Esperion Confirms NEXLETOL™ (bempedoic acid) Tablets to be Included in Assessment of Non-statin Medicines for Hypercholesterolemia by ICER

June 12, 2020

ANN ARBOR, Mich., June 12, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today confirms it has received notice that the Institute of Clinical and Economic Review (ICER) plans to assess new non-statin medicines for hypercholesterolemia in the U.S., including the clinical cost effectiveness and value of NEXLETOL. A report completion is targeted for February 2021. ICER generally only assesses medicines that are expected to have a meaningful impact in a therapeutic area. Esperion anticipates the assessment will find the same conclusions as the extensive pricing and value work already completed and the broad and high-quality managed care coverage already achieved for NEXLETOL.

Driven by its mission of Lipid Management for Everybody, a core tenant of Esperion is to provide medicines that are both accessible and affordable to patients. With over 70% commercial and 40% Medicare Part D formulary coverage already achieved, NEXLETOL has demonstrated significant value to the health care system. The achieved formulary coverage is primarily preferred brand tiers, simplified and minimized documentation and the lowest possible patient out-of-pocket costs.

Esperion is committed to providing oral, once-daily non-statin LDL-C-lowering treatment options that are affordable and accessible. Eligible patients with commercial drug insurance coverage may pay as little as $10 per fill, up to a 3-month supply. Esperion's mission is to remove or reduce cost as a burden for patients as they strive to achieve their long-term LDL-C goals.

“The Esperion team has made patient affordability and access our top priority. Fundamental to our belief is that, if a patient cannot access or afford their medicine, they will obtain zero benefit. Along these lines, we have conducted our own extensive insights work as early as 2018, established our medicines in their own compendium class and have been working with managed care all to arrive at the cost-effective price of our medicines,” said Mark Glickman, chief commercial officer of Esperion. “Esperion is proud to be a company that is truly patient centric, which means we must prove why using our medicines will benefit them holistically, so we started with their needs in mind from the very beginning.”

ICER had previously announced in July of last year that evaluating bempedoic acid was in their potential plans for 2020. The evaluation of ICER will be ongoing over the next several months and includes several steps in which the company and key stakeholders can provide information, comment and offer any relevant assistance.

CLEAR Cardiovascular Outcomes Trial

The effect of NEXLETOL or NEXLIZET on cardiovascular morbidity and mortality has not been determined. Esperion initiated a global cardiovascular outcomes trial (CVOT) to assess the effects of bempedoic acid on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease (CVD) who are only able to tolerate less than the lowest approved daily starting dose of a statin and are considered "statin averse." The CVOT — known as CLEAR Cardiovascular Outcomes Trial — is an event-driven, global, randomized, double-blind, placebo-controlled study that completed enrollment in August 2019 of 14,032 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

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. In the United States, more than 50 percent of ASCVD patients who are not able to reach their LDL-C with statins alone need less than a 40 percent reduction to reach their LDL-C threshold.

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 and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of expanded indications for their effect on cardiovascular events, and Esperion's expectations for the market for medicines to lower LDL-C, including the commercial launch and market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination 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.

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