

## Esperion Announces Late-Breaking Presentation of Final Results of Bempedoic Acid Pivotal Phase 3 Study 2 at the American College of Cardiology 2019 Scientific Sessions

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*–Study 2 Demonstrated Bempedoic Acid Significantly Lowered LDL-Cholesterol and Reduced hsCRP–  
–Over 52-Weeks, Bempedoic Acid was Observed to be Safe, Well-Tolerated, and Adverse Event Profile was Similar to that of Placebo–  
–Bempedoic Acid is an Oral, Once-daily ATP Citrate Lyase (ACL) Inhibitor that Reduces Cholesterol and Fatty Acid Synthesis in the Liver–  
–Study 2 Results were Presented by Anne C Goldberg MD, FACP, FAHA, FNLA at the American College of Cardiology 2019 Scientific Sessions–*

ANN ARBOR, Mich., March 18, 2019 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today announced the Phase 3 results from Study 2 (1002-047, also known as CLEAR Wisdom) of bempedoic acid were presented at the American College of Cardiology Scientific Sessions & Expo in New Orleans. Bempedoic acid is being developed as a complementary, cost-effective, convenient, once-daily, oral therapy for the treatment of patients with elevated low-density lipoprotein cholesterol (LDL-C). Bempedoic acid and the bempedoic acid / ezetimibe combination tablet new drug applications have been submitted to the United States Food and Drug Administration, as well as are under regulatory review for marketing authorization by the European Medicines Agency.

The late-breaking presentation, titled "Efficacy and Safety of Bempedoic Acid Added to Maximally Tolerated Statins in Patients with Hypercholesterolemia and High Cardiovascular Risk: The CLEAR Wisdom Trial" was delivered by Anne C. Goldberg MD, FACP, FAHA, FNLA, Professor of Medicine, Division of Endocrinology, Metabolism and Lipid Research at Washington University, St. Louis.

The presentation highlighted results from the primary endpoint LDL-C lowering at 12-weeks and key secondary endpoint of safety and tolerability over 52-weeks, including that bempedoic acid:

- significantly lowered LDL-cholesterol by 17 percent on background maximally tolerated statin therapy, and maintained significant reductions in LDL-cholesterol for 52 weeks;
- significantly lowered high-sensitivity C-reactive protein (hsCRP), an important marker of the underlying inflammation associated with cardiovascular disease, by 19 percent;
- had an adverse event profile that was similar to that of placebo (BA 70.1% vs placebo 70.8%) and serious adverse event profile that was generally similar to that of placebo (BA 20.3% vs placebo 18.7%);
- showed fewer adjudicated major adverse cardiac events compared with placebo (BA 6.1% vs placebo 8.2%);
- showed no worsening of glycemic measurements in patients with a history of diabetes including a 12-week reduction in hemoglobin A1c of 0.21 percent;
- was observed to be safe and well-tolerated.

"In the CLEAR Wisdom Trial, bempedoic acid was shown to be safe and well-tolerated and also provided significantly lowering of LDL-cholesterol in patients on background maximally tolerated statin therapy," said Anne C. Goldberg MD, FACP, FAHA, FNLA, Professor of Medicine, Division of Endocrinology, Metabolism and Lipid Research at Washington University, St. Louis and lead study author. "These results show that bempedoic acid could be an important new, oral treatment option for high-risk patients who require additional LDL-C lowering."

"CLEAR Wisdom was the final clinical study from our global, pivotal Phase 3 LDL-C lowering program for bempedoic acid. We are pleased to reiterate the findings from our topline results, which showed that bempedoic acid had an adverse event profile similar to placebo, as well as significantly lowered LDL-C and hsCRP over the course of the study," said Tim M. Mayleben, president and chief executive officer of Esperion. "We continue to be encouraged by these results and believe bempedoic acid and the bempedoic acid / ezetimibe combination tablet will serve an important unmet need for patients who require additional LDL-C lowering and are not reaching their goals with existing treatment options."

### **Design of Global Pivotal Phase 3 Study 2 (1002-047, also known as CLEAR Wisdom)**

The 52-week, global, pivotal Phase 3 randomized, double-blind, placebo-controlled, multicenter study evaluated the efficacy and safety of bempedoic acid 180 mg/day versus placebo. The study was conducted at 86 sites in North America and Europe. A total of 779 patients were randomized 2:1 to receive bempedoic acid or placebo. The primary efficacy objective was to assess the 12-week LDL-C lowering efficacy of bempedoic acid versus placebo. Secondary objectives included evaluating the safety and tolerability of bempedoic acid versus placebo, the 24-week and 52-week LDL-C lowering efficacy of bempedoic acid versus placebo, and its effects on other risk markers after 12 weeks of treatment, including hsCRP.

### **Bempedoic Acid / Ezetimibe Combination Tablet**

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination tablet 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 the LDL receptors. Phase 3 data demonstrated that this safe and well-tolerated combination results in a 35 percent lowering of LDL-C when used with maximally tolerated statins, a 43 percent lowering of LDL-C when used as a monotherapy, and a 34 percent reduction in high sensitivity C-reactive protein (hsCRP).

### **Bempedoic Acid**

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ATP Citrate Lyase inhibitor that, reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Similar to statins, bempedoic acid also reduces hsCRP, a key marker of inflammation associated with cardiovascular disease. Completed Phase 2 and Phase 3 studies conducted in almost 4,800 patients, and approximately 3,100 patients treated with bempedoic acid, have demonstrated an additional 20 percent LDL-C lowering when used with maximally tolerated statins, up to 30 percent LDL-C lowering as monotherapy, 35 percent LDL-C lowering in combination with ezetimibe when used with maximally tolerated statins and up to 48 percent LDL-C lowering in combination with ezetimibe as monotherapy.

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. The company initiated a global cardiovascular outcomes trial (CVOT) to assess the effects of bempedoic acid on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease (CVD) who are only able to tolerate less than the lowest approved daily starting dose of a statin and considered "statin intolerant." The CVOT — known as CLEAR Outcomes — is an event-driven, global, randomized, double-blind, placebo-controlled study expected to enroll approximately 12,600 patients with hypercholesterolemia and high CVD risk at over 1,000 sites in approximately 30 countries.

### **Esperion's Commitment to Patients with Hypercholesterolemia**

High levels of LDL-C can lead to a build-up of fat and cholesterol in and on artery walls (known as atherosclerosis), potentially leading to cardiovascular events, including heart attack or stroke. In the U.S., 96 million people, or more than 37 percent of the adult population have elevated LDL-C. There are approximately 18 million people in the U.S. with atherosclerotic cardiovascular disease (ASCVD) who live with elevated levels of LDL-C despite taking maximally tolerated lipid-modifying therapy — including individuals considered statin intolerant — leaving them at high risk for cardiovascular events. More than 50 percent of ASCVD patients who are not able to reach their LDL-C goals with statins alone, need less than a 40 percent reduction to reach their LDL-C threshold.

Esperion's mission as the Lipid Management Company is to deliver once-daily, oral therapies that complement existing oral drugs to provide the additional LDL-C lowering that these patients need.

### **The Lipid Management Company**

Esperion is the Lipid Management Company passionately committed to developing and commercializing complementary, cost-effective, convenient, 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 tablet, are targeted therapies that have been shown to significantly lower 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](http://www.esperion.com) and follow us on Twitter at <https://twitter.com/EsperionInc>.

### **Forward Looking Statement: Esperion**

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 the bempedoic acid / ezetimibe combination tablet and bempedoic acid and the therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination tablet and bempedoic acid, including Esperion's timing, designs, plans and announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, Esperion's expectations for the market for therapies to lower LDL-C, including the market adoption of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, if approved, the expected upcoming milestones described in this press release, and Esperion'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 Esperion's studies, that positive results from a clinical study of bempedoic acid may not be sufficient for FDA or EMA approval or necessarily be predictive of the results of future or ongoing clinical studies, that notwithstanding the completion of Esperion's Phase 3 clinical development program for LDL-C lowering, the FDA or EMA may require additional development in connection with seeking regulatory approval, that Esperion or its strategic collaborators are able to successfully commercialize the bempedoic acid / ezetimibe combination tablet and bempedoic acid, if approved, that existing cash resources may be used more quickly than anticipated, 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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