

## **Esperion Announces U.S. FDA Acceptance of New Drug Applications (NDAs) for Both Bempedoic Acid and the Bempedoic Acid / Ezetimibe Combination Tablet for Filing and Regulatory Review**

May 5, 2019

- *Bempedoic Acid is an Oral, Once-daily ATP Citrate Lyase (ACL) Inhibitor that Reduces Cholesterol and Fatty Acid Synthesis in the Liver –*
- *February 21, 2020 PDUFA Target Date Goal for Bempedoic Acid and February 26, 2020 PDUFA Target Date Goal for the Bempedoic Acid / Ezetimibe Combination Tablet –*
- *The FDA also communicated there is no current plan to hold an advisory committee meeting to discuss the applications –*

ANN ARBOR, Mich., May 05, 2019 (GLOBE NEWSWIRE) -- Esperion (Nasdaq: ESPR) announced today that the U.S. Food and Drug Administration (FDA) has accepted both New Drug Applications for bempedoic acid and the bempedoic acid / ezetimibe combination tablet for filing and regulatory review. Bempedoic acid and the bempedoic acid / ezetimibe combination tablet were developed to be complementary, cost-effective, convenient, once-daily, oral therapies for the treatment of patients with elevated low-density lipoprotein cholesterol (LDL-C) who need additional LDL-C lowering despite the use of currently accessible therapies.

The PDUFA (Prescription Drug User Fee Act) goal date for the completion of the bempedoic acid NDA review is set for February 21, 2020, and the PDUFA goal date for completion of the bempedoic acid / ezetimibe combination tablet NDA review is set for February 26, 2020. These dates are consistent with our expectations and reflect the standard review period. The FDA has communicated that there is no current plan to hold an advisory committee meeting to discuss the applications.

“It is exceptional that our New Drug Applications for both bempedoic acid and bempedoic acid / ezetimibe combination tablet have been accepted for filing. The acceptances validate the extraordinary effort and high-quality submissions of our Lipid Management Team and brings our once-daily, oral bempedoic acid-based therapies one step closer to the physicians and patients who will benefit from them,” said Tim M. Mayleben, president and chief executive officer of Esperion. “Our team of Lipid Management Experts remains focused on serving the needs of the millions of patients in the US not at their LDL-C goal despite currently available therapies.”

### **Esperion's Global Pivotal Phase 3 LDL-C Lowering Program to Support FDA and EMA Submissions**

Esperion completed its global, pivotal, Phase 3 clinical development program and announced positive cumulative results in October 2018. The program evaluated the safety, tolerability and consistent, complementary LDL-C-lowering efficacy of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in patients with atherosclerotic cardiovascular disease (ASCVD), or who are at a high risk for ASCVD, with hypercholesterolemia who continue to have elevated levels of LDL-C despite the use of maximally-tolerated statins and ezetimibe, leaving them at high risk for cardiovascular events. The program included five studies totaling approximately 4,000 patients, four for bempedoic acid and one for the bempedoic acid / ezetimibe combination tablet.

- Two pivotal studies evaluated bempedoic acid (Studies 1 and 2) in 3,008 patients with ASCVD on maximally-tolerated statins, with top-line results reported in May 2018 and October 2018, respectively;
- Two pivotal studies evaluated bempedoic acid (Studies 3 and 4) in 613 patients with ASCVD, or at a high risk for ASCVD, considered statin averse, with top-line results reported in May 2018 and March 2018, respectively;
- One pivotal study evaluated the bempedoic acid / ezetimibe combination tablet (053 Study) in 382 patients with ASCVD, or at high risk for ASCVD, on maximally tolerated statins, with top-line results reported in August 2018.

Bempedoic acid and the bempedoic acid / ezetimibe combination tablet new drug applications are under regulatory review by the U.S. FDA and the marketing authorization applications for these product candidates are under review by the European Medicines Agency (EMA).

### **Bempedoic Acid**

Bempedoic acid is our lead, non-statin, complementary, orally available, once-daily, LDL-C lowering therapy. With a targeted mechanism of action, bempedoic acid is a first-in-class, ATP Citrate Lyase (ACL) 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 3 studies conducted in more than 4,000 patients, with over 2,600 patients treated with bempedoic acid, have produced an additional 18 percent LDL-C lowering when used with moderate- and high-intensity statins and 28 percent LDL-C lowering when used with no background statin.

### **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 a 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 combination results in a 29 percent LDL-C lowering when used with maximally tolerated statins, a 44 percent LDL-C lowering when used with no background statin (post-hoc analysis), and a 34 percent reduction in high sensitivity C-reactive protein (hsCRP).

### **CLEAR Outcomes**

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. Esperion 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 averse." 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 averse — 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 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 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 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 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 global cardiovascular outcomes trial and other ongoing clinical studies for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, timing for the review and approval of the NDAs and the MAAs and 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, and the expected upcoming milestones described in this press release. 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 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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