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Esperion Therapeutics Provides Clinical Development and Regulatory Update for Bempedoic Acid

*On track to initiate global pivotal Phase 3 studies and CVOT in the fourth quarter
Aligned with global regulatory authorities on a consistent definition of statin intolerance
Conference Call and Webcast on Tuesday, June 28, 2016 at 4:30 p.m. Eastern Time*

ANN ARBOR, Mich., June 28, 2016 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ:ESPR), a late-stage pharmaceutical company focused on developing and commercializing first-in-class oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today provided updates on the bempedoic acid (ETC-1002) clinical development program and regulatory plans. The clinical program has two major components: the global pivotal Phase 3 efficacy and safety studies, and the planned global cardiovascular outcomes trial (CVOT) in patients with elevated LDL-C levels who are unable to tolerate statins (statin intolerance). The Company intends to initiate global pivotal Phase 3 efficacy studies for LDL-C lowering in patients with hypercholesterolemia, and a CVOT specifically in statin intolerant patients who are at high risk for cardiovascular (CV) disease, in the fourth quarter of 2016.

For Europe, the Company engaged with the European Medicines Agency (EMA) resulting in alignment on the definition of statin intolerance and key design features of the global Phase 3 LDL-C lowering program and CVOT. The planned LDL-C lowering efficacy studies, together with the ongoing long-term safety and tolerability study (1002-040) initiated in January 2016, are designed to support a submission for an LDL-C lowering Marketing Authorization Application (MAA) for bempedoic acid in patients with elevated LDL-C, including statin intolerant patients, in Europe by 2019. The CVOT is designed to support a MAA submission for bempedoic acid for CV disease risk reduction in statin intolerant patients in Europe by 2022.

For the United States (U.S.), the Company engaged with the U.S. Food and Drug Administration (FDA or the Agency) resulting in alignment on the definition of statin intolerance, key design features of the CVOT, and the regulatory approval pathway for a CV disease risk reduction indication in statin intolerant patients for bempedoic acid. However, the FDA did not provide clarity on a regulatory pathway for an LDL-C lowering indication in the U.S. in statin intolerant patients at this time. The Agency indicated its position regarding an LDL-C lowering indication could be impacted by potential future changes in their view of LDL-C lowering as a surrogate endpoint or the possibility of a shift in the future standard-of-care for statin intolerant patients with elevated LDL-C levels. In the event LDL-C lowering is no longer a surrogate endpoint for initial approval in the future, Esperion would plan to submit a New Drug Application (NDA) to FDA for a CV disease risk reduction indication on the basis of a successful completion of the CVOT, which would include the results of the LDL-C lowering efficacy studies, by 2022.

"We are pleased with our discussions and engagement with the FDA and EMA on the definition of statin intolerance and key design features of our planned CVOT. Scientific advice received from EMA provided clarity on the regulatory approval pathways for both an LDL-C lowering indication and a cardiovascular disease risk reduction indication in statin intolerance for bempedoic acid in Europe," said Tim Mayleben, president and chief executive officer of Esperion Therapeutics. "Following engagement with FDA on the LDL-C lowering statin intolerance program for bempedoic acid in the U.S., the regulatory pathway for an LDL-C lowering indication is not well defined at this time due to the Agency's view of a potentially evolving landscape. However, we remain confident in our ability to recruit and treat a patient population that will continue to be relevant to care in the U.S. at the time we seek approvals for bempedoic acid. We look forward to advancing our global Phase 3 and CVOT clinical programs later this year, which we anticipate will support our future global regulatory and marketing application submissions."

Esperion Global Cardiovascular Outcomes Trial

The Company intends to initiate the planned CVOT in statin intolerant patients who are at high risk for CV disease in the fourth quarter of 2016. The global CVOT — Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (CLEAR) Outcomes — will be conducted in cooperation with the Cleveland Clinic Coordinating Center for Clinical Research (C5Research), with Steven E. Nissen, MD, Department Chair, Cardiovascular Medicine, Cleveland Clinic, serving as study chairman.

The CLEAR Outcomes trial is a randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid in statin intolerant patients who are at high risk of CV disease. The global study is expected to enroll about 12,600 patients at up to 1,000 sites in approximately 30 countries. Patients enrolled in the study will be required to have a history of, or be at high risk for, CV disease with LDL-C levels between 100 mg/dL and 190 mg/dL despite background lipid-lowering therapy. The trial will be an event-driven study with the primary efficacy endpoint of the effect of bempedoic acid versus placebo on the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, hospitalization for unstable angina, or coronary revascularization; also referred to as "five-component MACE").

"The CLEAR Outcomes study for bempedoic acid is a critical step in identifying patients who are unable to tolerate statins," said A. Michael Lincoff, MD, Director of C5Research, Vice Chairman for Research, Department of Cardiovascular Medicine, Cleveland Clinic. "This study is a well-designed and appropriately powered cardiovascular outcomes trial in these patients. We are highly confident that we will be able to identify these patients in this outcomes study. Those of us in clinical practice see these patients frequently and we need more accessible therapeutic options for them in our treatment armamentarium. As an oral therapy which provides 30 percent LDL-C lowering as monotherapy, is well-tolerated, and can easily be combined with currently available oral LDL-C lowering therapies, we hope to learn whether bempedoic acid can benefit these patients with statin intolerance."

Esperion Global Pivotal Phase 3 LDL-C Lowering Program

In the fourth quarter of 2016, the Company plans to initiate global pivotal Phase 3 efficacy studies in patients with elevated LDL-C levels, including statin intolerant patients. The global Phase 3 LDL-C lowering program is anticipated to include approximately 2,000 patients on optimized background lipid-modifying therapy with LDL-C levels of ≥ 130 mg/dL for patients without atherosclerotic cardiovascular disease (ASCVD) and ≥ 100 mg/dL for patients with ASCVD or heterozygous familial hypercholesterolemia (HeFH).

The global pivotal Phase 3 efficacy studies are expected to measure the change in LDL-C from baseline at 12 and 24 weeks. This program is also designed to produce 52 weeks of safety data, comprising an appropriately sized safety database at the time of initial MAA submission for the LDL-C lowering indication in Europe by 2019.

Esperion 2016 Anticipated Milestones and Financial Outlook

Milestone	Date
Initiate bioavailability study for Fixed Dose Combination of bempedoic acid and ezetimibe	July
Announce top-line results from high-dose statin studies (-035 and -037)	September
Initiate CLEAR Outcomes global CVOT	Q4 2016
Initiate global pivotal Phase 3 LDL-C efficacy studies	Q4 2016

Esperion expects full-year 2016 net cash used in operating activities to be between \$65 to \$75 million and its cash and cash equivalents and investment securities to be approximately \$220 million at December 31, 2016. Current cash resources are expected to be sufficient to fund operations into early 2019 and the anticipated announcement of top-line results from the global pivotal Phase 3 LDL-C lowering and long-term safety clinical studies.

Conference Call and Webcast Information

Esperion's management 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 41576970. 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, along with slides to accompany this update. 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 two weeks.

About Bempedoic Acid

Bempedoic acid is a first-in-class ACL inhibitor inhibiting cholesterol biosynthesis and works to lower elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. Phase 1 and 2 studies conducted previously in more than 700 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 24 percent when added to stable statin therapy. It is expected that bempedoic acid will provide incremental LDL-C reduction on top of currently available background lipid-regulating therapies.

Esperion's Commitment to Patients with Hypercholesterolemia

In the U.S., 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 is to provide patients and physicians with a new therapy to significantly decrease elevated levels of LDL-C, without muscle-related side effects. Esperion-discovered and developed, bempedoic acid is an oral LDL-C lowering therapy in Phase 3 development. The Company plans to develop bempedoic acid as a monotherapy as well as a fixed-dose combination with ezetimibe, with a particular focus on patients with elevated LDL-C who are unable to tolerate statin therapy. It is estimated that approximately 5-20 percent of patients who are prescribed statins are considered statin intolerant.

About Esperion Therapeutics

Esperion Therapeutics, Inc. is a late-stage pharmaceutical company focused on developing and commercializing oral therapies for the treatment of patients with elevated LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease; the leading cause of death around the world. Bempedoic acid, the Company's lead product candidate, dramatically lowers LDL-C levels and could potentially reduce elevated levels of LDL-C in patients with hypercholesterolemia, especially those that can't tolerate statins. 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 therapeutic potential of, and clinical development plan for, bempedoic acid, the Company's plans regarding its Phase 3 program and planned CVOT, in each case including estimates regarding the timing that the correlative NDA or MAA could be filed, and the Company's expected cash and liquidity position and outlook. 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 patient enrollment in the Company's studies, the risk that FDA may require additional studies or data that Esperion may need to change the design of its Phase 3 program, the impact of future changes in FDA's view of LDL-C lowering as a surrogate endpoint or standard-of-care treatment for patients with elevated LDL-C levels, that positive results from a clinical study of bempedoic acid may not 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 the planned cardiovascular outcomes trial may not demonstrate that bempedoic acid leads to cardiovascular risk reduction, or the risk that other unanticipated developments or data could interfere with the scope of development and commercialization of bempedoic, as well as other risks detailed in Esperion's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. 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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