March 20, 2017

Esperion Announces FDA Confirmation Regarding Regulatory Pathway to Approval for an LDL-C Lowering Indication for Bempedoic Acid

- Global Pivotal Phase 3 Program Design Can Support Approval for an LDL-C Lowering Indication -
- Proposed LDL-C Lowering Indication Will Include Patients with High CVD Risk, Specifically Those with ASCVD and/or HeFH -
- On Track to Submit NDA for an LDL-C Lowering Indication by 1H 2019 -
- Conference Call and Webcast on Monday, March 20, 2017 at 8:00 a.m. Eastern Time -

ANN ARBOR, Mich., March 20, 2017 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ:ESPR), the lipid management company focused on developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today announced the U.S. Food and Drug Administration (FDA) recently confirmed that Esperion's LDL-C lowering program is adequate to support approval of an LDL-C lowering indication for bempedoic acid.

Esperion plans to submit a new drug application (NDA) by 1H 2019 for an LDL-C lowering indication based on the successful completion of the global pivotal Phase 3 program. The proposed product label would include specific language for use of bempedoic acid as an adjunct to maximally tolerated statin therapy in patients with hypercholesterolemia, specifically those at high cardiovascular disease (CVD) risk with atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH) who require additional LDL-C lowering.

"We are very pleased to have achieved clarity from FDA regarding Esperion's LDL-C lowering development program," said Tim M. Mayleben, president and chief executive officer of Esperion. "Our experienced lipid management team has worked closely with regulatory authorities and our key advisors to achieve this encouraging outcome. We continue to believe that bempedoic acid has the potential to provide physicians with a complementary and convenient oral treatment option that's cost-effective for their patients with hypercholesterolemia who require additional LDL-C lowering. We remain focused on completing the global pivotal Phase 3 program for bempedoic acid and reporting top-line results from our long-term safety and tolerability study by Q2 2018 and top-line results from our ongoing Phase 3 LDL-C lowering efficacy studies by mid-2018."

Interactions with FDA also addressed the ongoing cardiovascular outcomes trial (CVOT), **C**holesterol **L**owering via B**E**mpedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes for bempedoic acid in patients with or at high risk for CVD who are only able to tolerate less than the lowest approved daily starting dose of a statin and are considered statin intolerant. For purposes of the CVOT, agreement has been reached with FDA that the following definition of statin intolerance is acceptable for the CVOT: "the inability to tolerate two or more statins, one at the lowest approved daily starting dose, due to an adverse effect," as defined in CLEAR Outcomes. The lowest approved daily starting statin doses include an average daily dose of <5 mg rosuvastatin, <10 mg of atorvastatin, <10 mg simvastatin, <20 mg lovastatin, <40 mg pravastatin, <40 mg fluvastatin and <2 mg of pitavastatin. In CLEAR Outcomes, patients and investigators will provide written confirmation that the patient is statin intolerant and that the patient is aware of the benefits of statins in reducing the risk of cardiovascular events and death. The Company expects to submit an NDA for a cardiovascular disease risk reduction indication to the FDA and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) by 2022, upon successful completion of CLEAR Outcomes.

Global Pivotal Phase 3 Program

The Phase 3 clinical development program initiated in January 2016 with a global pivotal 52-week long-term safety and tolerability study (Study 1) in patients with hypercholesterolemia (with ASCVD and/or HeFH) at high CVD risk and whose LDL-C is not adequately controlled with current lipid-modifying therapies. Patient enrollment of more than 2,200 patients was completed in January 2017 and top-line results from this study are expected by Q2 2018. An open-label extension study (1002-050) of Study 1 was initiated in February 2017 to collect additional patient safety data.

Three additional global pivotal Phase 3 LDL-C lowering efficacy studies initiated in December 2016 and are currently enrolling patients at high CVD risk with hypercholesterolemia who are inadequately treated with current lipid-modifying therapies and require additional LDL-C lowering:

- Study 2: patients with ASCVD and/or HeFH who have LDL-C levels of ≥100 mg/dL;

- Study 3: patients who are only able to tolerate less than the lowest approved daily starting dose of their statin and considered "statin intolerant" who have LDL-C levels of ≥100 mg/dL;
- Study 4: patients on low dose or less than low dose of their statin who are taking ezetimibe who have LDL-C levels of ≥100 mg/dL.

The overall global pivotal Phase 3 program is expected to enroll approximately 3,200 patients at high CVD risk with hypercholesterolemia on optimized background lipid-modifying therapy. Top-line results from our long-term safety and tolerability study are expected by Q2 2018 with top-line results from the three LDL-C lowering efficacy studies expected by mid-2018. Submissions of an NDA to the FDA and a MAA to the EMA for an LDL-C lowering indication are expected by 1H 2019.

CLEAR Outcomes CVOT

The CLEAR Outcomes CVOT, initiated in the fourth quarter of 2016, is expected to enroll approximately 12,600 patients with hypercholesterolemia and high CVD risk at more than 600 sites in approximately 30 countries. Patients enrolling in the study will be required to have a history of, or be at high-risk for, CVD with LDL-C levels between 100 mg/dL and 190 mg/dL despite background lipid-lowering therapy, resulting in an expected average baseline LDL-C level in all patients of approximately 135 mg/dL. The CVOT is currently enrolling patients, expected to enroll over a 30-month period and on track to be well-underway by 1H 2019, when we expect to submit our LDL-C lowering indication global regulatory submissions.

The Company expects to submit an NDA for cardiovascular disease risk reduction to the FDA and a MAA to EMA by 2022, upon the successful completion of CLEAR Outcomes.

Conference Call and Webcast Information

Esperion's lipid management team will host a conference call to discuss these updates. The call can be accessed by dialing (877) 831-3840 (domestic) or (253) 237-1184 (international) five minutes prior to the start of the call and providing access code 81741000. A live, listen-only webcast of the conference call can be accessed on the investor relations section of the Esperion website at investor.esperion.com. A webcast replay of the call will be available approximately two hours after completion of the call and will be archived on the Company's website for approximately 90 days.

About Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, orally available, once-daily ACL inhibitor that has been shown to reduce cholesterol biosynthesis and lower elevated levels of LDL-C by up-regulating the LDL receptor, but may potentially reduce the occurrence of muscle-related side effects. Completed Phase 1 and 2 studies in more than 800 patients treated with bempedoic acid have produced clinically relevant LDL-C lowering results of up to 30 percent as monotherapy, approximately 50 percent in combination with ezetimibe, and an incremental 20+ percent when added to stable statin therapy.

Esperion's Commitment to Patients with Hypercholesterolemia

In the United States, 78 million people, or more than 20 percent of the population, have elevated LDL-C; an additional 73 million people in Europe and 30 million people in Japan also live with elevated LDL-C. Esperion's mission as the lipid management company is to provide patients and physicians with convenient, complementary, cost-effective, once-daily, oral therapies to significantly reduce elevated levels of LDL-C in patients inadequately treated with current lipid-modifying therapies. It is estimated that 40 million patients in the U.S. are taking statins with approximately 5-20 percent of these patients only able to tolerate less than the lowest approved daily starting dose of their statin and considered "statin intolerant." Esperion-discovered and developed, bempedoic acid is a targeted LDL-C lowering therapy in Phase 3 development. The Company has two Phase 3 products in development: 1) bempedoic acid (monotherapy) an oral, once-daily pill, and 2) an oral, once-daily fixed dose combination pill of bempedoic acid and ezetimibe (BA+EZ).

The Lipid Management Company

Esperion Therapeutics, Inc. is the lipid management company passionately committed to developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated LDL-C. 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 therapies that will make a substantial impact on reducing global CVD; the leading cause of death around the world. Bempedoic acid, the Company's lead product candidate, is a targeted therapy that has been shown to significantly reduce elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies. For more information, please visit www.esperion.com and follow us on Twitter at https://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 the regulatory approval pathway for bempedoic acid, the therapeutic potential of, and clinical development plan for, bempedoic acid, including the Company's timing, designs, plans, and announcement of results regarding its global Phase 3 long-term safety and tolerability program for bempedoic acid. Any express or implied statements contained in this press release that are not statements of historical fact, including interpretation of guidance given by the FDA, 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, changes in the FDA guidance for regulatory approval, delays or failures in the Company's studies, including risks regarding the FDA's interpretation of the Company's clinical trial results, the risk that U.S. Food and Drug Administration may require additional studies or data, that Esperion may need to change the design of its Phase 3 program, that positive results from a clinical study of bempedoic acid may not be sufficient for FDA approval or necessarily be predictive of the results of future clinical studies, particularly in different or larger patient populations, that existing cash resources may be used more quickly than anticipated, that Esperion's global Phase 3 long-term safety and tolerability program for bempedoic acid may not produce sufficient safety or tolerability results or show meaningful change in LDL-C or other key lipid measures of patients, if approved that Esperion's product could have labeling restrictions that impact its marketing and adoption, or the risk that other unanticipated developments or data could interfere with the scope of development and commercialization of bempedoic acid, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. The FDA guidance described in this release was given as of a specific date and the FDA could change its position on the clinical endpoints or other standards for review/approval. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Actual results could differ from those described therein. 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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