LODOCO, which reduces coronary inflammation
- Cleerly - Trial sponsor providing Cleerly software to analyze patients' coronary computed tomography angiography (CCTA) scans and Cleerly's investigational plaque staging system
- CPC Clinical Research - Academic research organization serving as the clinical, data and statistical coordination center for the trial
- Heartbeat Health - A virtual cardiology provider for the trial
- Lexicon Pharmaceuticals - Providing in-kind support of Inpefa, which significantly reduces the risk of death and hospitalization/urgent visits to the doctor for heart failure
- Academic Leadership:
    - Study Chair Deepak Bhatt, MD, MPH, FACC, FAHA, FESC, MSCAI, Director of Mount Sinai Heart; Dr. Valentin Fuster Professor of Cardiovascular Medicine, Icahn School of Medicine at Mount Sinai Health System
    - Co-Chair David Maron, MD, C.F. Rehnborg Professor and Professor of Medicine; Director, Stanford Prevention Research Center, Stanford University School of Medicine
    - Co-Chair Marc Bonaca, MD, MPH, FAHA, FACC, Executive Director of CPC Clinical Research, William R. Hiatt Endowed Chair in Cardiovascular Research, Professor of Medicine; Cardiology & Vascular Medicine and Director of Vascular Research, University of Colorado School of Medicine

"We are thrilled to start the TRANSFORM trial, which we believe will be a landmark study to demonstrate how a personalized care strategy, fueled by AI, can revolutionize the way we think about the prevention of cardiovascular events," said James K. Min, MD, FACC, FESC, MSCCT, Founder and CEO of Cleerly. "By focusing on the individual's actual coronary artery disease, rather than just risk factors, we aim to prevent heart attacks. We look forward to the progression of this trial with our partners and the results in coming years."

"Esperion is excited to collaborate with these nationally recognized partners on this groundbreaking and revolutionary study," said JoAnne Foody, MD, FACC, FAHA, Chief Medical Officer of Esperion. "Cardiovascular disease remains the number one killer of men and women worldwide, so it's critical to focus on prevention, and utilizing AI combined with observation of the disease itself is a progressive approach to preventing cardiovascular events before they happen in the first place."

TRANSFORM will enroll patients at 100-200 sites across the U.S. and treat atherosclerosis in patients with either no symptoms or a history of heart disease in order to reduce myocardial infarction (heart attacks). The trial will utilize Cleerly's investigational plaque staging system in the experimental arm to inform treatment and medication decisions made by providers.

"The TRANSFORM trial brings together the power of AI for staging coronary disease and the well-documented benefits of advanced lipid lowering, anti-thrombotic, anti-inflammatory and cardiometabolic medications to create an individual care plan for patients at risk for cardiovascular events," said Udo Hoffmann, MD, MPH, Chief Scientific Officer of Cleerly. "We are excited to partner with academic leaders, professional societies, pharmaceutical companies and healthcare providers to provide scientific proof for a new paradigm in the primary prevention of cardiovascular disease that is similar to what has been established for decades in the prevention of cancer."

Participants will be randomly assigned to the personalized care strategy or to traditional care, and all participants will undergo a CCTA scan at baseline and at 24 months. Patients assigned to traditional care will be treated by their primary care providers using available treatment guidelines, and CCTA results will be provided at the end of the study. Separately, those assigned to the personalized care strategy will have an investigational coronary artery disease (CAD) plaque staging system report for both

baseline and at 24-months, and CCTA results will be provided to the central cardiologist-led team for discussion and care planning with the patient.

“As study chair and lead investigator, I am excited to embark on the TRANSFORM trial, which we hope will showcase the transformative potential of a personalized care strategy empowered by CCTA scans and AI,” said Deepak L. Bhatt, MD, MPH, FACC, FAHA, FESC, MSCAI, Director of Mount Sinai Heart and Dr. Valentin Fuster Professor of Cardiovascular Medicine at Icahn School of Medicine at Mount Sinai. “This trial provides us the opportunity to revolutionize cardiovascular event prevention and ultimately save lives from heart disease. I eagerly anticipate the collaboration with all valued partners across this trial and the forthcoming results to help us shape the future of cardiovascular care.”

TRANSFORM trial recruitment is scheduled to close in fall 2025 and results can be expected in late 2028. For more information, please visit transformtrial.org.

INDICATION
NEXLIZET or NEXLETOL are 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.
Limitations of Use: The effect of NEXLIZET or NEXLETOL on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION
NEXLIZET is contraindicated in patients with a known hypersensitivity to ezetimibe tablets. Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported with ezetimibe, a component of NEXLIZET.
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, and may lead to the development of gout, especially in patients with a history of gout. 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 occurred within weeks to months of starting NEXLIZET or NEXLETOL. Tendon rupture may occur more frequently in patients over 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with renal failure, and patients with previous tendon disorders. Discontinue NEXLIZET or NEXLETOL at the first sign of tendon rupture. Avoid NEXLIZET or NEXLETOL in patients who have a history of tendon disorders or tendon rupture.

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

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 the 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 esperionscience.com and follow us on X at twitter.com/EsperionInc.

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