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Bempedoic Acid Global Phase 3 Clinical Program to Include Patients on Any Statin at Any Dose

1002-035 Study Meets Primary Endpoint of Incremental LDL-C Lowering Added to Atorvastatin 80 mg
Bempedoic Acid Had No Effect on the PK of Atorvastatin and Was Observed to be Safe and Well-Tolerated
Conference Call and Webcast on October 13, 2016 at 8:00 a.m. Eastern Time

ANN ARBOR, Mich., Oct. 13, 2016 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ:ESPR), a pharmaceutical company focused on developing and commercializing oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C), today announced the bempedoic acid global pivotal Phase 3 LDL-C lowering clinical development program will include patients with hypercholesterolemia on any statin at any dose based on positive top-line results from its Phase 2 pharmacokinetics and pharmacodynamics (PK/PD) study of bempedoic acid added to atorvastatin 80 mg (1002-035), and the previously completed Phase 1 and Phase 2 studies.

Top-line results from 1002-035 demonstrated the eight-week study met its primary endpoint of greater LDL-C lowering from baseline of 22 percent (p=0.0028) with bempedoic acid 180 mg compared with placebo with all patients on a background of atorvastatin 80 mg. Bempedoic acid also demonstrated an incremental reduction of 35 percent (p=0.0020) in high-sensitivity C-reactive protein (hsCRP), an important marker of the underlying inflammation associated with cardiovascular disease. Bempedoic acid added to atorvastatin 80 mg produced no clinically relevant effects on atorvastatin PK, and appeared to be safe and well-tolerated, with no serious adverse events reported.

"With the positive clinical results of bempedoic acid added to high-dose statins, and following engagement with global regulatory agencies, we are pleased to include in our ongoing global Phase 3 program patients with elevated LDL-C levels inadequately treated with current lipid-modifying therapies, including patients on any statin at any dose," said Tim Mayleben, president and chief executive officer of Esperion Therapeutics. "Bempedoic acid has demonstrated consistent LDL-C lowering efficacy, safety, and tolerability in completed Phase 1 and Phase 2 studies, including most recently in combination with high-dose statins. We believe that bempedoic acid is well-positioned as a once-daily, oral therapy for patients with hypercholesterolemia taking maximally tolerated statin therapy and/or ezetimibe who require additional LDL-C lowering, including patients considered 'statin intolerant'. We remain keenly focused on initiating both the bempedoic acid global Phase 3 efficacy program and our cardiovascular outcomes study before year-end."

Global Pivotal Phase 3 CLEAR LDL-C Lowering Program

Prior to year-end, Esperion plans to initiate three global pivotal Phase 3 Cholesterol Lowering via BEmpedoic Acid, an ACL-inhibiting Regimen (CLEAR) LDL-C lowering efficacy studies — 1002-046, 1002-047, and 1002-048 — in patients with hypercholesterolemia who are inadequately treated with current lipid-modifying therapies.

The LDL-C lowering studies will include patients on optimized background lipid-modifying therapy, including maximally tolerated statin therapy, with LDL-C levels of ≥130 mg/dL for patients without atherosclerotic cardiovascular disease (ASCVD) and ≥100 mg/dL for patients with ASCVD and/or heterozygous familial hypercholesterolemia (HeFH). The CLEAR LDL-C lowering efficacy studies are designed to measure the change in LDL-C from baseline at 12 weeks. Top-line results from the global pivotal Phase 3 CLEAR LDL-C lowering program are anticipated in mid-2018. Submissions are expected in the first half of 2019 for a New Drug Application to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application to the European Medicines Agency (EMA) for an LDL-C lowering indication.

The proposed high-level global Phase 3 design details are included below, as well as updates to the design of the ongoing CLEAR Harmony long-term safety study. Additional design details for 1002-046, 1002-047, and 1002-048 will be made available when the studies initiate later this quarter.

- **1002-046:** 24-week study to assess the 12-week LDL-C efficacy primary endpoint of bempedoic acid 180 mg versus placebo in hypercholesterolemic patients (with or without ASCVD) not adequately treated with current lipid-modifying therapies. This study is designed to enroll 300 patients only able to tolerate less than the lowest approved daily starting dose of a statin and can be considered "statin intolerant." This study is expected to initiate before year-end.

- **1002-047:** 52-week study to assess the 12-week LDL-C efficacy primary endpoint of bempedoic acid 180 mg versus placebo in hypercholesterolemic patients (with ASCVD and/or HeFH) not adequately treated with current lipid-modifying therapies. This study is designed to enroll approximately 750 patients and is expected to initiate before year-end.

- **1002-048:** 12-week study to assess the LDL-C efficacy primary endpoint of bempedoic acid 180 mg versus placebo in hypercholesterolemic patients (with or without ASCVD) when added to ezetimibe. This study is designed to enroll approximately 225 patients and is also expected to initiate before year-end.

- **CLEAR Harmony (1002-040):** Initiated in January 2016, CLEAR Harmony is a 52-week, long-term safety study designed to enroll hypercholesterolemic patients (with ASCVD and/or HeFH) who are not adequately treated with current lipid-modifying therapies. At initiation, this study included 900 patients, but has been expanded to 1,950 patients to further support the Company's expected first half 2019 regulatory submission for an LDL-C lowering indication. As a result of the expanded enrollment, top-line results for CLEAR Harmony are now expected by mid-2018.

The global Phase 3 LDL-C lowering efficacy studies are designed to support a broad label for the use of bempedoic acid for LDL-C lowering in hypercholesterolemic patients (> 100 mg/dL) who are inadequately treated with current lipid-modifying therapies. In Europe, it is expected that there would be specific language included within the label for the use of bempedoic acid in patients who are considered "statin intolerant."

Phase 2 (1002-035) and Phase 1 (1002-037) Clinical Results Summary

The Phase 2 PK/PD eight-week, U.S.-based, multi-center, randomized, double-blind, parallel group clinical study (1002-035) evaluated 68 patients on stable atorvastatin 80 mg per day. All patients in the study received atorvastatin 80 mg for four weeks. Patients were then randomized to receive either bempedoic acid 180 mg, or placebo, for four weeks. The primary objectives of the study were to assess the LDL-C lowering efficacy of bempedoic acid versus placebo on a background of atorvastatin 80 mg, as well as multiple-dose plasma PK of atorvastatin 80 mg alone and in combination with bempedoic acid. Secondary objectives included assessment of the effect of bempedoic acid on lipid and cardiometabolic biomarkers, including hsCRP; and characterization of the tolerability and safety of bempedoic acid.

Top-line results from 1002-035 demonstrated the eight-week study met its primary endpoint of greater LDL-C lowering of 22 percent (p=0.0028) from baseline with bempedoic acid 180 mg compared with placebo with all patients on a background of atorvastatin 80 mg. There was a 13 percent reduction in LDL-C in the bempedoic acid group and a nine percent increase in LDL-C in the placebo group when added to background atorvastatin 80 mg. Bempedoic acid also demonstrated an incremental reduction of 35 percent (p=0.0020) in high-sensitivity C-reactive protein (hsCRP), an important marker of the underlying inflammation associated with cardiovascular disease. Bempedoic acid added to atorvastatin 80 mg produced no clinically relevant effects on atorvastatin PK, and appeared to be safe and well-tolerated, with no serious adverse events reported.

The Company also announced positive top-line results from its Phase 1, open-label, clinical pharmacology study (1002-037) to assess the PK levels in healthy volunteers receiving single doses of the highest doses of the most commonly prescribed statins — atorvastatin 80 mg, rosuvastatin 40 mg, simvastatin 40 mg and pravastatin 80 mg — when added to steady-state bempedoic acid 180 mg. The PK profiles demonstrated in 1002-037 were consistent with those seen in previous studies conducted with bempedoic acid, and did not increase with the highest doses of the statins tested in combination with bempedoic acid. Together, with the results of 1002-035, these data support enrollment of patients with hypercholesterolemia on any statin at any dose in the global pivotal Phase 3 CLEAR LDL-C clinical development program.

Conference Call and Webcast Details

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 98706260. 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 that reduces cholesterol biosynthesis and lowers 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 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 to 22 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 is to provide patients and physicians with a new oral therapy to significantly reduce elevated levels of LDL-C in patients inadequately treated with current lipid-modifying therapies. 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 (FDC) with ezetimibe, with a particular focus on patients inadequately treated with current lipid-modifying therapies. It is estimated that approximately 5-20 percent of patients who are prescribed statins are only able to tolerate less than the lowest approved daily starting dose of their statin ("statin intolerant").

About Esperion Therapeutics

Esperion Therapeutics, Inc. is a 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, significantly reduces 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 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 program and timing of an NDA submission for bempedoic acid, in each case including that submissions for an LDL-C lowering indication could be filed in the United States and Europe prior to the completion of a cardiovascular outcomes trial, or CVOT. 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 the Company's studies, including in patient enrollment, 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, the CVOT 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 acid, as well as other risks detailed in Esperion's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2015 and subsequently filed Quarterly Reports on Form 10-Q. 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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