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Esperion Completes Patient Enrollment in Global Pivotal Phase 3 Program for Bempedoic Acid

— Pivotal Phase 3 Top-Line Results for Bempedoic Acid Expected in the Second and Third Quarters of 2018 —
— NDA Submission for LDL-C Lowering Indication for Bempedoic Acid Planned by First Quarter 2019 —

ANN ARBOR, Mich., Oct. 02, 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 completion of patient enrollment in the global pivotal phase 3 program for bempedoic acid. Top-line results from Studies 1, 3 and 4 are expected in the second quarter of 2018, with top-line results from Study 2 expected in the third quarter of 2018. The pivotal Phase 3 program for the bempedoic acid / ezetimibe combination pill remains on track to initiate this quarter, with top-line results expected by the fourth quarter of 2018. The four Phase 3 studies comprising the global pivotal Phase 3 program for bempedoic acid along with the single Phase 3 bridging study for the combination pill are expected to support two New Drug Application (NDA) submissions for LDL-C lowering indications for the bempedoic acid / ezetimibe combination pill and bempedoic acid by the first quarter of 2019.

"There are approximately 25 million patients living with hypercholesterolemia in the U.S. and Europe who are inadequately treated with current lipid-modifying therapies, including those patients who are unable to tolerate less than the lowest approved daily starting dose of statins or who are unable to access the therapies they need," said Tim Mayleben, president and chief executive officer of Esperion Therapeutics. "The tremendous progress made by our Lipid Management Team to rapidly enroll our global pivotal Phase 3 program for bempedoic acid is a significant step forward as we continue to progress toward the goal of providing these patients and their physicians with once-daily, oral options to lower LDL-C, especially for those whose therapeutic and economic needs are not currently being met, as we approach the most eventful and transformative year yet for Esperion in 2018."

Bempedoic Acid Global Pivotal Phase 3 Program

The ongoing Phase 3 program for bempedoic acid includes four global pivotal studies that enrolled almost 3,600 high cardiovascular disease (CVD) risk patients with hypercholesterolemia and atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH), or who are high risk primary prevention, on optimized background lipid-modifying therapy and with elevated levels of LDL-C. These patients are on two distinct types of background lipid-modifying therapy: 1) patients on their maximally tolerated statin therapy, and 2) patients only able to tolerate less than the lowest approved daily starting dose (e.g., patients considered statin intolerant).

Global Pivotal Phase 3 Study 1: This 52-week long-term safety and tolerability study fully enrolled 2,230 patients with ASCVD and/or HeFH whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are taking maximally tolerated statin therapy. Top-line results are expected to be announced by the second quarter of 2018.

Global Pivotal Phase 3 Study 2: This 52-week LDL-C lowering efficacy and safety study fully enrolled 779 patients with ASCVD and/or HeFH whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are taking maximally tolerated statin therapy. Top-line results are expected to be announced by the third quarter of 2018.

Global Pivotal Phase 3 Study 3: This 24-week LDL-C lowering efficacy study fully enrolled 345 high CVD risk patients with ASCVD and/or HeFH, or who are high risk primary prevention, whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are only able to tolerate less than the lowest approved daily starting dose of a statin and considered statin intolerant. Top-line results are expected to be announced by the second quarter of 2018.

Global Pivotal Phase 3 Study 4: This 12-week LDL-C lowering efficacy study fully enrolled 227 high CVD risk patients with ASCVD and/or HeFH, whose LDL-C is not adequately controlled with current lipid-modifying therapies, including ezetimibe, and who are only able to tolerate the lowest approved daily starting dose of a statin and considered statin intolerant. Top-line results are expected to be announced by the second quarter of 2018.

Bempedoic Acid / Ezetimibe Combination

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of

cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination pill is our lead, non-statin, orally available, once-daily, LDL-C lowering therapy. Inhibition of ATP Citrate Lyase (ACL) by bempedoic acid reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Inhibition of Niemann-Pick C1-Like 1 (NPC1L1) by ezetimibe results in reduced absorption of cholesterol from the gastrointestinal tract, thereby reducing delivery of cholesterol to the liver, which in turn upregulates LDL receptors. Previously completed Phase 2 data demonstrated that this safe and well tolerated combination results in a 48 percent lowering of LDL-C, a 26 percent reduction in high sensitivity C-reactive protein (hsCRP), and may potentially be associated with a lower occurrence of muscle-related side effects.

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor, and may potentially be associated with a lower occurrence of muscle-related side effects. Completed Phase 1 and 2 studies conducted in approximately 1,200 patients and over 800 patients treated with bempedoic acid have produced clinically relevant LDL-C lowering results of up to 30 percent as monotherapy 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 are therefore considered to be statin intolerant. Esperion-discovered and developed, bempedoic acid is a targeted LDL-C lowering therapy in Phase 3 development. The company has two convenient, cost-effective, complementary, orally available, LDL-C lowering therapies in Phase 3 development: 1) a once-daily, oral bempedoic acid / ezetimibe combination pill, and 2) bempedoic acid, a once-daily, oral pill.

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 cardiovascular disease; the leading cause of death around the world. Bempedoic acid and the company's lead product candidate, the bempedoic acid / ezetimibe combination pill, are targeted therapies that have 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 therapeutic potential of, and clinical development plan for, the bempedoic acid / ezetimibe combination and bempedoic acid, including the Company's timing, designs, plans and announcement of results regarding its Phase 3 program and the Company's cash position and financial 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 the Company's studies, the 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 the bempedoic acid / ezetimibe combination and 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 Esperion's global Phase 3 program for bempedoic acid may not produce positive results, or that other unanticipated developments or data could interfere with the scope of development and commercialization of the bempedoic acid / ezetimibe combination and bempedoic acid, and the other risks detailed in Esperion's filings with the Securities and Exchange Commission. 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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