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# **Esperion Announces Initiation of Phase 2 Study of Bempedoic Acid Added-On to a PCSK9 Inhibitor**

ANN ARBOR, Mich., July 26, 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 initiation of a Phase 2 clinical study (1002-039) to assess the efficacy and safety of bempedoic acid when added-on to an injectable proprotein convertase subtilisin/kexin type 9 inhibitor (PCSK9i) therapy. This non-registrational study will assess the incremental LDL-C lowering efficacy and continued safety and tolerability of a once-daily, oral bempedoic acid pill added-on to an injectable biologic therapy in patients with elevated LDL-C levels. Top-line results are expected by the first quarter of 2018.

The eight-week, Phase 2, randomized, double-blind, placebo-controlled study will evaluate the efficacy and safety of once-daily, oral bempedoic acid 180 mg and once-monthly injection of Repatha® (evolocumab) 420 mg versus placebo. The study is expected to enroll approximately 50 patients with hypercholesterolemia at approximately 20 sites across the U.S. The primary objective of the study is to assess the incremental LDL-C lowering efficacy of bempedoic acid versus placebo in patients receiving PCSK9i therapy. Secondary objectives include assessing the safety and tolerability of bempedoic acid versus placebo in patients on PCSK9i therapy and effects on other risk markers, including non-high-density lipoprotein cholesterol (non-HDL-C), total cholesterol, apolipoprotein B (apoB) and high sensitivity C-reactive protein (hsCRP).

"From our recent market research it's clear there remains a strong preference among patients, physicians and payers for convenient, cost-effective, once-daily, oral LDL-C lowering therapies that can be used with currently available therapies," said Tim M. Mayleben, president and chief executive officer of Esperion. "It is important to note that we don't intend to explore bempedoic acid added-on to a PCSK9i in further studies due to their limited use to date. In this Phase 2 study, we anticipate that we will see the favorable safety, tolerability and incremental LDL-C lowering efficacy that we have come to expect from bempedoic acid."

#### **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 more than 1,000 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 therapies 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, 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 <a href="https://twitter.com/EsperionInc">www.esperion.com</a> and follow us on Twitter at <a href="https://twitter.com/EsperionInc">https://twitter.com/EsperionInc</a>.

#### **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 from the 1002-039 Phase 2 clinical study and the therapeutic potential of bempedoic acid when added to injectable PCSK9i therapy. 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, that existing cash resources may be used more quickly than anticipated, that the 1002-039 Phase 2 clinical study may not produce sufficient safety and tolerability results or show meaningful change in LDL-C or other efficacy measures, 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. 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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