

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **March 30, 2020**

**Esperion Therapeutics, Inc.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation)

**001-35986**  
(Commission File Number)

**26-1870780**  
(I.R.S. Employer  
Identification No.)

**3891 Ranchero Drive, Suite 150**  
**Ann Arbor, MI**  
(Address of principal executive offices)

**48108**  
(Zip Code)

Registrant's telephone number, including area code: **(734) 887-3903**

**Not Applicable**

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ESPR	NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

## Item 8.01. Other Events.

Esperion Therapeutics, Inc. (the “Company”) previously announced that on February 21, 2020, the U.S. Food and Drug Administration (“FDA”) approved NEXLETOL™ (bempedoic acid) tablet as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C, and on February 26, 2020, the FDA approved NEXLIZET™ (bempedoic acid and ezetimibe) tablet as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. The effect of NEXLETOL and NEXLIZET on cardiovascular morbidity and mortality has not been determined.

Also, the Company announced in February 2020 that NEXLETOL will be commercially available for U.S. patients on March 30, 2020, and NEXLIZET will be commercially available for U.S. patients in July 2020. Both NEXLETOL and NEXLIZET will be available by prescription only.

On January 31, 2020, the Company announced that the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency (“EMA”) adopted a positive opinion for the Marketing Authorisation Applications (“MAAs”) of both the bempedoic acid and bempedoic acid / ezetimibe combination tablets, recommending approval for the treatment of hypercholesterolemia and mixed dyslipidemia. The two MAAs will be applicable to all 28 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein.

On April 6, 2020, the Company issued press releases announcing that the European Commission approved NILEMDO™ (bempedoic acid) tablet and NUSTENDI™ (bempedoic acid and ezetimibe) tablet for the treatment of hypercholesterolemia and mixed dyslipidemia. Copies of the Press Releases are furnished herewith as Exhibit 99.1 and Exhibit 99.2.

On March 30, 2020, the Company issued a press release announcing the commercial launch of NEXLETOL. A copy of the Press Release is furnished herewith as Exhibit 99.3.

The Company is supplementing the risk factors previously included in Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 27, 2020, to add the following new risk factor under the section entitled “Risks Related to our Business and the Clinical Development and Commercialization of our Product Candidates”:

***The outbreak of the novel strain of coronavirus, SARS-CoV-2, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our commercial launch of NEXLETOL, our intended commercial launch of NEXLIZET, and operations and sales in general.***

In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, SARS-CoV-2 and COVID-19 have spread to multiple countries, including the United States. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. In response to the spread of SARS-CoV-2 and COVID-19, our commercial and medical organizations have suspended personal interactions with physicians and customers and will be conducting activities virtually.

As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely impact our business, including our clinical development and commercialization plans for the bempedoic acid and bempedoic acid / ezetimibe fixed dose combination tablets. As a result of the current pandemic, or future pandemics, we may not be able to meet expectations with respect to NEXLETOL and NEXLIZET sales or attain or maintain profitability and positive cash-flow from operations. Our ongoing clinical studies for bempedoic acid tablet and the timing for the review and approval of expanded indications for their effect on cardiovascular events may be impacted as well. Business interruptions from the current or future pandemics may also adversely impact the third parties we solely rely on to sufficiently manufacture NEXLETOL and NEXLIZET and to produce our product candidates in quantities we require, which may impair the commercialization of NEXLETOL and NEXLIZET and our research and development activities.

Some factors from the COVID-19 outbreak that may delay or otherwise adversely affect our business generally, and the third parties which we rely upon, include business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak impacts our business, including our commercial results and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

*Please also refer to the complete Item 1A of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2020 for additional risks and uncertainties facing the Company that may have a material adverse effect on the Company's business prospects, financial condition and results of operations.*

#### **Cautionary Note on Future Updates**

The statements contained and incorporated herein reflect the Company's current views with respect to future events, which may change significantly as the global consequences of the COVID-19 pandemic rapidly develop. Accordingly, the Company does not undertake and specifically disclaims any obligation to update any forward-looking statements.

#### **Item 9.01. Financial Statements and Exhibits.**

d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release issued by the Company on April 6, 2020, furnished herewith.</a>
<a href="#">99.2</a>	<a href="#">Press Release issued by the Company on April 6, 2020, furnished herewith.</a>
<a href="#">99.3</a>	<a href="#">Press Release issued by the Company on March 30, 2020, furnished herewith.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 6, 2020

Esperion Therapeutics, Inc.

By: /s/ Tim M. Mayleben  
Tim M. Mayleben  
President and Chief Executive Officer



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**Esperion Announces European Commission Approval of the NILEMDO™ (bempedoic acid) Tablet for the Treatment of Hypercholesterolemia and Mixed Dyslipidemia**

*– First Oral, Once-Daily, Non-Statins LDL-Cholesterol Lowering Medicine Approved in Europe in Almost Two Decades for Indicated Patients –*

*– NILEMDO Is Approved for Patients Who Require Additional LDL-Cholesterol Lowering on a Background Statin, Other Lipid-Lowering Therapies, or Considered Statin-Intolerant –*

*– Pharmacology Section Highlights NILEMDO Reduced HbA1c on Average of 0.2% Versus Placebo in Patients with Diabetes –*

*– Daiichi Sankyo Europe to Lead EU Commercialization, Cardiovascular Sales Organization Exceeds 1,000 Professionals –*

*– Esperion to Receive \$150 Million Milestone Payment Upon First Commercial Sale –*

ANN ARBOR, Mich., April 6, 2020 (GLOBE NEWSWIRE) — Esperion (NASDAQ: ESPR) announced today the European Commission approved the NILEMDO™ (bempedoic acid) tablet, an oral, once-daily, non-statin LDL-cholesterol (LDL-C) lowering medicine. NILEMDO is a first-in-class ATP Citrate Lyase (ACL) inhibitor that lowers LDL-C by inhibition of cholesterol synthesis in the liver.

The European Commission approved NILEMDO for use in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

“Millions of patients across the European Economic Area have needed a new daily, non-statin pill to help them achieve their LDL-C goals,” said Tim M. Mayleben, president and chief executive officer of Esperion. “For those who require additional non-statin lowering of their bad cholesterol, NILEMDO will fit easily into their daily routines whether that is with their statin or without because they are statin intolerant. Esperion is committed to finding new ways to affordably manage lipids and won’t stop until everyone can achieve their goals.”

The European Society of Cardiology and European Atherosclerosis Society recommend intensively lowering LDL-C to reduce cardiovascular risk. Even today, up to 80% of patients do not reach recommended LDL-C goals despite receiving treatments such as statins<sup>1</sup>, and are at increased risk of a heart attack or stroke. NILEMDO provides patients and their physicians an important new oral, once-daily non-statin option.

“NILEMDO finally provides a preferred daily pill that easily fits into the routines of those struggling with high levels of bad cholesterol, which includes patients that are statin intolerant,” said Professor Kausik K. Ray, MBChB, MD, MPhil, FRCP, Professor of Public Health at the School of Public Health, Imperial College London and a Consultant Cardiologist and member of the Phase 3 steering committee for Esperion. “NILEMDO is a first-in-class medicine and an oral alternative that we have not had in nearly two decades.”

The approval of NILEMDO is supported by a global pivotal Phase 3 LDL-C lowering program conducted in more than 3,600 patients. NILEMDO provides additional LDL-C lowering of up to 28 percent compared to placebo when added onto other lipid-lowering therapies. Results from the Phase 3 development program have been published in *The New England Journal of Medicine*, *The Journal of the American Medical Association*, *The Journal of the American Heart Association* and *Atherosclerosis*.

The benefit with NILEMDO is its ability to reduce levels of LDL-C in patients with hypercholesterolaemia or mixed dyslipidaemia when administered alone and in combination with other lipid-modifying medicinal products. NILEMDO also reduced non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B) and total cholesterol (TC). Notably, the pharmacology section of the NILEMDO label highlights that among the subset of patients with diabetes (n=1,134), lower levels of hemoglobin A1c (HbA1c) were observed as compared to placebo (on average 0.2%).

NILEMDO was generally well-tolerated in clinical studies. The most commonly reported adverse reactions with NILEMDO during pivotal trials were hyperuricaemia, pain in extremity and anaemia. The majority of adverse reactions reported with NILEMDO were mild to moderate in severity and balanced in occurrence with adverse events in patients receiving placebo. More patients on NILEMDO compared to placebo discontinued treatment due to muscle spasms, diarrhea, pain in extremity and nausea, although differences between NILEMDO and placebo were not significant.

Daiichi Sankyo Europe has licensed exclusive commercialization rights to NILEMDO and NUSTENDI™ (bempedoic acid and ezetimibe) tablet in the European Economic Area and Switzerland from Esperion. Daiichi Sankyo’s European cardiovascular commercial capabilities include more than 1,000 professionals dedicated to the commercialization of cardiovascular medicines and includes synergies with an existing portfolio of novel oral anticoagulant and antiplatelet products. Under terms of the agreement, Esperion has already received a \$150 million upfront payment, will receive \$150 million milestone upon first commercial sale in the territory, up to \$900 million in total milestones as well as tiered royalties between 15% – 25%.

### **CLEAR Cardiovascular Outcomes Trial**

The effect of bempedoic acid on cardiovascular morbidity and mortality has not 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 are considered "statin averse." The CVOT — known as CLEAR Cardiovascular Outcomes Trial — is an event-driven, global, randomized, double-blind, placebo-controlled study that completed enrollment in August 2019 of over 14,000 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

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## Esperion Therapeutics

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 medicines that will make a substantial impact on reducing global cardiovascular disease, the leading cause of death around the world. For more information, please visit [www.esperion.com](http://www.esperion.com) and follow us on Twitter at [www.twitter.com/EsperionInc](https://www.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 clinical development and commercialization plans for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of expanded indications for their effect on cardiovascular events, and Esperion's expectations for the market for medicines to lower LDL-C, including the commercial launch and market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet in the European Union. 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 clinical development and commercialization plans or approval of expanded indications, that existing cash resources may be used more quickly than anticipated, the impact of COVID-19 on our business, clinical activities and commercial development plans, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and 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.

## References

- (1) Fox KM, et al. Treatment patterns and low-density lipoprotein cholesterol (LDL-C) goal attainment among patients receiving high- or moderate-intensity statins. *Clin Res Cardiol* 2018; 107: 380–388.
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**Esperion Announces European Commission Approval of the NUSTENDI™ (bempedoic acid and ezetimibe) Tablet for the Treatment of Hypercholesterolemia and Mixed Dyslipidemia**

*– First Non-Statins, LDL-C Lowering Combination Medicine Ever Approved in Europe –*

*– NUSTENDI Is Approved for Patients Who Require Additional LDL-Cholesterol Lowering on a Background Statin, Other Lipid-Lowering Therapies, or Considered Statin Intolerant –*

*– Daiichi Sankyo Europe to Lead EU Commercialization, Cardiovascular Sales Organization Exceeds 1,000 Professionals –*

*– Esperion to Receive \$150 Million Milestone Payment Upon First Commercial Sale –*

ANN ARBOR, Mich., April 6, 2020 (GLOBE NEWSWIRE) — Esperion (NASDAQ: ESPR) announced today the European Commission approved the NUSTENDI™ (bempedoic acid and ezetimibe) tablet, an oral, once-daily, non-statin LDL-cholesterol (LDL-C) lowering medicine for hypercholesterolemia and dyslipidemia in Europe. NUSTENDI contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine.

The European Commission approved NUSTENDI for use in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe,
- alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone, or
- in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.

“For the first time, a non-statin once-a-day pill with significant efficacy will be available across Europe to fight bad cholesterol,” said Tim M. Mayleben, president and chief executive officer of Esperion. “This is a major advancement for the millions of patients needing an additional option to use with their statin and know it’s important for them to achieve recommended LDL-C goals or for those that may be statin intolerant.”

The European Society of Cardiology and European Atherosclerosis Society recommend intensively lowering LDL-C to reduce cardiovascular risk. Even today, up to 80% of patients do not reach recommended LDL-C goals despite receiving treatments such as statins<sup>1</sup>, and are at increased risk of a heart attack or stroke. NUSTENDI provides patients and their physicians an important new oral, once-daily non-statin option.



“There is a compelling need for a once-daily pill with the kind of efficacy NUSTENDI (bempedoic acid plus ezetimibe combination) can provide for millions of patients, including those that are statin intolerant,” said Professor Kausik K. Ray, MBChB, MD, MPhil, FRCP, Professor of Public Health at the School of Public Health, Imperial College London and a Consultant Cardiologist and member of the Phase 3 steering committee for Esperion. “This daily medicine will be beneficial for those that need additional lowering of bad cholesterol on top of statins but will also provide a convenient alternative for a significant number of people who cannot tolerate statins. These patients now have an efficacious oral option to lower their bad cholesterol. A single combination pill aides adherence, a critical factor to maintain long-term reductions in bad cholesterol.”

The approval of NUSTENDI is supported by the Phase 3 Fixed Combination Tablet LDL-C Lowering program, as well as safety data from the NILEMDO™ (bempedoic acid) tablet global pivotal Phase 3 LDL-C lowering program and the existing ezetimibe safety profile. NUSTENDI lowered LDL-C by a mean of 38 percent compared to placebo when added on to maximally tolerated statins. Results have been published in *The European Journal of Preventive Cardiology*.

The benefit with NUSTENDI is its ability to reduce levels of LDL-C in patients with hypercholesterolaemia or mixed dyslipidaemia when administered alone and in combination with other lipid-modifying medicinal products. NUSTENDI also reduced non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B) and total cholesterol (TC). Notably, the pharmacology section of the NUSTENDI label highlights that among the subset of patients with diabetes (n=1,134), lower levels of hemoglobin A1c (HbA1c) were observed as compared to placebo (on average 0.2%).

NUSTENDI was generally well-tolerated in clinical studies. The most commonly reported adverse reactions with NUSTENDI were hyperuricaemia and constipation. The majority of adverse reactions reported with NUSTENDI were mild to moderate in severity and balanced in occurrence with adverse events in patients receiving placebo. In pooled placebo-controlled clinical trials with bempedoic acid, a component of NUSTENDI, more patients on bempedoic acid compared to placebo discontinued treatment due to muscle spasms, diarrhea, pain in extremity and nausea, although differences between bempedoic acid and placebo were not significant.

Daiichi Sankyo Europe has licensed exclusive commercialization rights to NILEMDO and NUSTENDI in the European Economic Area and Switzerland from Esperion. Daiichi Sankyo's European cardiovascular commercial capabilities include more than 1,000 professionals dedicated to the commercialization of cardiovascular medicines and includes synergies with an existing portfolio of novel oral anticoagulant and antiplatelet products. Under terms of the agreement, Esperion has already received a \$150 million upfront payment, will receive \$150 million milestone upon first commercial sale in the territory, up to \$900 million in total milestones as well as tiered royalties between 15% – 25%.

### **CLEAR Cardiovascular Outcomes Trial**

The effect of bempedoic acid on cardiovascular morbidity and mortality has not 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 are considered "statin averse." The CVOT — known as CLEAR Cardiovascular Outcomes Trial — is an event-driven, global, randomized, double-blind, placebo-controlled study that completed enrollment in August 2019 of over 14,000 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

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## Esperion Therapeutics

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 medicines that will make a substantial impact on reducing global cardiovascular disease, the leading cause of death around the world. For more information, please visit [www.esperion.com](http://www.esperion.com) and follow us on Twitter at [www.twitter.com/EsperionInc](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 the clinical development and commercialization plans for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of expanded indications for their effect on cardiovascular events, and Esperion's expectations for the market for medicines to lower LDL-C, including the commercial launch and market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet in the European Union. 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 clinical development and commercialization plans, or approval of expanded indications, that existing cash resources may be used more quickly than anticipated, the impact of COVID-19 on our business, clinical activities and commercial development plans, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and 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.

## References

- (1) Fox KM, et al. Treatment patterns and low-density lipoprotein cholesterol (LDL-C) goal attainment among patients receiving high- or moderate-intensity statins. *Clin Res Cardiol.* 2018; 107: 380–388.
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**Esperion Announces Commercial Availability of the NEXLETOL™ (bempedoic acid) Tablet and Pledges a Conscientious Launch During Unprecedented Moment in Healthcare**

March 30, 2020

*– First Oral, Once-Daily, Non-Statin LDL-Cholesterol Lowering Medicine in the U.S. in Nearly 20 Years for Indicated Patients Awaiting a New Option –*

*– Esperion Aims to Set New Industry Standard by Pricing NEXLETOL for Patient Affordability and Access –*

*– Company Repurposes Healthcare Provider Education and Support Material Encouraging Remote Education and Virtual Visits with our Lipid Experts During This Extraordinary Time –*

ANN ARBOR, Mich., March 30, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESRP) announced today that NEXLETOL™ (bempedoic acid) tablet, an oral, once-daily, non-statin LDL-Cholesterol (LDL-C) lowering medicine is now available in U.S. pharmacies. Esperion is committed to respecting the valuable time of healthcare providers in the current environment while also remaining steadfast to the patients awaiting new options to manage their bad cholesterol.

NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

“We are dedicated to providing patient access and affordability for the millions of patients continuing to struggle with their bad cholesterol especially during this unique time,” said Mark Glickman, chief commercial officer of Esperion. “There were no new oral non-statin options for LDL-C lowering in nearly 20 years, and we know NEXLETOL is an anticipated solution for the appropriate patients that have not been able to reach their LDL-C goals and could benefit from NEXLETOL immediately.”

Elevated LDL-C contributes to a buildup of fat in the arteries and is a key risk factor for cardiovascular disease, which is the leading cause of death in the U.S. and one of the most expensive chronic conditions. Despite standard of care treatments, including statin therapy, it is estimated nearly 15 million ASCVD or HeFH patients on maximally tolerated statins in the U.S. cannot achieve guideline recommended LDL-C levels.

Esperion is committed to providing oral, once-daily non-statin LDL-C lowering treatment options that are affordable and accessible. NEXLETOL is available at a list price of around \$10 per day to payers. Eligible patients with commercial drug insurance coverage for NEXLETOL may pay as little as \$10 per fill, up to a 3-month supply. For those that need NEXLETOL, Esperion’s mission is to considerably reduce cost as a burden for patients as they strive to achieve their long-term LDL-C goals.

“We recognize this is an incredibly demanding time for healthcare providers and are committed to respecting their time by adapting our introduction of NEXLETOL to provide the most flexible learning approach possible,” Glickman said. “We are convinced as the healthcare community begins to discover the benefits of this medicine for their patients, it will become clear the immediate future should be brighter for many people battling bad cholesterol.”

There are several ways to reach us based on your preference. Healthcare providers with questions regarding NEXLETOL can call 833-377-7633 (833 ESPRMED) and select OPTION 1 where our medical information team is available from Monday-Friday (except holidays) 8:00 a.m. to 8:00 p.m. Eastern Time to assist you. If preferred, you can submit your questions by email, via [medinfo@esperion.com](mailto:medinfo@esperion.com). If interested in speaking with a sales representative from Esperion please call 833-377-7633 (833 ESPRMED) and select OPTION 2. Press OPTION 3, for Copay questions. Visit [www.esperion.com](http://www.esperion.com) for general information about our company.

**NEXLETOL™ (bempedoic acid) Tablet**

NEXLETOL is a first-in-class ATP Citrate Lyase (ACL) inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating LDL receptors. Phase 3 studies detailed in the label were conducted in more than 3,000 patients, with over 2,000 patients treated with NEXLETOL, demonstrated an average 18 percent placebo corrected LDL-C lowering when used in patients on moderate or high-intensity statins. NEXLETOL was approved by the FDA in February 2020.

**Indication and Limitation of Use**

NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

## Important Safety Information

### • Warnings and Precautions:

- *Hyperuricemia: Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate. The risk for gout events with NEXLETOL was higher in patients with a prior history of gout although gout also occurred more frequently than placebo in patients treated with NEXLETOL who had no prior gout history.*
  - *Tendon Rupture: Tendon rupture has occurred. Discontinue NEXLETOL at the first sign of tendon rupture. Avoid NEXLETOL in patients who have a history of tendon disorders or tendon rupture.*
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• Adverse Reactions:

- The most common (incidence  $\geq$  2% and greater than placebo) adverse reactions are upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia and elevated liver enzymes.

• Drug Interactions:

- *Simvastatin*: Avoid concomitant use of NEXLETOL with simvastatin greater than 20 mg.
- *Pravastatin*: Avoid concomitant use of NEXLETOL with pravastatin greater than 40 mg.

• Use in Specific Populations

- *Pregnancy*: Based on mechanism of action, may cause fetal harm.
- *Lactation*: Breastfeeding is not recommended with NEXLETOL.

Patients or their physicians are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 or report side effects to Esperion at 833-377-7633 (833 ESPRIMED).

Click here to see the [full prescribing information](#) for NEXLETOL™ (bempedoic acid) tablet.

### CLEAR Cardiovascular Outcomes Trial

The effect of bempedoic acid on cardiovascular morbidity and mortality has not 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 are considered "statin averse." The CVOT — known as CLEAR Cardiovascular Outcomes Trial — is an event-driven, global, randomized, double-blind, placebo-controlled study that completed enrollment in August 2019 of over 14,000 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

### Esperion Therapeutics

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 medicines that will make a substantial impact on reducing global cardiovascular disease, the leading cause of death around the world. For more information, please visit [www.esperion.com](http://www.esperion.com) and follow us on Twitter at [www.twitter.com/EsperionInc](https://www.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 clinical development and commercialization plans for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of expanded indications for their effect on cardiovascular events, and Esperion's expectations for the market for medicines to lower LDL-C, including the commercial launch and market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet in the European Union. 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 clinical development and commercialization plans or approval of expanded indications, that existing cash resources may be used more quickly than anticipated, the impact of COVID-19 on our business, clinical activities and commercial development plans, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and 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.

### References

(1) Fox KM, et al. Treatment patterns and low-density lipoprotein cholesterol (LDL-C) goal attainment among patients receiving high- or moderate-intensity statins. *Clin Res Cardiol* 2018; 107: 380–388.

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